

#### Summary

**AUDIT DECISION** 

**CERTIFIED** 

**DECISION DATE 07/15/2022** 

RECERTIFICATION DATE

01/12/2023

**EXPIRATION DATE** 

03/28/2023

**CERTIFICATION NUMBER** 

68927 | 154426

AUDIT TYPE SURVEILLANCE

**AUDIT DATES** 

06/21/2022 - 06/22/2022

ISSUE DATE 07/15/2022

**AUDIT RATING** 



**Excellent** 

# Facility & Scope

### Proper Beverage (66659)

Proper Beverage 4432 S. Buttermilk Ct. #400 Hudsonville, MI 49426 United States

#### **Food Sector Categories:**

16. Ice, Drink, and Beverage Processing

#### **Products:**

Beverage Manufacturing

## **Scope of Certification:**

FSC 16: Ice, Drink & Beverage

## Certification Body & Audit Team

#### **Eurofins**



Assurance

2200 Rittenhouse St. Suite 150 Des Moines, IA 50321 United States

**Phone #:** 515-299-6979

**CB#:** CB-1-Eurofins

**Accreditation Body: JAS ANZ** 

Accreditation Number: Z14430415UD

**Lead Auditor:** Gilbert, Warren (9633) **Technical Reviewer:** Mitchell, Kim (125817)

Hours Spent on Site: 16 Hours of ICT Activities: 0 Hours Spent Writing Report: 8

## 2.5.4 Internal Audits and Inspections (Mandatory)

Internal audits (SQF) are conducted quarterly. The entire SQF program is reviewed during this inspection. Quarterly reviews were observed to be complete and current and signed by the plant manager and the Senior manager. Were reviewed for the months of June, July and August 2021. Findings were observed to follow the CAR procedure. The CAR log was observed to be current complete, verified and validated by the practitioner. The CAR Log and reports are maintained by the practitioner. The QA Mgr. has been trained in internal auditing and has trained internal staff. Audits are currently not conducted by a multi-functional team. A consultant assists with these inspections The SQF system has been reviewed in its entirety by the practitioner and the senior manager. Minor: There is currently no internal audits or GMP inspections other than the SQF systems review which happens quarterly.

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

#### **RESPONSE: MINOR**

EVIDENCE: There is currently no internal audits or GMP inspections other than the SQF systems review which happens quarterly.

ROOT CAUSE: Although tasks were completed and GMP's followed there was no documentation of internal audits.

**CORRECTIVE ACTION:** General GMP and internal audit was created as well as the SOP.

VERIFICATION OF CLOSEOUT: WAG - Updated audit schedule observed and one completed.

**COMPLETION DATE:** 07/08/2022 **CLOSEOUT DATE:** 07/13/2022

udit Statements	
SQF Practitioner Name	Name the designated SQF Practitioner  RESPONSE: Larry Griesbach
SQF Practitioner Email	Email of the designated SQF Practitioner  RESPONSE: larry.griesbach@properbeverage.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas <b>RESPONSE:</b> Larry Griesbach; Senior Mgr./SQF Practitioner, Mitch Iwan; Consultant
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details
	<b>RESPONSE:</b> The Facility is leased and was found to be well maintained and in good operating condition and newer construction. It is approximately 30k sqft with 24 employees, 2 shifts 5 days/week.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) <b>RESPONSE:</b> Larry Griesbach; Senior Mgr./SQF Practitioner, Mitch Iwan; Consultant
Auditor Recommendation	Auditor Recommendation  RESPONSE: Maintain Certification once corrective action approved.

#### Section Responses

## 2.1.1 Management Responsibility (Mandatory)

The SQF System was fully implemented on May 1, 2021. There is a company policy posted in the employee and Corp breakroom. It states commitment to food safety and the SFQ system and its continuous improvement. It is signed and dated by the senior manager 5/12/22 (English). There is a current Org. chart which was found to be complete and identifies the senior manager and back-up. Senior manager is involved in monthly internal audits and ensures CAR's are closed in a timely manner. There is a practitioner onsite (Senior Manager) which is a full time employee and was able to show SQF system competency throughout the audit process. The practitioner received HACCP training dated 4/15-16/21 (Professional Food Safety). Job descriptions for the senior manager and practitioner were observed to be complete and current and identified their role in supporting the SQF system. The senior manager supports the ongoing commitment to the SQF system via customer complaint review, CAR's closure, internal audit review, etc. Employees are trained to report food safety concerns to a peer per the company GMP training. Food Safety culture has been implemented. Employees interviewed were found to be fully aware of their responsibility to report food safety risks and stop production if necessary. Monthly employee food safety culture trainings are conducted by the practitioner. The effectiveness of this program is managed against product "holds". There are no blackout dates other than regular holidays.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

2.1.1.4 Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to: i.

Oversee the development, implementation, review, and maintenance of the SQF System; ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

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

**RESPONSE:** COMPLIANT

# 2.1.2 Management Review (Mandatory)

There is a current and complete food safety manual which is manual. The practitioner manages and maintains the FSM. The Food safety team (senior manager, practitioner and consultant) reviews the entire SQF system on a monthly basis. The review included finding and CAR's. Internal audit findings (trends) are used to monitor the food safety culture progression and what to target. All changes to the program are documented on the change log in the document control folder. There have been no changes to date. Monthly meetings records between the practitioner and the senior manager were observed for January through May 2022. Internal audits, HACCP and Customer Complaints were reviewed during this process. All records were found to be complete and current.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

# 2.1.3 Complaint Management (Mandatory)

There is a complete and current customer complaint SOP which is managed by the practitioner and includes involvement from the senior manager. A complete and ongoing complaint log in managed by the practitioner. Complaints identified are immediately reviewed by the recall team and root cause is to be completed. Trending of complaints is to be completed as received. All records were found to be well maintained. There have been no food safety complaints to date. The practitioner maintains all records and is managed by the practitioner.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.2.1 Food Safety Management System (Mandatory)

There is a complete and current FSM which is managed by the practitioner and maintained electronically and manually on the company cloud and by the practitioner. The FSM is made available for all employees as needed. All products are covered in the scope. Raw, ingredient, packing and finished product specifications are included in the manual. Any changes to the program are approved by the senior manager and the practitioner.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

### 2.2.2 **Document Control (Mandatory)**

There is a document control program which contains a complete and current register of all controlled documents. All records and SOP's are the responsibility of the QA Dept. and are maintained on a company cloud. There is a current register of documents supporting the SQF system.

**2.2.2.1** The methods and responsibility for maintaining document control and ensuring staff have access to current requirements and instructions shall be documented and implemented. Current SQF System documents and amendments to documents shall be maintained.

**RESPONSE: COMPLIANT** 

# 2.2.3 Records (Mandatory)

The practitioner manages and maintains all records. Food Safety Records were found to be readily accessible and are to be maintained for 2yrs.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

2.2.3.3 Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Retention periods shall be in accordance with customer, legal, and regulatory requirements, at minimum the product shelf-life or established by the site if no shelf-life exists.

**RESPONSE: COMPLIANT** 

### 2.3.1 Specification, Formulation and Realization

This company operates solely as a beverage co-packer and has no R&D process. Customers supply all ingredients and packaging. The company manages the process through the approved supplier program.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** This operation is a co-packer and have no products of their own.

2.3.1.2 New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure product safety. Product formulations shall be developed by authorized persons to ensure that they meet the intended use. Where necessary, shelf life trials shall be conducted to validate and verify a new product's: i. Pre-consumer handling and storage requirements, including the establishment of "use by," "best before dates," or equivalent terminology; ii. Microbiological criteria, where applicable; and iii. Consumer preparation, where applicable, and storage and handling requirements.

**RESPONSE:** NOT APPLICABLE

2.3.1.3 A food safety plan shall be validated and verified by the site food safety team for each new product and its associated process through conversion to commercial production and distribution or where a change to ingredients, process, or packaging occurs that may impact food safety.

**RESPONSE:** NOT APPLICABLE

**2.3.1.4** Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment.

**RESPONSE:** NOT APPLICABLE

**2.3.1.5** The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination.

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

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

There is a documented Specifications management program which has been implemented. A complete and current register of raw and packing material specifications was observed. C of A's for labeling legislative concerns was observed. All packing materials have either C'of A's or Letters of Guarantee. Finished product labels are reviewed. All were found to be current. Validation was found to be completed on all raw and packing materials. There is a complete and current register of finished product specifications for all products. All elements have been validated by the practitioner. Labeling, micro and packing requirements are included. The register is maintained on the company shared drive and managed by the practitioner. Product specs were observed for Blue Raspberry and were observed to be complete and current. A complete and current Service Provider register was observed to be complete and current including contracts (plumbing, PCO, micro testing lab, forklifts, calibration).

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

2.3.2.5 Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may vary by crop or by season).

2.3.2.6 Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**2.3.2.9** Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable: i. Microbiological, chemical, and physical limits; ii. Composition to meet label claims; iii. Labeling and packaging requirements; and iv. Storage conditions.

**RESPONSE: COMPLIANT** 

**2.3.2.10** Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained. A list of all the above specifications shall be maintained and kept current.

**RESPONSE:** COMPLIANT

### 2.3.3 Contract Manufacturers

There are currently no co-mans.

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

## 2.3.4 Approved Supplier Program (Mandatory)

There is a complete and implemented approved supplier program which includes all raw and packing materials. Food Defense and Fraud are addressed in the Approved Supplier Questionnaire. Suppliers are required; at this time, to complete the questionnaire. One questionnaires have been compiled then a determination shall be made regarding how the program requirements shall move forward. The approved supplier program includes past and current history including food safety audits, delivery, recalls, insurance, etc.. There is a complete register of all approved suppliers. All suppliers are reviewed annually. Materials from non-approved suppliers are to be placed on hold to be dispositioned by the Practitioner.

2.3.4.1 The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier shall be documented and implemented. A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained. Code Amendment #2 Approved supplier registers shall include supplier contact details. All approved and emergency suppliers shall be registered.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**2.3.4.4** The receipt of raw materials, ingredients, processing aids, and packaging from nonapproved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

**2.3.4.6** Supplier audits shall be based on risk (as determined in 2.3.4.2) and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

**RESPONSE: COMPLIANT** 

### 2.4.1 Food Legislation (Mandatory)

There is a written and implemented food legislative change program which the practitioner is in charge of communicating events to staff via email. The practitioner is responsible for managing warnings from the local state inspector. The practitioner receives warning emails from the FDA website, periodicals and seminars. The CB and SQFI have been identified to be notified in writing within 24 hours of an event.

2.4.1.1 The site shall ensure that at the time of delivery to customers finished products shall comply with food safety legislation applicable in the country of manufacture and sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice.

**RESPONSE: COMPLIANT** 

**2.4.1.2** The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented.

**RESPONSE:** COMPLIANT

**2.4.1.3** SQFI and the certification body shall be notified in writing within twenty-four (24) hours as a result of a regulatory warning or event. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

**RESPONSE:** COMPLIANT

## 2.4.2 Good Manufacturing Practices (Mandatory)

There are written and implemented GMP's which meet the module 2 and 11 requirements. Control measure have been put in place to ensure the effectiveness of the program via monthly operations meeting review.

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

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

**RESPONSE: COMPLIANT** 

# 2.4.3 Food Safety Plan (Mandatory)

There is a complete and current HACCP plan which meets the requirements of the Codex. There is a designated team which reviews the program annually with the last review on 10/1/21. The practitioner is responsible to ensure changes made to production have been updated and the senior manager signs off on changes. All support pre-requisite program were observed to be complete and current. There is one HACCP plan. There are no identified CCPs. a Pasteurization process has been added and is not considered a CCP due to each batch is sent to a 3rd party lab for testing before shipping. PH is not considered a CCP however there is a complete and current risk assessment supporting this decision. There is a complete flow diagram with matching hazard analysis. Regulatory compliance has been identified for the USA. The facility follows FSMA guidelines which was observed to be compliant. The effectiveness of the program is tested annually during the SQF systems review. Records for the process were observed for the month of September 2021 for all CCP's and were found to be complete and current.

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

**RESPONSE: COMPLIANT** 

2.4.3.2 The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant raw materials, packaging, processing aids, products, and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food safety team.

**RESPONSE: COMPLIANT** 

**2.4.3.3** The scope of each food safety plan shall be developed and documented including the start and endpoints of the processes under consideration and all relevant inputs and outputs.

**RESPONSE:** COMPLIANT

**2.4.3.4** Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions.

**RESPONSE:** COMPLIANT

2.4.3.5 The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative uses of the product.

**RESPONSE:** COMPLIANT

2.4.3.6 The food safety team shall develop and document a flow diagram covering the scope of each food safety plan The flow diagram shall include every step in the process, all raw materials, packaging, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation.

**RESPONSE:** COMPLIANT

**2.4.3.7** The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

**RESPONSE: COMPLIANT** 

2.4.3.8 The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.

2.4.3.9 The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.

**RESPONSE: COMPLIANT** 

2.4.3.10 Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

**RESPONSE: COMPLIANT** 

2.4.3.11 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard(s) and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).

**RESPONSE: COMPLIANT** 

2.4.3.12 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency.

**RESPONSE:** COMPLIANT

**2.4.3.13** The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.

**RESPONSE: COMPLIANT** 

**2.4.3.14** The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur.

**RESPONSE: COMPLIANT** 

**2.4.3.15** Procedures shall be in place to verify that critical control points are effectively monitored and appropriate corrective actions are applied. Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

**2.4.3.17** Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.

**RESPONSE:** COMPLIANT

## 2.4.4 Product Sampling, Inspection and Analysis

There is an onsite lab used for quality and pH monitoring. No micro testing is conducted onsite. All sampling records were found to be complete and current and managed by the QA dept. There is an onsite "Quality" Lab. No micro testing is conducted on-site. Work instruction were observed which identify how the sampling process shall be completed and managed. Sampling personnel are trained and updated annually by the practitioner. All records are maintained on the company cloud. External testing is completed by a 3rd party lab (Summit Labs Labs ISO 17025) for each pasteurized batch. Test results were observed from November 2021. Testing included plate count, yeast/mold, coliforms, staph, E.coli. No concerns were observed.

2.4.4.1 The methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in-progress, and finished product shall be documented and implemented. The methods applied shall ensure that inspections and analyses are completed at regular intervals as required and to agreed specifications and legal requirements. Sampling and testing shall be representative of the process batch and ensure that process controls are maintained to meet specification and formulation.

2.4.4.2 Product analyses shall be conducted to nationally recognized methods or company requirements, or alternative methods that are validated as equivalent to the nationally recognized methods. Where internal laboratories are used to conduct input, environmental, or product analyses, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025, including annual proficiency testing for staff conducting analyses. External laboratories shall be accredited to ISO/IEC 17025, or an equivalent international standard, and included on the site's contract service specifications list (refer to 2.3.2.11).

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

**2.4.4.6** Records of all inspections and analyses shall be maintained.

**RESPONSE: COMPLIANT** 

## 2.4.5 Non-conforming Materials and Product

There is a complete and implemented hold program which is managed by the practitioner. There is a designated hold area in the warehouse and product was observed to be tagged correctly and stored in the designated hold area. Product is dispositioned by the practitioner and validation of the disposition is maintained. A complete and current hold log was observed. During the audit product was placed on hold for metal detection and was observed to follow the process. The product was observe to follow the designated process. No concerns observed.

2.4.5.1 The responsibility and methods outlining how to handle non-conforming product, raw material, ingredient, work-in-progress, or packaging, which is detected during receipt, storage, processing, handling, or delivery, shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled, and/or disposed of in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product; and ii. All relevant personnel are aware of the organization's quarantine and release requirements applicable to product placed under quarantine status.

**RESPONSE: COMPLIANT** 

**2.4.5.2** Quarantine records and records of the handling, corrective action, or disposal of nonconforming materials or product shall be maintained.

**RESPONSE:** COMPLIANT

#### 2.4.6 Product Rework

There is no rework.

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

**RESPONSE:** NOT APPLICABLE

## 2.4.7 Product Release (Mandatory)

There is a written and implemented positive release program which is managed by the QA dept. QA signs off to ensure all records have been filled out correctly and there are no concerns. 2 samples are pulled from each batch and sent to a 3rd party lab for micro testing. Product is released once the samples have been approved. Records were reviewed for the month of Oct 11, 2021 were found to be complete and current.

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel, and only after all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met. Records of all product releases shall be maintained.

**RESPONSE: COMPLIANT** 

2.4.7.2 Product release shall include a procedure to confirm that product labels comply with the food legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1). If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use.

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

# 2.4.8 Environmental Monitoring

There is an implemented monitoring program which is identified by zones 1,2,3,4. with 1 being equipment contact surfaces and is tested monthly by a 3rd party (Summit Labs). There is a designated schedule and map of the testing process. Supporting Lab records from November 2021 were observed to be complete and current. All testing is tracked and trended. No concerns were observed.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

## 2.5.1 Validation and Effectiveness (Mandatory)

There is a documented Validation program managed by the practitioner. There is an implemented validation program which was observed during the walk through. Trailer inspection records for the months of 8/4/21 were found to be validated weekly. Validation of trailer temperature management was conducted in which temp monitoring device was sent in a shipment. All records are maintained on the company cloud.

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

**RESPONSE: COMPLIANT** 

### 2.5.2 Verification Activities (Mandatory)

There is a documented verification program which is managed by the practitioner. The program included a schedule which identified methods, responsibility and frequency. The schedule was observed to be complete and current.

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

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

**RESPONSE: COMPLIANT** 

## 2.5.3 Corrective and Preventative Action (Mandatory)

There is a documented and implemented CAR program which is managed by the practitioner. All records of CAR's were found to be complete, current and well managed. All identified CAR's were closed accordingly. Internal audits were reviewed for the month of February 2022. Findings were observed to follow the CAR procedure. The CAR log was observed to be current complete, verified and validated by the practitioner. The CAR Log and reports are maintained by the practitioner.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

### 2.5.4 Internal Audits and Inspections (Mandatory)

Internal audits (SQF) are conducted quarterly. The entire SQF program is reviewed during this inspection. Quarterly reviews were observed to be complete and current and signed by the plant manager and the Senior manager. Were reviewed for the months of June, July and August 2021. Findings were observed to follow the CAR procedure. The CAR log was observed to be current complete, verified and validated by the practitioner. The CAR Log and reports are maintained by the practitioner. The QA Mgr. has been trained in internal auditing and has trained internal staff. Audits are currently not conducted by a multi-functional team. A consultant assists with these inspections The SQF system has been reviewed in its entirety by the practitioner and the senior manager. Minor: There is currently no internal audits or GMP inspections other than the SQF systems review which happens quarterly.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: MINOR** 

**EVIDENCE:** There is currently no internal audits or GMP inspections other than the SQF systems review which happens quarterly.

ROOT CAUSE: Although tasks were completed and GMP's followed there was no documentation of internal audits.

**CORRECTIVE ACTION:** General GMP and internal audit was created as well as the SOP.

**VERIFICATION OF CLOSEOUT:** WAG - Updated audit schedule observed and one completed.

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

**RESPONSE:** COMPLIANT

## 2.6.1 Product Identification (Mandatory)

All product was observed to be identified throughout the entire production process. Product is tracked throughout changeovers. The QA dept. manages and maintains all records which were found to be complete and current. Production reports were observed for the month of November 2021 and were found to be complete, current, verified and validated. All product is identified and tracked through destination.

2.6.1.1 The methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage shall be documented and implemented to ensure: i. Raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products are clearly identified during all stages of receipt, production, storage, and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements.

**RESPONSE: COMPLIANT** 

2.6.1.2 Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person. Procedures shall be implemented to ensure that label use is reconciled and any inconsistencies investigated and resolved. Product changeover and label reconciliation records shall be maintained.

**RESPONSE:** COMPLIANT

## 2.6.2 **Product Trace (Mandatory)**

There is a written product trace/recall program which identifies the practitioner as responsible for managing the process. All product is to be able to be traced "one up and one down". Trace/Mock recalls are conducted on Raw, finished and contact packaging. Traceability is tested annually. The last test was conducted in 8/9/21 for Watermelon Flavor for finished product. The recall took 1.25 hrs. to complete. No concerns were observed and product traced to 100%. Records are maintained by the practitioner.

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

**RESPONSE:** COMPLIANT

### 2.6.3 Product Withdrawal and Recall (Mandatory)

There is a written product trace/recall program which identifies the practitioner as responsible for managing the process. All product is to be able to be traced "one up and one down". Mock recalls are conducted on Raw, finished and contact packaging. Traceability is tested annually. A Mock Recall was conducted on 8/9/21 for Watermelon Flavor. It was completed in 1.25hrs to 100% complete. No concerns were observed. Records are maintained by the practitioner.

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

**RESPONSE:** COMPLIANT

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

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

### 2.6.4 Crisis Management Planning

There is a written product trace/recall program which identifies the practitioner as responsible for managing the process. All product is to be able to be traced "one up and one down". Mock recalls are conducted on Raw, finished and contact packaging. Traceability is tested annually. A Mock Recall was conducted on 8/9/21 for Watermelon Flavor. It was completed in 1.25hrs to 100%complete. No concerns were observed. Records are maintained by the practitioner.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

# 2.7.1 Food Defense Plan (Mandatory)

There is a documented and implemented Food Defense program which is managed by the practitioner. The program includes 9 major areas of concern which are included in the annual inspection process. A complete threat assessment has been completed. A test of the system was completed on 1/11/22 in which a 3rd party tried to access the facility and did not gain access.

**2.7.1.1** A food defense threat assessment shall be conducted to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident.

**RESPONSE:** COMPLIANT

A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum: i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident; ii. The name of the senior site management person responsible for food defense; iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points; iv. The methods implemented to protect sensitive processing points from intentional adulteration; v. The measures taken to ensure the secure receipt and storage of raw materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents; vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, and finished products are held under secure storage and transportation conditions; and vii. The methods implemented to record and control access to the premises by site personnel, contractors, and visitors.

**RESPONSE:** COMPLIANT

2.7.1.3 Instruction shall be provided to all relevant staff on the effective implementation of the food defense plan (refer to 2.9.2.1).

**RESPONSE: COMPLIANT** 

**2.7.1.4** The food defense threat assessment and prevention plan shall be reviewed and tested at least annually or when the threat level, as defined in the threat assessment, changes. Records of reviews and tests of the food defense plan shall be maintained.

## 2.7.2 Food Fraud (Mandatory)

There is an implemented Food Fraud program which is the responsibility of the practitioner and the management team. A complete and current vulnerability assessment has been completed on all processes and ingredients. There is a complete mitigation program which identifies higher risk suppliers and they are managed against GFSI certification. Records are maintained on the company cloud.

**2.7.2.1** The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained.

**RESPONSE: COMPLIANT** 

**2.7.2.2** A food fraud mitigation plan shall be developed and implemented that specifies the methods by which the identified food fraud vulnerabilities shall be controlled, including identified food safety vulnerabilities of ingredients and materials.

**RESPONSE: COMPLIANT** 

2.7.2.3 Instruction shall be provided to all relevant staff on the effective implementation of the food fraud mitigation plan (refer to 2.9.2.1).

**RESPONSE: COMPLIANT** 

**2.7.2.4** The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually with gaps and corrective actions documented. Records of reviews shall be maintained.

**RESPONSE: COMPLIANT** 

### 2.8.1 Allergen Management (Mandatory)

There are no allergens at this facility. There is a documented program in the case where allergens are used. Employees are trained to manage allergens (lunchroom) by hand washing and GMP training.

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors; iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known; iv. A list of allergens that is accessible to relevant staff; v. The control of hazards associated with allergens and incorporated into the food safety plan, and vi. Management plans for control of the identified allergens.

**RESPONSE: COMPLIANT** 

**2.8.1.2** Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens.

**RESPONSE: COMPLIANT** 

**2.8.1.3** Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

**RESPONSE:** COMPLIANT

2.8.1.4 Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.

**RESPONSE: COMPLIANT** 

**2.8.1.5** Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.

**RESPONSE:** COMPLIANT

**EVIDENCE:** N/A no allergens

**2.8.1.6** Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

**RESPONSE: COMPLIANT** 

EVIDENCE: N/A no allergens

**2.8.1.7** The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured.

**RESPONSE: COMPLIANT** 

EVIDENCE: N/A no allergens

**2.8.1.8** The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.

**RESPONSE:** COMPLIANT

EVIDENCE: N/A no allergens

2.8.1.9 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures.

**RESPONSE: COMPLIANT** 

EVIDENCE: N/A no allergens

**2.8.1.10** Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable.

**RESPONSE: COMPLIANT** 

**EVIDENCE:** N/A no allergens

**2.8.1.11** Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.

**RESPONSE:** COMPLIANT

## 2.9.1 Training Requirements

The Practitioner is responsible for the overall food safety training needs. All staff are trained in GMP's, SQF, HACCP, Crisis Management and Food Defense upon hire and annually.

**2.9.1.1** The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented (refer to 2.1.1.6).

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

# 2.9.2 Training Program (Mandatory)

There is a complete training program for all staff are trained in GMP's, SQF, HACCP and Food Defense upon hire and annually. There is a complete and current schedule which includes full time. All training is provided in English. HACCP training is provided to all employees. Employees were interviewed and were found to understand HACCP. There is a complete training program and register for all staff which includes GMP's, HACCP, Food Defense, SQF. Training occurs upon hire and annually. Training and trainer are identified. Topic, description, date, signature are included on the register. Employees are required to complete training quizzes after each training. Tests were observed to be complete and current for all employees.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

## 11.1.1 Premises Location and Approval

There is a current operators license from the State of Michigan. No adjacent buildings were observed to pose any food safety concerns.

11.1.1.1 The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities. The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

**RESPONSE:** COMPLIANT

## 11.1.2 Building Materials

All product contact surfaces were found to be in good operating condition and constructed of S.S.. No food safety risks were observed. Floors were found to be in good condition with no cracks or standing water. Drains were found to be well maintained and cleanable. No waste traps were observed in the production area. Wall to wall, floor to wall, etc. were found to be tight fitting with no debris build-up. No overhead water or other pipes or ducting was observed near open product zones. There are no drop ceilings at this facility. Doors and hatches were found to be of solid construction and self closing. Overheads are included in the sanitation program. No concerns were observed. Stairs and platforms were observed to be well maintained and pose no food safety concern. Toe stops and grating was observed near any open product zones. Ducts and piping are cleaned per the PM schedule.

11.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions. Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** There are no stairs or catwalks.

### 11.1.3 Lightings and Light Fittings

All light fitting were found to be in good working condition and to pose no food safety risk. Lighting in the warehouse was found to be high enough not to pose a risk with forklifts, etc. All lighting was found to be shatter shielded. Adequate lighting was found throughout the facility. No food safety concerns were observed.

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

**RESPONSE:** COMPLIANT

11.1.3.2 Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling. Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

# 11.1.4 Inspection/ Quality Control Area

There is a quality inspection area located in the lab which is separate from the production area. The lab has handwash stations and waste is managed separately from production waste.

11.1.4.1 If online inspection is required, a suitable area close to the processing line shall be provided for the inspection of product (refer to 2.4.4). The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to handwashing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

## 11.1.5 Dust, Insect, and Pest Proofing

No insects were observed anywhere in the facility. Doors, windows, etc. were found to be tight fitting. Doors are self-closing. Insect traps were found to be clean and operating. Tin cats and exterior bait stations were found to be in good operating condition.

11.1.5.1 All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed, and proofed against dust, vermin, and other pests. External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against entry of dust, vermin, and other pests.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

11.1.5.3 Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or exposed.

**RESPONSE: COMPLIANT** 

#### 11.1.6 Ventilation

Ventilation was found to be adequate throughout the facility. No off odors were found. All exhaust vents were observed to be well maintained and controlled insects and any condensation concerns.

**11.1.6.1** Adequate ventilation shall be provided in enclosed processing and food handling areas. Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination.

**RESPONSE:** COMPLIANT

**11.1.6.2** All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.5 to prevent unsanitary conditions.

**RESPONSE:** COMPLIANT

**11.1.6.3** Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s).

**RESPONSE:** COMPLIANT

**11.1.6.4** Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and shall be kept clean.

**RESPONSE: COMPLIANT** 

### 11.1.7 Equipment and Utensils

Equipment was observed to be well maintained and constructed of food grade materials. Equipment rooms were observed to support good hygiene. All equipment was observed to be cleanable to support sanitation. Containers were found to be well maintained. Nonconforming equipment is removed from service and is required to follow the hold program. Forklifts are electric.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

## 11.1.8 Grounds and Roadways

The overall grounds were found to be well maintained. All doors were found to be locked and controlled. The parking and loading areas are fully paved. Overall the facility and premises was observed to be neat, clean and orderly.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.2.1 Repairs and Maintenance

There is a written and implemented PM program which is managed by the Maintenance manager and includes a schedule of all equipment and the building structure. The program is manual. The program included all equipment and the building structure itself. Work instructions are included for each PM. Food grade grease only is used in the facility. Food grade and non food grade are maintained in separate cabinets. No paint was observed on product contact equipment. Records reviewed were found to be complete and current. Signatures were observed on all paperwork. Equipment was observed to be in good operating condition. The exterior of the facility was observed to be well maintained. No temporary repairs were observed. There is no overhead equipment

**11.2.1.1** The methods and responsibility for the maintenance and repair of plant, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination.

11.2.1.2 Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety.

**RESPONSE: COMPLIANT** 

**11.2.1.3** Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**11.2.1.6** Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions.

**RESPONSE: COMPLIANT** 

**11.2.1.7** Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product.

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

#### 11.2.2 Maintenance Staff and Contractors

Maintenance staff and contractors were observed to follow company GMP's. All employees, visitors and contractors are required for sign off on company GMP's. Tools are managed throughout the facility. Tools were observed to be managed throughout the facility. Pre-Op inspections are conducted prior to starting up equipment after a a PM has been completed.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 11.2.3 Calibration

There is a complete and current calibration program. The register was found to be complete and match scales, Records for the pH meter, thermometers and scales was found to be current. All equipment is calibrated by a 3rd party which are ISO 17025 certified. Calibration records from June 2022 for all equipment was observed to be complete and current. Equipment which cannot be calibrated is to be removed and disposed of by the practitioner. Any affected product shall be dispositioned by the practitioner.

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

**RESPONSE: COMPLIANT** 

**11.2.3.2** Equipment shall be calibrated against national or international reference standards and methods or to an accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**11.2.3.4** Procedures shall be documented and implemented to address the resolution of potentially affected products when measuring, testing, or inspection equipment is found to be out of calibration.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**11.2.3.6** A directory of measuring, testing, and inspection equipment that require calibration and records of the calibration tests shall be maintained.

**RESPONSE: COMPLIANT** 

#### 11.2.4 Pest Prevention

A 3rd party PCO (Rose) is used to manage pest control in the facility. The overall pest control program was found to be complete and current including contacts, licenses, insurance, SDS's forms, pest trending, Target pest. Trending's of all findings were identified and managed against. The practitioner also inspects the program annually with the last inspection being 8/17/2021 and was found to be verified and validated by the practitioner and senior manager. Employees are trained not to handle chemicals and none are stored onsite. The PCO manages all chemicals. The PCO manages empty containers. No pest concerns were observed throughout the facility. Pets are not allowed onsite.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

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

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

### 11.2.5 Cleaning and Sanitation

There is a written and implemented sanitation program for the entire operation of the facility. There is an internal sanitation crew which cleans at the end of the day. Weekly and monthly sanitation reports for the months of Sept. through Dec. 2021 were observed to be complete and validated. Pre and Post-Op inspections are conducted daily prior to the start of each shift. Inspections were observed for the month of September 2021 and were found to be complete and validated. Detergents and other chemicals are managed and controlled in a locked cage when not in use and SDS form were observed to be current. Chemicals are managed internally by the Sanitation crew and also by the Chemical supplier. Chemical pumps are calibrated and are checked weekly and documented. Food contact equipment is swabbed and verified prior to production start-up. Equipment found to be not clean is re-cleaned and tested again. Records were observed to be complete, current and validated.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

11.2.5.4 Cleaning-in-place (CIP) systems, where used, shall not pose a chemical contamination risk to raw materials, ingredients, or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored, and recorded (e.g., chemical and concentration used, contact time, and temperature). CIP equipment, including spray balls, shall be maintained, and any modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.

**RESPONSE: COMPLIANT** 

**11.2.5.5** Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of processing areas, product handling equipment, and storage areas as well as the tools themselves.

**RESPONSE:** COMPLIANT

11.2.5.6 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these cleaning operations shall be controlled so they do not interfere with manufacturing operations, equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

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

**RESPONSE: COMPLIANT** 

#### 11.3.1 Personnel Welfare

Company GMP's state that no employees are to work near open product zones if they have illness or open cuts or wounds. Employees are separated when possible to support the Covid management plan. Employees are required to report cuts or sores and are not allowed to work in the filling area.

11.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed. Code Amendment #1 A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

**RESPONSE: COMPLIANT** 

**EVIDENCE:** There are no open product zones.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

### 11.3.2 Handwashing

Hand wash stations were observed throughout the facility prior to entering the production areas. Sinks are constructed of S.S. with warm water, soap Handsfree operation and paper towel. All employees wear gloves when working and change gloves if they leave their work station. All employees were observed washing their hands after leaving the rest room, lunch room etc. Handwash signs were observed on exits doors. No concerns were observed.

11.3.2.1 All personnel shall have clean hands, and hands shall be washed by all staff, contractors, and visitors: i. On entering food handling or processing areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating, or drinking; and v. After handling wash down hoses, cleaning materials, dropped product, or contaminated material.

**RESPONSE: COMPLIANT** 

**11.3.2.2** Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

**RESPONSE:** COMPLIANT

11.3.2.3 Handwashing stations shall be constructed of stainless steel or similar non-corrosive material and at a minimum supplied with: i. A potable water supply at an appropriate temperature; ii. Liquid soap contained within a fixed dispenser; iii. Paper towels in a hands-free cleanable dispenser; and iv. A means of containing used paper towels.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

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

**RESPONSE: COMPLIANT** 

## 11.3.3 Clothing and Personal Effects

All employees where smocks which are managed by a 3rd party. Visitors must follow company GMP's when entering the production areas. Per company GMP's, employees, visitor or contractors are not allowed to wear jewelry on the production floor. No food safety concerns were observed. Hooks are provided for hanging smocks prior to leaving the high risk production area.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**11.3.3.6** Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned. All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

**RESPONSE:** COMPLIANT

**11.3.3.7** Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities.

**RESPONSE:** COMPLIANT

11.3.3.8 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or into any area where food is exposed. Wearing plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted, provided these items are properly covered and do not pose a food safety risk. All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.

**RESPONSE: COMPLIANT** 

## 11.3.4 Visitors

All visitors and contractors must follow company GMP's and none were observed not following. Visitors are required to read and sign off on understanding the company GMP's. During Covid all visitor are required to fill out a questionnaire and to have their temperature checked.

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

**RESPONSE:** COMPLIANT

11.3.4.2 All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 11.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

Staff amenities were found to be in good operating condition, well ventilated, warm water, soap and paper towels. Employee showers are not provided. Employee change rooms were found to be located away from production. The change room was found to be neat, clean and orderly. Rest rooms and hand wash stations were observed to be neat, clean and orderly with hot water, soap, paper towel, hands free operation. Sufficient restrooms are provided to the number of current employees. Restrooms were observed to be easily maintained. The lunch room was observed to be neat, clean and orderly. Microwave, refrigerator and storage is provided to employees. Wash hands signs were observed on all exit doors. Adequate ventilation was found and no vending machine are provided. Outdoor employee eating areas were observed to be neat, clean and orderly. Dedicated waste containers are provided. Staff amenities were found to be in good operating condition, well ventilated, warm water, soap and paper towels. Employee showers are not provided. Employee change rooms were found to be located away from production. The change room was found to be neat, clean and orderly. Rest rooms and hand wash stations were observed to be neat, clean and orderly with hot water, soap, paper towel, hands free operation. Sufficient restrooms are provided to the number of current employees. Restrooms were observed to be easily maintained. The lunch room was observed to be neat, clean and orderly. Microwave, refrigerator and storage is provided to employees. Wash hands signs were observed on all exit doors. Adequate ventilation was found and no vending machine are provided. Outdoor employee eating areas were observed to be neat, clean and orderly. Dedicated waste containers are provided.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

11.3.5.6 Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii.

Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and vi. Kept clean and tidy. Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas.

**RESPONSE:** COMPLIANT

**11.3.5.7** Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations.

**RESPONSE:** COMPLIANT

11.3.5.8 Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.3.

11.3.5.9 Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii.

Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.4.1 Staff Engaged in Food Handling and Processing Operations

There is a dedicated process and employee flow to the production floor to ensure the is no potential for contamination and none was observed. Per company GMP's, no eating, tobacco or jewelry are allow in the production floor and none was observed. The production flow is such that no risks were observed. Water is provided to employees via a water fountain located away from production areas. Sensory evaluations are conducted in a Lab which is located away from production in the Lab which is identified as such.

11.4.1.1 All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor.

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.5.1 Water Supply

Water is provided by the Township of Hudsonville, MI. Adequate supply was observed. There is no contingency plan if water supply in deemed unusable. Product shall shut down if that is the case. No water is stored onsite. Internal water testing is provided by Paragon Labs. No concerns were observed. No cross contamination concerns were observed within the facility.

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

**RESPONSE:** COMPLIANT

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

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**EVIDENCE:** There is no non-potable water stored onsite.

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

**RESPONSE: COMPLIANT** 

**EVIDENCE:** No water is stored onsite

#### 11.5.2 Water Treatment

There is no water treatment.

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

### 11.5.3 Water Quality

Internal water testing is provided by Summit Labs. Water is tested monthly and records were observed to be complete and current. No concerns were observed.

11.5.3.1 Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for: i. Washing, thawing, and treating food; ii. Handwashing; iii. Conveying food; iv. An ingredient or food processing aid; v. Cleaning food contact surfaces and equipment; vi. The manufacture of ice; or vii. The manufacture of steam that will come into contact with food or be used to heat water that will come into contact with food.

**RESPONSE: COMPLIANT** 

11.5.3.2 Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

## 11.5.4 Ice Supply

No ice is used.

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

### 11.5.5 Air and Other Gasses

No compressed air is used for processing.

**11.5.5.1** Compressed air or other gases (e.g., nitrogen or carbon dioxide) that contact food or food contact surfaces shall be clean and present no risk to food safety.

**RESPONSE:** NOT APPLICABLE

11.5.5.2 Compressed air systems and systems used to store or dispense other gases that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually.

**RESPONSE:** NOT APPLICABLE

## 11.6.1 Receipt, Storage and Handling of Goods

Storage at the facility was observed to be well managed. There is a dedicated FIFO rotation of raw and finished materials. Raw materials are maintained separately from finished goods. Fleet EL trucks are to be used for overflow condition. Records are maintained on the company cloud. All product is shipped at ambient temperatures. Overall storage for all dry ingredients was found to be well maintained and dry. Racking was found to be in good operating condition. Pallet jacks are used.. Adequate ventilation was observed throughout the facility ensuring no hazardous gas build-up.

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

**RESPONSE:** COMPLIANT

11.6.1.2 Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-contamination risks. Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**11.6.1.4** Procedures shall be in place to ensure that all ingredients, materials, work- in-progress, rework, and finished product are utilized within their designated shelf-life.

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

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

## 11.6.2 Cold Storage, Freezing and Chilling of Foods

Raw ingredients are received and stored refrigerated prior to production. The cooler was observed to be well maintained. No condensate concerns were observed. Adequate refrigeration was observed for the current load.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

Overall storage for all dry ingredients was found to be well maintained and dry. Racking was found to be in good operating condition. Forklifts used were electric. Adequate ventilation was observed throughout the facility ensuring no hazardous gas build-up.

**11.6.3.1** Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration and prevent packaging from becoming a harborage for pests or vermin.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

# 11.6.4 Storage of Hazardous Chemicals and Toxic Substances

There is an implemented chemical control program which is managed by the practitioner. A complete and current chemical register/inventory was observed. Hazardous chemicals were observed to be locked and controlled in the maintenance shop cabinet and in a caged area in the warehouse. Only maintenance handles hazardous chemicals and controls how they are disposed of. Spill control is available to match a 55 gallon drum.

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

**RESPONSE: COMPLIANT** 

11.6.4.2 Storage of hazardous chemicals and toxic substances shall be: i. Located in an area with appropriate signage indicating that the area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii.

Adequately ventilated; iv. Stored where intended and not comingled (e.g., food versus non-food grade); v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces. Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

11.6.4.3 Hazardous chemicals and toxic substances shall be correctly labeled and: i. Used only according to manufacturers' instructions; ii.

Controlled to prevent contamination or a hazard to raw and packaging material, work-inprogress, finished product, or product contact surfaces; iii. Returned to the appropriate storage areas after use; and iv. Be compliant with national and local legislation.

**RESPONSE: COMPLIANT** 

11.6.4.4 Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of food processing equipment and surfaces in food contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel.

**RESPONSE:** COMPLIANT

11.6.4.5 Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals,: i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use; ii. Be provided first aid equipment and personnel protective equipment (PPE); and iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements.

**RESPONSE:** COMPLIANT

**11.6.4.6** The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are: i. Not reused; ii. Segregated and securely stored prior to collection; and iii. Disposed through an approved vendor.

**RESPONSE: COMPLIANT** 

11.6.4.7 In the event of a hazardous spill, the site shall: i. Have spillage clean-up instructions to ensure that the spill is properly contained; and ii. Be equipped with PPE, spillage kits, and cleaning equipment.

**RESPONSE: COMPLIANT** 

## 11.6.5 Loading, Transport, and Unloading Practices

There is a written and implemented loading/unloading program which includes materials handling inspections and trailer inspection. Trailer temperatures are checked on refrigerated products. Temperature logs were reviewed for the months of July and August 2021 and were found to be complete and current. No cross contamination concerns were observed.

**11.6.5.1** The practices applied during loading, transport, and unloading of food shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

### 11.7.1 High-Risk Processes

This was a Low Risk operation however a pasteurization process has been added since the last SQF audit which is now considered a High Risk process. There is a documented process for managing pasteurizations records from May 2022 were observed to be complete and current. No concerns were observed. Ambient air is tested annually per the Environmental program.

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Product is sealed in the can prior to the pasteurization process therefore employees are not required to wear separate clothing.

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

**RESPONSE: COMPLIANT** 

### 11.7.2 Thawing of Food

There is no thawing of food.

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

## 11.7.3 Control of Foreign Matter Contamination

There is a implemented foreign materials control program which includes glass/brittle plastic, pallets and instrument dials are included. Inspections were observed for Oct. 2021 were found to be complete and current. There is a complete and current glass register which is inspected monthly. No loose objects were observed on equipment. There is a dedicated pallet inspection program which is documented on the trailer inspection log. Scrap pallets are removed from the facility as needed and documented on the trailer inspection log. Gaskets are inspected during the sanitation process. Knives and other sharps are managed accordingly. No concerns were observed. Gaskets and impeller inspections are included in the sanitation process.

11.7.3.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff. Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

**RESPONSE:** COMPLIANT

11.7.3.2 Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation). Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition.

**RESPONSE: COMPLIANT** 

**11.7.3.3** Regular inspections of food handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory.

**RESPONSE:** COMPLIANT

**11.7.3.4** Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.7.4 Detection of Foreign Objects

There is no metal detection in the process. Screams and filters are used to manage foreign materials. Filters are inspected at the start of the shift and documented on the Pre-Op inspection report. Records were observed to be complete and current.

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

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

**RESPONSE: COMPLIANT** 

**11.7.4.3** Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated, and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

**RESPONSE: COMPLIANT** 

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

**RESPONSE: COMPLIANT** 

**11.7.4.5** In all cases of foreign matter contamination, the affected batch or item shall be isolated, inspected, reworked, or disposed of. Records shall be maintained of the disposition.

**RESPONSE: COMPLIANT** 

## 11.8.1 Waste Disposal

All waste was observed to be well managed and no overflow conditions were observed throughout the facility. Line leads are responsible to ensure there are no over flow conditions and make arrangements as needed. Only company trademarks are used and discarded into recycling process. All trolley's and waste bins were found to be in good operating condition and identified as such. Dumpsters were found to be well maintained. Waste materials given to a local farmer is maintained away from good product and identified as such. This waste is removed from the facility daily. The waste management program is reviewed as part of the Pre-Op inspection process.

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

**RESPONSE: COMPLIANT** 

**11.8.1.2** Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.

**RESPONSE: COMPLIANT** 

**11.8.1.3** Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements.

**RESPONSE:** COMPLIANT

**11.8.1.4** Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin.

**RESPONSE:** COMPLIANT

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

**RESPONSE: COMPLIANT** 

11.8.1.6 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

**RESPONSE:** COMPLIANT

11.8.1.7 Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health.

**RESPONSE:** COMPLIANT

**11.8.1.8** Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards.

**11.8.1.9** Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards.

**RESPONSE:** COMPLIANT

**11.8.1.10** Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports.