# SQF Food Safety Audit Edition 9
## Better Booch, LLC. - Better Booch

## Summary

**AUDIT DECISION**
CERTIFIED

**CERTIFICATION NUMBER**
28652 | 151921

**AUDIT RATING**
96
Excellent

**DECISION DATE**
02/23/2022

**AUDIT TYPE**
UNANNOUNCED

**RECERTIFICATION DATE**
02/07/2023

**AUDIT DATES**
02/01/2022 - 02/02/2022

**EXPIRATION DATE**
04/23/2023

**ISSUE DATE**
02/23/2022

## Facility & Scope

**Better Booch, LLC. (52347)**
Better Booch
2538 E. 53rd St.
Huntington Park, CA 90255
United States

**Food Sector Categories:**
16. Ice, Drink, and Beverage Processing

**Products:**
Sector Category 16: Ice, Drink, Beverage Processing. Products: Brewed teas, fermented tea

**Scope of Certification:**
Sector Category 16: Ice, Drink, Beverage Processing. Products: Brewed teas, fermented tea

## Certification Body & Audit Team

**SAI Global**
680 George Street
Sydney, NSW
Australia

**CB#:** CB-1-SAI
**Accreditation Body:** JAS-ANZ
**Accreditation Number:** Z1440295AS

**Lead Auditor:** Wallace, Michael (9682)
**Technical Reviewer:** Glodek , Agnieszka (204863)

**Hours Spent on Site:** 16
**Hours of ICT Activities:** 0
**Hours Spent Writing Report:** 6

## Non-Conforming

## 2.5.3 Corrective and Preventative Action (Mandatory)

Minor: The site does not have documentation as to reasons for delayed NCRs closures due to delayed to back ordered parts, need more time to deem root cause appropriate for contractor delays. The responsibility and methods for managing corrective and preventative actions is the QA Manager. The responsibility for implementation, verification, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations for the sites food safety requirements have been documented and implemented. Deviations from food safety requirements may include customer complaints, nonconformances from GMPs, internal inspections and internal audits are documented. Records reviewed were September 2021 thru December 2021.

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

**RESPONSE:** MINOR

**EVIDENCE:** The site does not have documentation as to reasons for delayed NCRs closures due to delayed to back ordered parts, need more time to deem root cause appropriate for contractor delays.

**ROOT CAUSE:** Each CA was being reviewed as a part of our weekly corrective action meeting and delays were being discussed, but they were not necessarily being documented in the sheet.

**CORRECTIVE ACTION:** A "Current Status" section was added to this dashboard to track delays and items affecting the closure of CA and non-conformances. This section will be reviewed and updated weekly to ensure the timely closure of CAs. SOP was updated as well to reflect this requirement.

**VERIFICATION OF CLOSEOUT:** Reviewed the Dashboard and Corrective Actions and Preventive Action SOP. Reviewed training register. PMW 2/22/2022

**COMPLETION DATE:** 02/15/2022 **CLOSEOUT DATE:** 02/22/2022

## 2.9.1 Training Requirements

Minor: The site does not have a defined schedule to insure refresher training is carried out annually. The Training requirements are dated 2/8/21. The Quality Manager is responsible for determine g what training is required for each job position at the site. Permanent employee must undergo annual refresher training. The training also includes new employee training requirements. Work instructions are available and in English.

**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:** MINOR

**EVIDENCE:** The site does not have a defined schedule to insure refresher training is carried out annually.

**ROOT CAUSE:** These items we completed in January last year, but the holidays and COVID delayed our ability to get these trainings completed before the audit window.

**CORRECTIVE ACTION:** Annual refresher training items are now color coded green in the Training matrix and training records with a key explaining that. Training SOP was updated to reflect this as well. Annual refresher training on key food safety programs was conducted.

**VERIFICATION OF CLOSEOUT:** Reviewed training register. PMW 2/22/2022

**COMPLETION DATE:** 02/10/2022 **CLOSEOUT DATE:** 02/22/2022

## 11.1.1 Premises Location and Approval

Minor: The site does not have a defined schedule to insure refresher training is carried out annually. The site has assess the exterior of the facility for food safety issues.

**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:** MINOR

**EVIDENCE:** The site does not have a current risk assessment on file to assess local activities that may have impact on food safety

**ROOT CAUSE:** This requirement was overlooked during the transition to SQF 9.0

**CORRECTIVE ACTION:** Risk assessment was completed and added to our master document list. This risk assessment will be reviewed annually and updated accordingly as a part of our annual review process. SOP was updated to reflect the need to review and maintain this risk assessment.

**VERIFICATION OF CLOSEOUT:** Reviewed the Risk Assessmsnt for the surrounding area. PMW2/22/2022

**COMPLETION DATE:** 02/22/2022 **CLOSEOUT DATE:** 02/22/2022

## 11.1.7 Equipment and Utensils

Minor: The can line was not properly designed after the can wash rotator. The site has a 4 foot section that does not provide any covering over the can tops after cans are cleaned to prevent unintentional debris contamination. The overhead structure is maintained in good and clean condition. The Construction of premises and equipment policy is dated 11/9/20. Equipment and utensils have been designed, constructed, installed, operated and maintained to meet any applicable regulatory requirements and not to pose a contamination threat to products and equipment shall be hygienically designed and located for appropriate cleaning. When purchasing new equipment, the Quality Manager, VP of Operations and CTO should consider these requirements in order to choose the appropriate options.

**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:** MINOR

**EVIDENCE:** The can line was not properly designed after the can wash rotator. The site has a 4 foot section that does not provide any covering over the can tops after cans are cleaned to prevent unintentional debris contamination. The overhead structure is maintained in good and clean condition.

**ROOT CAUSE:** This problem was overlooked when the canner was installed. While there no items being stored above this area, there are drop ceiling above and still is a risk for foreign material contamination that was overlooked.

**CORRECTIVE ACTION:** A stainless steel hood is being fabricated and installed over this area by a local fabricator. We have a quote and expect it to be installed by the end of the week.

**VERIFICATION OF CLOSEOUT:** reviewed the quite and the e-mail indacating instulation at the end of the week. PMW 2/22/2022

**COMPLETION DATE:** 02/22/2022 **CLOSEOUT DATE:** 02/22/2022

## Audit Statements

| | |
|---|---|
| **SQF Practitioner Name** | Name the designated SQF Practitioner<br>**RESPONSE:** Connor Armstrong |
| **SQF Practitioner Email** | Email of the designated SQF Practitioner<br>**RESPONSE:** connor@getbetterbooch.com |
| **Opening Meeting** | People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas)<br>**RESPONSE:** Franco Aguirre: Operations Manager, Trevor Wright: R&D Laboratory Technician, Connor Armstrong: Quality Assurance Manager, Louis Caballero: Facility Maintenance Manager, Evan Julien: CIO, Mike Wallace: SAI Global SQF Auditor |
| **Facility Description** | Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details<br>**RESPONSE:** This Unannounced Audit of FSC #16 building is a 5000 square foot BEVERAGE MANUFACTURING facility. The facility manufactures CANNED KOMBUCHA (12 oz. & 16 oz.). The processing area is 2000 square feet and the storage areas are 2500 square feet which are split into cooler/dry areas. The facility operates 5 days a week, 18 hours a day. There are 1 shifts at the facility: 8 am to 4:30 pm. There are 20 employees at the facility. The facility's process involves BREWING TEA TO PRODUCE, PACKAGE AND SHIP FINISHED KOMBUCHA PRODUCTS. The processing area consists of 1 line in 1 room. Products manufactured at this facility are distributed in the US only. |
| **Closing Meeting** | People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas)<br>**RESPONSE:** Trey Lockerbie: CEO, Connor Armstrong: Quality Assurance Manager, Evan Julien: CIO, Jesse Howck: Manager, Mike Wallace: SAI Global SQF Auditor |
| **Auditor Recommendation** | Auditor Recommendation<br>**RESPONSE:** Continue Certification upon closure of Non-Conformances. |

## Section Responses

### 2.1.1 Management Responsibility (Mandatory)

The Food Safety Commitment Policy is sign and dated 10/7/2021. The site is committed to receiving, storing, manufacturing and shipping safe and secure food to meet the requirements of the government agencies, customers and global Safety Initiative. The site utilizes HACCP/Preventive Controls based food safety programs supported by prerequisites programs. The site is committed to continuous improvements of its food safety processes through routine program reviews, internal audits, and incident root cause analysis to generate corrective and preventive actions. The Management Statement and Responsibility policy dated 10/07/2021 The statement includes but is not limited to responsibilities, management statement development and communication, job descriptions of key food safety personnel (Operations Manager and SQF Practitioner) and their back-ups HACCP in July of 2016 and internal auditing training. The Training requirements is dated 1/14/2022. Org chart is dated 10/27/20. SQF practitioner cert 10/7/2020 and HACCP cert is dated 6/11/2020. Employees are encouraged to communicate food safety issues, Resources and financial resources. The company is a very small operation with management as daily hand on operation.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

**EVIDENCE:** The site did not have any black out dates defined.

## 2.1.2 Management Review (Mandatory)

The Management Review policy 5/81/2021. The review procedure includes but is not limited to the food safety policy manual, internal and internal audits, customer complaints and hazard and risk management. The procedure includes but is not limited to documents Approval and review, safety updated and SOP changing. The reviews are documented on the document register and updates are maintained at the end of policy or procedure. Records sighted Monthly meetings a documented meeting noted are documented in Google Docs. Notes were present form January 20201 thru February 2022.

**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)

The Complaint Management policy is dated 10/28/20. The policy includes but is not limited to the personnel responsibilities including customer service, Quality team, and the VP of operations, the customer complaint handling process and quality evaluation of the product. Records Sighted Customer complaint log and trending is maintained YTD 2 complaints. One open complaint from 2021. The site is conducted fill line analysis to reduce spillage upon opening to prevent underfilling to cause legal issues. This issue does not a trend.

**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)

A food safety management system is documented and maintained electronic form. It outlines the methods the site will use to meet the requirements of the SQF Food Safety Code. It includes but is not limited to the policy statement, product covered under the scope and other documentations. The site has 2 CCP for the program and the Food Safety program and process flow were reviewed on 10/18/2021. The plan was signed VP of Operations, Chief Technology Officer and Operations Manager.

**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)

The Document Control policy dated 10/29/2020. All documents that are part of the food safety manual are kept within the company google drive to provide access to all employees. The QA manager is responsible for keeping documents up to date, plainly worded, and accessible to all employees. The latest revision date on the register do not match the dates on the reviewed documents. The Document list was last reviewed in 12/28/2021.

**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 Record policy is dated 11/5/2020. Record most shipping and receiving, brewing and production operations are recorded in an ERP software. Other operational records are kept in the company google drive. The policy includes but is not limited to record storage, recording procedures, and record retention. Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access. CCP records reviewed CCP 1 is Time and Temperature Time 30 minutes above 145*F and CCP 2 pH. Sanitation Pre-Check for Canning dated, 10/26/2021.

**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

The Research and Development policy dated 12/7/20. The policy includes but is not limited to product development (experimental), the safety, cost, scalability, and purpose of the product must all be considered and clearly defines; approval and scale up, HACCP validation and shelf life testing. Product formulations SOP 2.3.1 have been 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. taste evaluations, alcohol and micro are an example. The site has plan for release of products under Q-2. TH dated 1/18/2022. Scale up approval has not been completed approved. Product Launch for SB was reviewed. The las Shelf life test was conducted. Test last conducted #1574 conducted on 7 months and completed 1/25/2022, product was manufactured in 6/25/2021.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

Specifications are maintained in SOP 2.4.4 is the listed and Speciation's is 2.3.2, The Raw and Packaging Material policy dated 1/12/21. When a recipe from the Experimental log is approved for full-scale production, it is the QA managers responsibility to determine specifications and acceptability ranges for each ingredient used in the production's formula. Once specifications have been established for an ingredient, the ingredient must be added to the Master RM/PM list. New packaging materials must be also be assessed for safety and contamination concerns. Based on the risk assessment, raw ingredient requires either a Certificate of Analysis (COA) or Letter of Guarantee. Packaging materials that come into direct contact with food must be certified to meet regulatory 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 the register for raw and packaging material specifications and artwork labels are maintained. Finished product specifications are documented they include but are not limited to ingredient statement, chemical attributes, organoleptic attributes, allergens and handling conditions. The register is maintained. Finished product Specification MG dated 12/22/2021, Raw materials reviewed Organic Can sugar and Organic Yunnan Tea and Packaging materials (2) "A" and "Z" COA Alum Body Can 21 CFR 175.300 GFSI Current exp 2/13/2022. and for Hibiscus flower (peanut free).

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.3.3 Contract Manufacturers

The site does nit conduct contract manufacturing,

**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

**EVIDENCE:** The site does nit conduct contract manufacturing

**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

**EVIDENCE:** The site does nit conduct contract manufacturing

**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

**EVIDENCE:** The site does nit conduct contract manufacturing

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site does nit conduct contract manufacturing

## 2.3.4 Approved Supplier Program (Mandatory)

The site Supplier Approval Program dated 12/14/20. The approval process includes but is not limited to questionnaire, requesting COAs, letter of guarantee. If the supplier will be providing an ingredient, use of COA as a reference and test the product using in-house or outside laboratory facilities to confirm the accuracy of the listed product specifications. The approval program also includes other facilities under the same corporate owner ship, and emergency use and reevaluation process. Finished product specifications are documented they include but are not limited to ingredient statement, chemical attributes, organoleptic attributes, allergens and handling conditions. The register is maintained. The register contains a risk rating for the raw material and the associated supplier. Finished product Specification MG dated 12/22/2021, Raw materials reviewed Organic Can sugar and Organic Yunnan Tea and Packaging materials (2) “A” and “Z” COA Alum Body Can 21 CFR 175.300 GFSI Current exp 2/13/2022. and for Hibiscus flower (peanut free).

**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)

The site has a documented Food Legislation policy dated 1/10/18. The site is responsible for maintaining policies that are compliant with all applicable regulations. Monitoring company compliance is the responsibility of the Quality Assurance Manager and the Director of operations and includes but is not limited to Maximum residue limits, food safety, allergen and additive labeling, and legislative changes. The 24 hour notification is incorrect. The site plan included the e-mail for SQFI and SAI Global e-mail.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.2 Good Manufacturing Practices (Mandatory)

The Good Manufacturing Practices applicable to the scope of certification that outline how food safety is controlled and assured is documented. The Good Manufacturing Practices policy is dated 3/1/21. Reviewed on 12/28/2021.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.3 Food Safety Plan (Mandatory)

Food safety Plan HACCP Plan A multidisciplinary team that includes the SQF practitioner is documented. Annual Reviewed 10/18/2021 Product description page includes but is not limited to name, product characteristics, vulnerable groups, packaging, labeling, shelf life and distribution. List in-puts and out-puts Flow chart CCPs at steeping above 145F° for minimum of 30 minutes or more and CCP at Fermentation is pH below 4.6 the chart is verified. Hazard analysis with CCP identified at process step: Critical limits, monitoring, and corrective actions are documented. CCP #1-Steeping above 145F° for minimum of 30 minutes. Monitoring:( What, How. frequency, who) are documented. Beginning brew after 30 minutes and end of brew. Temperature is monitored by the brewer. CCP #2- Fermentation pH< 4.6 after pitching step and throughout fermentation. Monitoring: (what, frequency, who) is documented. Verification of monitoring (What, How, Frequency and Who) are documented. Verifications are documented for frequency and who. Corrective actions are documented. Records reviewed: June 2021 thru December 2021 and January 2022. Product disposition are decrumbed for products that do not meet any of the step requirements.

| | |
|---|---|
| **2.4.3.1** | A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. 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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**RESPONSE:** COMPLIANT |
| **2.4.3.9** | The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.<br>**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.<br>**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).<br>**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

The Product sampling, inspection and analysis policy is dated 12/22/20. It is the responsibility of the QA manager to determine the testing methods, assign who is responsible for testing, and criteria to test. This test occurs on raw materials, finished product, and work in progress. The QA manager is also responsible to audit claims on label to ensure that specifications correspond to label requirements that statement made on the label are correct. The parameter, methods, frequency, responsible, and records are documented in the policy. Proficiency testing is conducted. The test lists the sample, 7 individuals, method, Alcohol Distillation, Sample # RB 1725. Third party validations. Records Sighted Finished Product Micro test results reviewed: 10/20/2021 for CS flavor Batch #1700 and 4/15/2021 Flavor GB Batch #1490 Lab certification Accreditation ISO/IFC 17025:2017 valid thru 8/31/2022, Pre-ops (ATP Swabs) dated January 2022. Batch Records, CCP- steeping and pH (lot#, finish prod. Test, filter inspection). Records reviewed were July thru December 2021 QC checks (pkg lot, temp, brix,) records reviewed were July thru December 2021.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.5 Non-conforming Materials and Product

The Non-conforming product or Equipment policy. It is the responsibility of the Quality Manager to ensure that all non-conforming raw materials, packaging materials, WIP product, and finished product are effectively segregated and label to prevent inadvertent use. It is the responsibility of maintenance to properly label and communicate non-conforming equipment and machinery to prevent inadvertent use. The Procedure includes but is not limited to raw material, finished products, and processing equipment. Reviewed Non-conforming product from July 2021 thru December 2021. Disposition was documented on Non- conformance log and production log. No product is on quarantine.

**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

The site does not rework product.

**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

**EVIDENCE:** The site does not rework product.

## 2.4.7 Product Release (Mandatory)

The Finished product Release Specifications policy. Inhouse analytical methods are performed. Products are tested and several points during the process to ensure conformity. Analytical conformity must be met before it can be moved to the next step. The Release specifications for production include but is not limited to pre-production testing, packaged goods testing and out of limits results and /or quarantined product. Records reviewed" Pre-ops (ATP Swabs) dated January 2022. Batch Records, CCP- steeping and pH (lot#, finish prod. Test, filter inspection). Records reviewed were July thru December 2021 QC checks (pkg lot, temp, brix,) records reviewed were July thru December 2021.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.8 Environmental Monitoring

The Environmental Monitoring policy is dated 1/26/21. The site is wet for the most part a cold facility, the organism/pathogen of most concerns is listeria monocytogenes. Salmonella will be swabbed for the back-storage area and near raw ingredients that are stored in the cold storage. The site employs both direct pathogens testing as well as testing for indicator organisms to determine cleanliness and the potential for pathogen harborage. The chosen indicator organism test is APC 4-5 test weekly. The process includes but is not limited to selection of pathogens and chemicals hazards vis risk assessment, selection of appropriate sites for samples, zones, and frequency. Records Sighted Environmental Monitoring Listeria Species and Salmonella quarterly 6-8 sites. Average of total of 12 tests average 23 Zone 1, 20 Zone 2, 30 Zone 3 and 7 Zone 4 on a quarterly basis. Reviewed October thru December 2021 and January 2022. The site trends the samples as to the location. The site has had negative results for the last 2 years.

**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)

The Validation and Effectiveness schedule. The schedule outlines the validation activities and demonstrations of efficacy performed. The schedule includes the item/programs, validation methods, responsibility, frequency and records. Other validation activities reviewed and in place include personnel and personnel processing practices via an internal audit, calibrations via external service calibrations; water testing annual; and environmental monitoring via trending of results Production records were reviewed. Validation activities listed in this SOP include: Food Safety and CCPs, Pre-requisite programs currently in place. All validation activities are annual, or more often as needed. Validations in many situations are by third party. Such as equipment calibrations, and proficiency testing. The facility has a validated change over process from one product to another. The site is a batch process with validation process of removal of packaging and lines of excess product.

**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)

Batch Records, CCP- steeping and pH (lot#, finish prod. Test, filter inspection). QC checks (pkg lot, temp, brix,) Pre-ops (ATP Swabs) Batch Records, CCP- steeping and pH (lot#, finish prod. Test, filter inspection). QC checks Master sanitation schedule Dashboard Sanitation Tracking and Trending (daily, weekly, monthly, bi, quarterly) maintained CIP log (ATP Swabs, concentration) Weekly Maintenance schedule with PM zone, Frequency, Description, completed date. Daily instrument calibration log (thermometer, scale, ethanol meter, refractometer, pH meter) Weekly scale Monthly thermometer checks

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.5.3 Corrective and Preventative Action (Mandatory)

Minor: The site does not have documentation as to reasons for delayed NCRs closures due to delayed to back ordered parts, need more time to deem root cause appropriate for contractor delays. The responsibility and methods for managing corrective and preventative actions is the QA Manager. The responsibility for implementation, verification, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations for the sites food safety requirements have been documented and implemented. Deviations from food safety requirements may include customer complaints, nonconformances from GMPs, internal inspections and internal audits are documented. Records reviewed were September 2021 thru December 2021.

**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:** MINOR

**EVIDENCE:** The site does not have documentation as to reasons for delayed NCRs closures due to delayed to back ordered parts, need more time to deem root cause appropriate for contractor delays.

**ROOT CAUSE:** Each CA was being reviewed as a part of our weekly corrective action meeting and delays were being discussed, but they were not necessarily being documented in the sheet.

**CORRECTIVE ACTION:** A "Current Status" section was added to this dashboard to track delays and items affecting the closure of CA and non-conformances. This section will be reviewed and updated weekly to ensure the timely closure of CAs. SOP was updated as well to reflect this requirement.

**VERIFICATION OF CLOSEOUT:** Reviewed the Dashboard and Corrective Actions and Preventive Action SOP. Reviewed training register. PMW 2/22/2022

**COMPLETION DATE:** 02/15/2022 **CLOSEOUT DATE:** 02/22/2022

## 2.5.4 Internal Audits and Inspections (Mandatory)

The internal audits and inspection policy is dated 1/6/21. The inspections are used as a tool to verify that the GMPs and building/equipment maintenance is compliant with the SQF code and that employees are adhering to the GMP polices. The policy includes but is not limited to daily inspections, weekly walkthroughs, monthly internal audits, and third-party audits Records Sighted Weekly GMP walkthrough. Back-up Practitioner had Internal Auditing training was completed on 10/12/2018 and the QA manager had Internal Auditing training on 10/26/2020. Monthly GMP inspections have 7 area of the facility, every are is covered in 7 weeks. Area three was reviewed 11/1/2021, Area 1 5/24/2021 and Area 2 12/13/2021. The master link includes 9/20/2021 thru 1/17/2022. Corrective actions are documented in the dashboard.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.6.1 Product Identification (Mandatory)

Product identification policy is dated 1/15/21. The system is implemented to ensure the following items are clearly identified during all stages of receipt, production, storage, and dispatch. The procedure includes RM/PM lot numbers generation, raw and packaging materials, WIP product, finished product and product startup and changeover.

**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)

The product tray process is documented in the Product identification policy is dated 1/15/21. The sites ERP maintains product traceability at all times. The procedure includes but is not raw ingredients and packaging materials are inventoried in the ERP system by lot. The use of finished goods to fulfill sales orders is tracked in the ERP, Trace was conducted on 9/23/2021 for MG. Lot #1681. Manufactured 838 cases (10, 056 unites). The site shipped all 838 cases. All 838 cases were accounted for and shipped to one location. 100 % of the product was accounted for in less than three hours.

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

**RESPONSE:** COMPLIANT

## 2.6.3 Product Withdrawal and Recall (Mandatory)

The Product Recall procedure is dated 1/15/21. The policy is to outline procedures and systematic actions needed for recalling product from commerce that is determined to be unfit for distribution in compliance with government agency regulations and requirements. The recall program includes but is not limited to recall team, the team role description including legal advisor, recall classification, and SQFI and the certification body 24-hour notification. Emergency contact information is documented for customer. Records are maintained for previous test of the system. The system is tested annually, one step forward and on step backward.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.6.4 Crisis Management Planning

The Crisis Management policy was reviewed 11/1/19. The purpose is to provide strategic communication approaches to manage events or situations that are damaging and disruptive to the site overall success and reputation. The plan identifies the crisis types facing the site the includes but is not limited to natural disasters, fire, disease or illness, and human-error product harm. The crisis preparation outlies the methods used to identify product affected by a response the measures taken to verify the acceptability, the how to handle the media. The Crisis Management manual is dated 2/17/2022 was reviewed 1/6/2022 The manual includes but is not limited to the Crisis team and responsibilities, safety/legal counsel, responding to a crisis. The training of the team is dated January 2021. The measures to isolate and identify product affected by a response to a crisis and the measures taken to verify the acceptability of food prior to release is not documented in the plan. The annual Challenge was conducted on 12/23/2021.

**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)

The Food Defense policy is dated 1/27/21. The policy is intended to identify the requirements and procedure to be used in this facility in order to prevent intentional food contamination. The policy includes but is not limited to the food defense team, risk assessment, protection of product and personnel security (staff, visitors, outside perimeters, storage and transportation), and security of incoming products and supplies. Threat assessment was last reviewed 12/14/2021. The assessment sis based on the FDA Food Defense Builder.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.7.2 Food Fraud (Mandatory)

The Food Fraud policy is dated 2/3/21. The policy includes but is not limited to food fraud overview and emergency contact list. The vulnerability assessment addresses the adulteration, tampering over-run, theft, diversion simulation and counterfeiting. The Food Fraud Assessment repots includes the vulnerability assessment, materials included in the assessment, occurrence, and detection. The mitigation Strategy for each identified risk are documented with the conclusion on how to address the identified risk. the risk is Low. Threat assessment was last reviewed 12/20/2021. The site uses SAFE for whole spice.

**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)

The site does not handle or product any allergen product. The site has a documented Allergen control policy dated 1/11/21. The policy describes the efforts that must be undertaken by employee to protect against allergen contamination. The policy includes but is not limited to identification, traceability, re-work, the big 8, and sanitation and changeover. Annual allergen refresher training is conducted for the employees as part of the 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

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.9.1 Training Requirements

Minor: The site does not have a defined schedule to insure refresher training is carried out annually. The Training requirements are dated 2/8/21. The Quality Manager is responsible for determine g what training is required for each job position at the site. Permanent employee must undergo annual refresher training. The training also includes new employee training requirements. Work instructions are available and in English.

**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:** MINOR

**EVIDENCE:** The site does not have a defined schedule to insure refresher training is carried out annually.

**ROOT CAUSE:** These items we completed in January last year, but the holidays and COVID delayed our ability to get these trainings completed before the audit window.

**CORRECTIVE ACTION:** Annual refresher training items are now color coded green in the Training matrix and training records with a key explaining that. Training SOP was updated to reflect this as well. Annual refresher training on key food safety programs was conducted.

**VERIFICATION OF CLOSEOUT:** Reviewed training register. PMW 2/22/2022

**COMPLETION DATE:** 02/10/2022 **CLOSEOUT DATE:** 02/22/2022

**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)

The Training requirements are dated 2/8/21. The Quality Manager is responsible for determine g what training is required for each job position at the site. Permanent employee must undergo annual refresher training. The training also includes new employee training requirements. Work instructions are available and in English. A training skill register describing who has been trained in relevant skills are maintained with all the required elements. Training for GMP 5/20/2021, Pest control 5/15/2021, Chemical January 2021, allergens and Gluten January 2021, SQF Program January 2021, Food Security and Food Defense January 2021.

**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

Minor: The site does not have a defined schedule to insure refresher training is carried out annually. The site has assess the exterior of the facility for food safety issues.

**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:** MINOR

**EVIDENCE:** The site does not have a current risk assessment on file to assess local activities that may have impact on food safety

**ROOT CAUSE:** This requirement was overlooked during the transition to SQF 9.0

**CORRECTIVE ACTION:** Risk assessment was completed and added to our master document list. This risk assessment will be reviewed annually and updated accordingly as a part of our annual review process. SOP was updated to reflect the need to review and maintain this risk assessment.

**VERIFICATION OF CLOSEOUT:** Reviewed the Risk Assessmsnt for the surrounding area. PMW2/22/2022

**COMPLETION DATE:** 02/22/2022 **CLOSEOUT DATE:** 02/22/2022

## 11.1.2 Building Materials

Product contact surfaces and non-food contact surfaces do not pose a food safety risk. Majority of the process is enclosed. Drain constructed and located so they can be easily cleaned and not present a hazard and floors are sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions. Doors and windows and their frames in food processing, handing or storage areas or of material and construction which meets the same functional requirements as for internal walls and partitions. The site is not required to have a waste trap. No stairs, catwalks and platforms.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Waste trap system is not required.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** 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:** No stairs, catwalks and platforms.

## 11.1.3 Lightings and Light Fittings

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.

**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

A suitable area is provided for the inspection of the product.

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

**RESPONSE:** COMPLIANT

## 11.1.5 Dust, Insect, and Pest Proofing

External doors, including overhead dock doors in food handling areas used for product, pedestrian or truck access were insect-proofed. Electronic pest control devices are located as to not present a hazard. Doors are equipped with self-closing devise and or strip curtains.

**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

Adequate ventilation is provided in the enclosed processing and the product handling areas.

**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:** NOT APPLICABLE

**EVIDENCE:** The site does not conduct any cooking or heating of products.

**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

Minor: The can line was not properly designed after the can wash rotator. The site has a 4 foot section that does not provide any covering over the can tops after cans are cleaned to prevent unintentional debris contamination. The overhead structure is maintained in good and clean condition. The Construction of premises and equipment policy is dated 11/9/20. Equipment and utensils have been designed, constructed, installed, operated and maintained to meet any applicable regulatory requirements and not to pose a contamination threat to products and equipment shall be hygienically designed and located for appropriate cleaning. When purchasing new equipment, the Quality Manager, VP of Operations and CTO should consider these requirements in order to choose the appropriate options.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

**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:** MINOR

**EVIDENCE:** The can line was not properly designed after the can wash rotator. The site has a 4 foot section that does not provide any covering over the can tops after cans are cleaned to prevent unintentional debris contamination. The overhead structure is maintained in good and clean condition.

**ROOT CAUSE:** This problem was overlooked when the canner was installed. While there no items being stored above this area, there are drop ceiling above and still is a risk for foreign material contamination that was overlooked.

**CORRECTIVE ACTION:** A stainless steel hood is being fabricated and installed over this area by a local fabricator. We have a quote and expect it to be installed by the end of the week.

**VERIFICATION OF CLOSEOUT:** reviewed the quite and the e-mail indacating instulation at the end of the week. PMW 2/22/2022

**COMPLETION DATE:** 02/22/2022 **CLOSEOUT DATE:** 02/22/2022

**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

Measures are established to maintain a suitable external environment. Paths from amenities leading to site entrances shall be effectively sealed. Paths, roadways, and loading and unloading areas are maintained as to not present a hazard to the food safety operations of the premises. The grounds are sloped to prevent the pooling of water. Drains are separate from the site drainage system and regularly cleared of debris.

**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

The Premises and Equipment Maintenance policy is Maintenance program is dated 1/11/21. The policy includes but is not limited to the preventive maintenance, predictive maintenance, temporary repair and placement of tool during maintenance activities. The methods and responsibility for the maintenance and repair of plant, equipment and buildings are documented, planned and implemented in a manner that minimizes the risk of product, packaging or equipment contamination. The site utilized an excel spread sheet for the maintenance task. Paint is not used on food contact surfaces. Program and policy is documented for maintenance and contractors to remove tools and notify sanitation if cleaning is required. Tool accountability and sanitation is address in the PM signoff. The site has an Alchemy training system for equipment maintenance or repairs in product area. The training includes GMPs, food safety and safety requirement. Contractor Orientation Training and Group Practice Training. The site has a documented PM Master Schedule That lists equipment, frequency and description of activity to be conducted. PM records reviewed were August thru December 2021. When maintenance is completed, inspection is conducted by QA or sanitation as part of pre-operational inspection.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The paint is not used on food contact surfaces.

## 11.2.2 Maintenance Staff and Contractors

The Premises and Equipment Maintenance policy is Maintenance program is dated 1/11/21. Maintenance and Contractors are required to sign and obey the site's GMPs and hygiene protocols. Contractors are required to remove all tools and debris. The site has an SOP that outlines the responsibility for

**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

The Calibration policy is dated 5/14/2021. The policy includes the methods and frequency of the calibration of equipment. The policy also includes in the event that a measuring device that has been used is oud out of calibration. Scales (benchtop, Lab scale and brewers scale) are calibrated annually and verified weekly Records reviewed August thru December 2021. Monthly thermometer: in-house records reviewed June 2021 thru January 2022. Scale annual Calibration 8/27/2021 for 2 scales. Thermometer calibration due July 2023. pH conducted daily, reviewed August thru December 2021.

**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

Methods and responsibility for integrated pest management are defined. Pest control is contracted to a pest control company. For both buildings They provide b-monthly service to 33 interior devices, semi-monthly service, there are also has 33 interior traps, 3 light traps, exterior traps 19. All licenses: Business License 1/6/2022, PCO issued license issues 6/30/2022. Certificate of Insurance 6/1/2022 Activity reports, trap maps dated 1/4/2022, and other required documents are in place. During the audit, there was no pest activity observed. Approved chemical log was documented and current dated 1/7/2022. Trend reports reviewed October thru January 2022 The pest control program includes the following: methods for pest management; target pests; methods used to prevent and/or eliminate pests; inspection frequency; site map of devices; list of pesticides used and Safety Data Sheets for each. All required licenses and insurance certificates are in place and current. There is in place an employee training program on pest control regarding this service and includes information to employees not to bring in pesticides to work. Pesticide usage log is documented. Trends for pests and insects are documented and reviewed. Approved chemical list for the site is current. Records of all pest inspections conducted by the license's pest control operator at the frequency stated above are in place.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** 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

The Sanitation program dated 10/29/2021 The SOP encompasses the cleaning, the frequency, and the procedure. The program includes but is not limited to the general cleaning procedure, the requirements for the CIP system, and a master cleaning schedule and dashboard sanitation tracking and trending. Chemical inventory is dated 1/22/2022. The mix concentration is maintained on the CIP log . Reviewed. ATP, pH and PAA sanitizer documentation, Water Temp and wash cycle is standardized as aper the SOP. Caustic concentration. August thru December 2021.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.3.1 Personnel Welfare

No evidence of any employee with infectious diseases was present in product zones. No employees observed with exposed cuts, sores, or observed smoking, chewing, eating, drinking or spitting in product handling or storage areas. The site has a documented program for blood and body fluids and the precautions needed to protect product. Drinking fountains are present in the production area for employees to stay hydrated in the hot environment. Covid protocols are in place to prevent potential contamination of employee. The employees are required to report Covid or Covid symptoms.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.3.2 Handwashing

Hand wash sinks were stainless steel and were equipped with all required supplies. Hand wash sinks used in food handling areas are hands free taps. Liquid soap, paper towels and proper waste containers are provided. Hand sanitizer is available at each station. Glove are used on an as need basis, i.e., handling food products or food contact equipment. Signs are posted to remind the employees to wash hands. Signs were posted in English. Personnel in all processing and packaging areas, visitors and contractors were observed washing their hands where required. Glove use and corresponding hand washing by personnel in processing and packaging areas was observed. Covid Protocols are in place to prevent overcrowding.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.3.3 Clothing and Personal Effects

Clothing worn by staff working in food handling areas was properly maintained. Employees in all areas were observed wearing the appropriate clothing required for that process. Employees wear company issues uniforms that employees change into at the site. Plant supervisors perform inspections to verify that employees have clean clothing and shoes at the start of their shift. Disposable gloves used by employees were changed after breaks, when damaged, and upon re-entry into their work areas. Non-disposable gloves and aprons are stored in an appropriate manner. There was no evidence of employees wearing jewelry and other loose objects while in food handling areas. All visitors, management, maintenance and staff were wearing appropriate clothing and footwear within the processing operation. Visitors were required to remove jewelry and loose items prior to entry into any food handling area. The facility is not processing a high-risk food product. The employees are not required to wear protective outer clothing. Changing area is provided for the employees to don hairnets, beard nets, and hand washing. There are in place lockers for employees to store personal items and street clothing. Showers are not required; the site is not a high risk operation.

**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, management, maintenance and staff were wearing appropriate clothing and footwear within the processing operation. Visitors were required to remove jewelry and loose items prior to entry into any food handling area. Visitors' policy indicates, visitors exhibiting visible signs of illness are prevented from entering areas where food is handled, processed, or stored. Visitors were escorted throughout the facility, and followed all appropriate protocols.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

Staff amenities are supplied with appropriate lighting and ventilation and are available to all production staff. Hand wash sinks were stainless steel and were equipped with all required supplies. Hand wash sinks used in food handling areas are hands free taps. Liquid soap, paper towels and proper waste containers are provided. The facility is not processing a high-risk food product. The employees are not required to wear protective outer clothing. Changing area is provided for the employees to don hairnets, beard nets, and hand washing. There are in place lockers for employees to store personal items and street clothing. Showers are not required; the site is not a high risk operational Restrooms were observed to be designed so that they do not open directly into food handling areas, cater to the maximum staff and are designed for ease of cleaning. It was observed that sanitary drainage is separate from processing drains. The hand wash sinks are adjacent to all toilet rooms and were found to have in place all required supplies. Lunch areas are separated from processing, storage and handling areas. Lunchrooms were observed as properly ventilated, well lit, adequate in size, has a working sink, microwaves and refrigerators for employee lunches. Signs are posted in the appropriate language (English) reminding people to wash their hands before entering the processing area. Sink was provided to wash dishes. Refrigeration was provided for keeping personal food products cold. Hand sink for washing hands was located outside directly outside the lunchroom. Hand washing was required prior to entering the plant.

**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:** NOT APPLICABLE

**EVIDENCE:** The site is not a high risk operation.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Showers are not required.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

**11.3.5.9** Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.4.1 Staff Engaged in Food Handling and Processing Operations

Employees were following building and GMP protocols in production area access; exterior doors were kept closed when not used; employees were observed washing their hands upon entry into food handling areas; there was no evidence of any employees with exposed false fingernails or fingernail polish in food handling areas; Hair restraints are used where product is exposed. All food ingredients and packaging were stored in a compliant manner; and all waste containers were properly labeled and serviced regularly. Sensory evaluations are conducted in the Lab, or other designated areas, and only by qualified personnel. There is no sensory testing done on the production floor. Wash down hoses were stored in hose racks, and not on the floor.

**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 supplied from City Huntington Park. Through inspection, there was adequate supplies of both hot and cold water to enable effective cleaning. The back-flow valves within the site are inspected annually, as required by state and local authorities. The last backflow inspection was conducted January 2022. The site does not have any storage tanks on site. The site has the 2020 water report for heavy metals. The site has a documented protocol to follow in the event of Boil Order (unpotable water supply) the site has a protocol for sourcing water from a approved supplier of the health park. The site conducts test for arsenic in June 2021. Potability is semi annual and test, March 2020 and September 2020. E-coli, coliforms and APC.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site does not use non-potable water.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Water is not stored on-site.

## 11.5.2 Water Treatment

The treated water is monitored by the site to ensure effective target ranges for the hardened water are maintained. QA monitors the hardness levels pH daily. Water is not treated for potability. Equipment is monitored by the contract service provider. The site adds minerals daily.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.5.3 Water Quality

Water is teste annually for potability for various sites in the facility. The water is tested 2 times a year. Water is tested for potability by using the SMEWW 9221-B. The site tests for APC and Coliform.

**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:** NOT APPLICABLE

**EVIDENCE:** The site does not use ice.

## 11.5.4 Ice Supply

The site does not use ice in the manufacturing of product.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site does not use ice in the manufacturing of product.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site does not use ice in the manufacturing of product.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site does not use ice in the manufacturing of product.

## 11.5.5 Air and Other Gasses

The site uses compressed air, tests are conducted yeast, mold, Listeria and APC tested quarterly. Ambient air is tested (sponge yeast and mold) 2 times pers year. Test were conducted 3/25/2021 and 10/25/2021. Filters are changed annually 5/21/2021. Back up compressor has an indicator for filter changes. Inspections are done every other month., last inspection January 2021.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.6.1 Receipt, Storage and Handling of Goods

Ingredient storage areas are located away from wet fermenting processing areas. Racking was provided for the storage of products. Racking was examined and observed in compliant condition with no racking hazards present. All vehicles used in food handling areas do not present any hazard to the foods produced or stored. Storage rooms were observed in compliant condition. The room was maintained and constructed to allow for efficient and hygienic storage of raw materials, finished products, and packaging materials. Products are stored FIFO in the warehouse. The site uses third party sanitation and pest control. The site does not use alternative storage.

**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.

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site does not use alternative storage.

## 11.6.2 Cold Storage, Freezing and Chilling of Foods

The site has a freezer and cooler, the freezer is used for cold packs for shipping product and hop storage. The temperatures are documented and maintained electronically. The system is on an alarm system for when temperatures reach established target. The freezer is monitored manually with temper recording device readout system. The freezer not the cooler is not for food safety, but quality and shelf live. Quality issue not a food safety. Discharge lines are properly maintained to divert condensation and cleaning solutions from condensate pans to floor drains.

**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

Rooms used for the storage of product ingredients, packaging, and other dry goods are located away from wet areas. Racking was observed in good condition.

**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

Chemicals are stored in an appropriate manner, and do not present a hazard to staff, packaging, product or equipment. Chemicals used in the facility can pass through the municipal sewer system. There are no hazardous chemicals stored next to or directly over production utensils or product packaging. Everyday chemicals used in processing and packaging were observed stored in a compliant manner. Pesticides, rodenticides, fumigants and insecticides are not stored in the facility. Chemical storage was observed to meet local regulations, properly ventilated, signed, and secured. There was no evidence of chemical cross contamination. Chemical storage areas have in place instructions for use, a current inventory, first aid station, personal protection equipment, emergency shower, and chemical clean-up supplies. Hazardous chemicals are properly stored with spill containment.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.6.5 Loading, Transport, and Unloading Practices

The Loading, transport and unloading practices policy is dated 11/2/20. The practices are designed to ensure the integrity of raw material, packaging, and finished products in order to prevent cross-contamination through safe handling and storage practices. The policy includes but is not limited to loading temperatures, trailer inspections, transport, and unloading and check-in. Unloading practices are designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity. Products are shipped refrigerated for quality Records Sighted Incoming (BOL, lot#, temp, trailer inspection) dated 11/18/2021, 12/22/2021 and 2/6/2022. Outbound: temperature precool and depart temperature, security, cleanliness. Pest off smell and repairs product integrity. 12/2/2021 10/28/2021 and 12/17/2021.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.7.1 High-Risk Processes

The site is not engaged in High Risk processing.

**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:** NOT APPLICABLE

**EVIDENCE:** The site is not engaged in High Risk processing.

**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:** NOT APPLICABLE

**EVIDENCE:** The site is not engaged in High Risk processing.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site is not engaged in High Risk processing.

**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:** The site is not engaged in High Risk processing.

**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:** NOT APPLICABLE

**EVIDENCE:** The site is not engaged in High Risk processing.

## 11.7.2 Thawing of Food

The site does not thaw product. Frozen product can be added to the steeping process.

**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

**EVIDENCE:** The site does not thaw product. Frozen product can be added to the steeping process.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site does not thaw product. Frozen product can be added to the steeping process.

**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

**EVIDENCE:** The site does not thaw product. Frozen product can be added to the steeping process.

## 11.7.3 Control of Foreign Matter Contamination

The Foreign Material policy dated 5/20/2021 The QA manager is responsible for designing and updating

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.7.4 Detection of Foreign Objects

The site has a foreign material and Detections Policy dated 5/20/2021. The site does not have metal detection device. The site does not use screens, but filers are used. Filter sizes are 200 microns filter an 1 micron filter and then a Lenticular K 900 filter. Filters are inspected daily, bag filters are replaced per batch and inspected between batches. Inspections are conducted before and after each use for debris and particulates. Bag filters are used and disposed. Lenticular filter is inspection as part of the SOP cleaning for unusual debris.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The site does not use metal detection devices.

**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

Responsibility and methods for the handling of dry, wet and liquid waste are defined. Department managers are responsible for overseeing the removal of waste from the different areas within the facility and contacting waste removal company when waste bins are near full. QA is responsible for the overall sanitation program. Waste is being removed on a regular basis from processing areas, and that waste collection areas are adequately maintained. Solid processing wastes are adequately contained and held separately. Waste management is reviewed daily as part of the pre-operational inspections. The site did not have liquid waste that required special handling. All liquid waste was able to pass through the city sewer system. The site does not have to store liquid waste for removal. All liquid waste can pass through the municipal system. Inedible waste is not stored or used for animal feed. The site does not have Trade Marked products.

**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.<br><br>**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.<br><br>**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.<br><br>**RESPONSE:** NOT APPLICABLE<br><br>**EVIDENCE:** The site does not have Trade Marked products. |
| **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.<br><br>**RESPONSE:** NOT APPLICABLE<br><br>**EVIDENCE:** Inedible waste is not stored or used for animal feed. |
| **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.<br><br>**RESPONSE:** COMPLIANT |
| **11.8.1.9** | Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards.<br><br>**RESPONSE:** NOT APPLICABLE<br><br>**EVIDENCE:** The site does not have to store liquid waste for removal. All liquid waste can pass through the municipal system. |
| **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.<br><br>**RESPONSE:** COMPLIANT |