



# SQF Food Safety Audit Edition 8.1

## Harvest Valley Bakery, Inc. - Harvest Valley Bakery, Inc.

### Summary

**AUDIT DECISION**  
**CERTIFIED**

**CERTIFICATION NUMBER**  
**33521 | 109322**

**AUDIT RATING**

**95**  
**Good**

**DECISION DATE**  
**03/25/2021**

**AUDIT TYPE**  
**RECERTIFICATION**

**RECERTIFICATION DATE**  
**05/07/2021**

**AUDIT DATES**  
**02/09/2021 - 02/10/2021**

**EXPIRATION DATE**  
**07/21/2021**

**ISSUE DATE**  
**03/26/2021**

### Facility & Scope

**Harvest Valley Bakery, Inc. (54015)**  
Harvest Valley Bakery, Inc.  
348 Civic Rd  
Lasalle, IL 61301  
United States

**Food Sector Categories:**  
13. Bakery and Snack Food Processing

**Products:**  
Exclusions: None

**Scope of Certification:**  
Cookies, Bars, and Brownie Bites

### Certification Body & Audit Team

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

**Email:** GFSI@aibinternational.com

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

**Lead Auditor:** Adesanya, Yasir (207274)  
**Technical Reviewer:** Tellez-Lance, Angela (202423)

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

### Non-Conforming

### 11.2.2 Floors, Drains, and Waste Traps

Floors are constructed of smooth and dense impact resistant material and properly graded for effective drainage of overflow or waste water. Waste trap system was located at the mixing room away from food handling areas. Waste water during the audit was observed to be properly discharged. Drains were observed to be located and constructed for ease of cleaning and inspection. 11.2.2.1 -- Major -- Multiple long cracks were noticed on the floor surfaces of the facility. The cracks were observed in the dock area, warehouse, packing room and the mixing room.

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

**RESPONSE:** MINOR

**EVIDENCE:** Multiple long cracks were noticed on the floor surfaces of the facility. The cracks were observed in the dock area, warehouse, packing room and the mixing room.

**ROOT CAUSE:** It has been our intention to seal the remaining cracks in 2021. We have sealed most of the packing room and the mixing room. This was done last year. We will continue sealing cracks this spring.

**CORRECTIVE ACTION:** Cracks through out the facility will be sealed this spring. Outside temperatures will not allow this to be done now. Spring 2021

**VERIFICATION OF CLOSEOUT:** The auditor approve the corrective actions. The facility will seal all cracks when the weather warms up.

**COMPLETION DATE:** 02/16/2021    **CLOSEOUT DATE:** 03/11/2021

### 11.2.5 Lightings and Light Fittings

Lighting was of the appropriate intensity for employees to carry out their tasks efficiently. All lighting is either covered or is shatter-proof. 11.2.5.2 -- Minor -- Most plastic or glass fixtures were in good condition and protected from breakage. The exception was in the freezer, one bulb shield out of the three present was cracked and was not recorded in the self inspection audit. No exposed product near the cracked shield. In addition, there were pieces missing from the cracked shield.

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

**RESPONSE:** MINOR

**EVIDENCE:** Most plastic or glass fixtures were in good condition and protected from breakage. The exception was in the freezer, one bulb shield out of the three present was cracked and was not recorded in the self inspection audit. No exposed product near the cracked shield. In addition, there were pieces missing from the cracked shield.

**ROOT CAUSE:** This was missed during daily inspections of the freezer.

**CORRECTIVE ACTION:** Light shield has been replaced. During daily inspection it was not noted that the shield was broken. Will highlight area on freezer inspection so this is not missed again.

**VERIFICATION OF CLOSEOUT:** The cracked light shield was repaired.

**COMPLETION DATE:** 02/16/2021    **CLOSEOUT DATE:** 03/11/2021

### 11.2.9 Equipment, Utensils, and Protective Clothing

Specifications for the site's equipment, utensils and protective clothing, and purchase procedures for equipment are documented in 11.2.9.1 in the Standard Operating Procedures (11/1/2018) Section: Equipment Sourcing and Commissioning and GMP program and were seen to be appropriately implemented. Equipment and utensils, including tables, conveyors, bins and containers are designed, constructed and installed to meet regulatory requirements and prevent risks of contamination of the product. These items were found to be cleaned and stored properly after use to prevent cross contamination. Equipment surfaces were observed to be smooth, impervious and free from cracks and crevices. Containers and bins are made of non-toxic materials and were labeled or color-coded, for appropriate use with either edible or non-edible materials. There was no waste water discharge observed. Protective clothing meets documented specifications, is easily cleaned, and is made of material that will not contaminate food. Employees store protective clothing on racks adjacent to access points when going on breaks. All equipment, utensils and protective clothing are cleaned at appropriate frequencies and are properly stored to prevent contamination. 11.2.9.2 – Minor – The white seal on the mixer lid was observed damaged and with missing pieces on the left end. The white seal is a food grade material; however, its within close proximity of product (above the mixing bowl). There were no detector for the white seal. 11.2.9.8 – Minor – Old, dried product residue were observed stuck to the work bench/table in the mixing room. There were raw material containers stored underneath the table and were left opened occasionally during production. The table is to wipe down daily and thoroughly cleaned monthly.

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

**RESPONSE:** MINOR

**EVIDENCE:** The white seal on the mixer lid was observed damaged and with missing pieces on the left end. The white seal is a food grade material FDA approved as verified by the auditor; however, its within proximity of product (above the mixing bowl) and no apparent detector for the white seal if it falls in the process flow.

**ROOT CAUSE:** Added mixer seal to the daily morning walk through. Oversight by QA Manager not having this on the daily inspection sheet.

**CORRECTIVE ACTION:** Mixer lid seal has been replaced with food grade FDA approved material. Replacement seal has been ordered. Purchase order is attached.

**VERIFICATION OF CLOSEOUT:** The facility added the seal to daily walk through. The CAPA is approved.

**COMPLETION DATE:** 02/16/2021    **CLOSEOUT DATE:** 03/11/2021

- 11.2.9.8** All equipment, utensils and protective clothing shall be cleaned after use or at a frequency to control contamination and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

**RESPONSE:** MINOR

**EVIDENCE:** Old, dried product residue were observed stuck to the work bench/table in the mixing room. There were raw material containers stored underneath the table and were left opened occasionally during production. The table is to wipe down daily and thoroughly cleaned monthly.

**ROOT CAUSE:** While the table is cleaned on a daily basis the underside was missed during daily cleaning. Will follow up with employee involved as appropriate.

**CORRECTIVE ACTION:** Cleaned underside of the workbench/table. Cleaning the table is on the daily mixing room cleaning sheet. Will add underside to the form.

**VERIFICATION OF CLOSEOUT:** The table was added to the cleaning schedule. CAPA is approved.

**COMPLETION DATE:** 02/16/2021    **CLOSEOUT DATE:** 03/11/2021

### 11.3.2 Hand Washing

A policy covering hand washing requirements has been documented and implemented. Hand wash basins are located at appropriate employee access points to processing areas. Hand wash sinks are made of non-corrosive materials and supplied with tempered potable water. Soap in a fixed dispenser, paper towels and waste containers are available. Signs are posted reminding employees to wash their hands before returning to work. Signs are posted at hand wash station and in bathrooms. Employees are required to wash hands when wearing gloves. Interviews conducted with employees during the audit demonstrated that employees understand the hand washing requirements. Employees were observed to wash their hands properly during the audit and to use proper glove procedures. 11.3.2.5 – Minor – Personnel and auditor did not wash hands prior to entering product handling area during the tour of the facility. Equipment, utensils were touched during the tour.

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

**RESPONSE:** MINOR

**EVIDENCE:** Personnel and auditor did not wash hands prior to entering product handling area during the tour of the facility. Equipment, utensils were touched during the tour.

**ROOT CAUSE:** Overlooked by the Qa Manager and Office Manager.

**CORRECTIVE ACTION:** Added a handwashing sign to the entrance of the mixing room. Did a facility audit of all entrances going into food handling and processing areas to make sure the proper signs are in place.

**VERIFICATION OF CLOSEOUT:** CAPA is approved.

**COMPLETION DATE:** 02/16/2021    **CLOSEOUT DATE:** 03/11/2021

## Audit Statements

**SQF Practitioner Name** Name the designated SQF Practitioner  
**RESPONSE:** Skip DeMaso

**SQF Practitioner Email** Email of the designated SQF Practitioner  
**RESPONSE:** skip@harvestvalleybakery.com

**Opening Meeting** People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas)  
**RESPONSE:** Skip DeMaso: QA Manager/SQFP, Miranda DeMaso: Office Manager, Nancy Jenks: President and Yasir Adesanya: SQF Auditor.

**Facility Description** Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details)  
**RESPONSE:** A facility certification audit was conducted against SQF Ed8 FSC 13 Bakery and Snack Food Processing at the Harvest Valley Bakery Inc. located in LaSalle IL. The site is 44,000 square foot building with two packing rooms, a mixing room, a cooler and a freezer. Key equipment includes Oven, two mixers, two die cut machines, and two ovens. The site has developed FSMA compliant food safety plan: 1 HACCP plan with two CCPs, oven temperature, which varies per customers, and metal detector. The site has 18 employees including 7 in production, 1 mixer, 1 QA Tech, 1 maintenance manager/plant manager/shipping and receiving. Production team works 5 days a week from 6 am till 3/4 pm. FDA has visited the site on 2/27/2019 and did not leave a form 483.

**Closing Meeting** People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas)  
**RESPONSE:** Skip DeMaso: QA Manager/SQFP, Miranda DeMaso: Office Manager, Nancy Jenks: President and Yasir Adesanya: SQF Auditor.

**Auditor Recommendation** Auditor Recommendation  
**RESPONSE:** Issue a Certificate upon adequate closure of all Non-conformances.

## Section Responses

### 2.1.1 Food Safety Policy (Mandatory)

The site has a food safety commitment statement, called Quality and Food Safety Policy (1/5/2020) that senior management has implemented. It is signed by Nancy Jenks, President and Skip DeMaso, QA Manager. The Policy statement covers customer and regulatory requirements, the use of continuous improvement of the system and the review of food safety objectives. The Policy is communicated to the facility's staff by way of posting and on board and refresher training and is in languages used in the site (English and Spanish). The policy was observed to be posted in the office, employee main entrance and breakroom. Food Safety Objectives are 1) quality in product safety policies, 2) develop and implements food safety procedures and programs designed to ensure supply chain safety, 3) meet customer and regulatory requirements.

2.1.1.1	<p>Senior site management shall prepare and implement a policy statement that outlines as a minimum the: i. The site's commitment to supply safe food; ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; and iii. The site's commitment to establish and review food safety objectives.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.1.1.2	<p>The policy statement shall be: i. Signed by senior site management; ii. Made available in language understood by all staff; iii. Displayed in a prominent position; and iv. Effectively communicated to all staff.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.1.2	<p><b>Management Responsibility (Mandatory)</b></p> <p>An organizational chart, dated 11/1/2018, outlines the structure of staff having responsibility for food safety. Senior management has communicated this to the organization and provides the resources for implementation of the food safety systems. Skip DeMaso/QA Manager is the designated SQF Practitioner, is a full time employee of the facility and has HACCP (11/7/2017), SQF and PCQI (3/2/2018) training course certificates. The SQF Practitioner is responsible for the development, implementation and maintenance of the SQF System. Job descriptions are written for staff responsible for food safety, with coverage for absenteeism assigned. Job descriptions for QA Manager, QA technician, maintenance, mixer, and packers, were reviewed. Plant staff is required to report food safety issues to management, as evidenced by GMP Policy and Food Safety Training (Hazcom training conducted 1/05/2020) and interviews with employees: office manager, QA Manager, and Maintenance/shipping &amp; receiving /plant manager. Senior site management has processes in place to demonstrate continuous improvement and to ensure the integrity of the food safety systems when there are organizational or personnel changes. Objective evidences of continuous improvement include annual review (see answer to question 2.1.3), complaint management (see answer to question 2.1.4), food safety system manual review (see answer to question 2.2.1) , and so on.</p>
2.1.2.1	<p>The reporting structure describing those who have responsibility for food safety shall be identified and communicated within the site.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.1.2.2	<p>The senior site management shall make provision to ensure food safety practices and all applicable requirements of the SQF System are adopted and maintained.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.1.2.3	<p>The senior site management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.1.2.4	<p>Senior site management shall designate an SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF System, including good manufacturing practices outlined in 2.4.2, and the food safety plan outlined in 2.4.3. ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.1.2.5	<p>The SQF practitioner shall: i. Be employed by the site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code for Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.1.2.6	<p>Senior site management shall ensure the training needs of the site are resourced, implemented and meet the requirements outlined in system elements 2.9, and that site personnel have met the required competencies to carry out those functions affecting the legality and safety of food products.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.1.2.7	<p>Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements of the SQF Food Safety Code for Manufacturing, and are informed of their responsibility to report food safety problems to personnel with authority to initiate action.</p> <p><b>RESPONSE: COMPLIANT</b></p>

2.1.2.8	<p>Job descriptions for those responsible for food safety shall be documented and include a provision to cover for the absence of key personnel.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.2.9	<p>Senior site management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.2.10	<p>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.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.2.11	<p>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.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.3	<p><b>Management Review (Mandatory)</b></p> <p>The entire SQF System is reviewed annually by the site's Senior Management Team with the last review documented and completed on January 4, 2021. The review includes the food safety manual, internal and external audit findings, the investigations and resolutions of corrective actions and customer complaints with investigations and resolution. Food safety plans, Good Manufacturing Practices and the rest of the SQF system are reviewed by management when any potential changes are made in products and processes. The SQF Practitioner has updated senior site management team on a monthly basis at the Monthly Management Meeting, on any matters that impact the site's SQF System. Management review is done monthly basis. Monthly Food Safety and Quality Meeting minutes of 3/2/2020, 1/13/2020, 4/3/2020, and 1/13/2020 were reviewed during the audit.</p>
2.1.3.1	<p>The senior site management shall be responsible for reviewing the SQF System and documenting the review procedure. Reviews shall include: i. The policy manual; ii. Internal and external audit findings; iii. Corrective actions and their investigations and resolution; iv. Customer complaints and their resolution and investigation; v. Hazard and risk management system; and vi. Follow-up action items from previous management review.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.3.2	<p>The SQF practitioner (s) shall update senior site management on a (minimum) monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented. The SQF System in its entirety shall be reviewed at least annually.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.3.3	<p>Food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be reviewed and updated as needed when any potential changes implemented have an impact on the site's ability to deliver safe food.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.3.4	<p>Records of all management reviews and updates shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.4	<p><b>Complaint Management (Mandatory)</b></p> <p>The site's written Complaint policy is found in the document 2.1.4 Customer Complaint Management (11/1/2018). It defines the methods and responsibilities for handling customer complaints and has been implemented. The investigation of complaints is handled by SQF Practitioner, with corrective actions and records kept of each complaint and resolution. There was no complaints in 2018 , 1 food safety related complaint in 2019 and one complaint in 2020. Records of complaints were reviewed for Complaint # FM 2.1.4 (5/14/2020) -product overdone and very crummy, and showed that investigation and corrective actions of the complaints had been put into place.</p>
2.1.4.1	<p>The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities, arising from products manufactured or handled on site, shall be documented and implemented.</p> <p><b>RESPONSE:</b> COMPLIANT</p>

2.1.4.2	<p>Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.4.3	<p>Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.3.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.4.4	<p>Records of customer complaints and their investigations shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.5	<p><b>Crisis Management Planning</b></p> <p>The site's written Crisis Management Plan is found in document 2.1.5 Crisis Management Planning (1/1/2019). The Plan has been implemented and addresses serious disaster threats to the extended interruption of the business. President has oversight of the Plan and a Crisis Management team has been identified and trained as evidenced by meeting minutes (08/20/2020). The Plan includes responses to a business interruption, isolating and identifying affected product and a current crisis alert list. The Crisis Management Plan includes internal/external communications and sources of legal and expert advice. A power outage occurred on August 20, 2020 involving power loss in the whole facility. Records are maintained in Food Safety Manual, including follow-up corrective actions of this review and annual test of the Crisis Management Plan.</p>
2.1.5.1	<p>A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.5.2	<p>The crisis management plan shall include as a minimum: i. A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure a response does not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations and media.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.5.3	<p>The crisis management plan shall be reviewed, tested and verified at least annually.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.1.5.4	<p>Records of reviews of the crisis management plan shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.2.1	<p><b>Food Safety Management System (Mandatory)</b></p> <p>A food safety manual has been developed and is maintained in digital. It is dated 11/1/2018 and maintained by SQF Practitioner. The food safety manual contains the scope of the certification, a list of products in the scope, the organizational chart and food safety policies, programs and procedures that make up the site's SQF System. A hard copy is available in the QA office.</p>
2.2.1.1	<p>A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site will use to meet the requirements of the SQF Food Safety Code for Manufacturing, be made available to relevant staff and include: i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The scope of certification; iv. A list of the products covered under the scope of certification; v. Food safety procedures, pre-requisite programs, food safety plans; and vi. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.2.1.2	<p>All changes made to food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be validated or justified.</p> <p><b>RESPONSE:</b> COMPLIANT</p>

## 2.2.2 Document Control (Mandatory)

The site has implemented its policy called 2.2.2 &3 Document & Record Control (1/1/2018) defining the methods and responsibilities for document control. Records were found during the audit to be readily accessible and properly stored. A current list of all SQF documents is maintained and documents were observed to be stored securely and are accessible. The register of SQF documents is called Document Register (1/1/2019), and is found in the Food Safety Manual.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

- 2.2.2.3** Documents shall be safely stored and readily accessible.

**RESPONSE:** COMPLIANT

## 2.2.3 Records (Mandatory)

The site has implemented its policy for verifying and retaining records found in the document called 4.2.2 &3 Document & Record Control (1/1/2018). The facility has documented procedures for recording production as well as the proper correcting and initialing of errors. The site has implemented its policy for verifying and retaining records found in the document called 4.2.2.3 Document & Record Control (1/1/2018). The facility has documented procedures for recording production as well as the proper correcting and initialing of errors. Records retention time is 10 years.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.3.1 Product Development and Realization

The policy defining the methods and responsibilities for commercialization of new products, called 4.3.1 Product Development and Realization ( See SOP 2.3.1) (2/06/2019) has been implemented. Self-life is deterred by the customers. The site is 100% private label company. New product approval record was reviewed for Double Chocolate Chip Minis(product Code 03070 D) which were approved on July 1, 2020 and signed off by the customer for formulation, nutrition labels, ingredients, and trial samples.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT



2.3.1.4	<p>A food safety plan shall be validated and verified for each new product and its associated process through conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food safety.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.1.5	<p>Records of all product design, process development, shelf life trials and approvals shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.2	<p><b>Raw and Packaging Materials</b></p> <p>Specifications for raw materials, packaging, ingredients, additives, chemicals and processing aids have been documented. Current registers were reviewed for raw materials, packaging materials and labels. Specifications for Oat Flour, Wheat Flour and film were reviewed and found to be current. A policy defining the methods and responsibilities for developing and maintaining specifications has been documented and implemented in 2.3.2 Specifications for Raw Materials and Packaging. Raw and packaging materials are verified to ensure product safety, regulatory requirements and fit for purpose requirements are met. These are done by means of the receipt of Letters of Guarantee, Certificates of Compliance and/or Certificates of Analysis. Food contact packaging, PE totes, has a certificate of conformance from the supplier, indicating that it does not present a risk of chemical migration to food products. Product labels are approved by the customer and Designated company personnel along with specification, who is qualified to ensure they are accurate and meet regulatory requirements. There is a register of raw material, ingredients and packaging specifications, which were all found to be current.</p>
2.3.2.1	<p>Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety shall be documented and kept current.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.2.2	<p>All raw and packaging materials and ingredients shall comply with the relevant legislation in the country of manufacture and country of destination, if known.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.2.3	<p>The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.2.4	<p>Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, certificate of analysis, or sampling and testing.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.2.5	<p>Verification of packaging materials shall include: i. Certification that all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.2.6	<p>Finished product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.2.7	<p>A register of raw and packaging material specifications and labels shall be maintained and kept current.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.3	<p><b>Contract Service Providers</b></p> <p>Descriptions of services provided by all contract service providers having an impact on food safety are documented in 2.3.3 Contract Service Provider (11/1/2018). A list of current contract service providers is maintained in active Vendors and found to include providers of services such as uniform service, pest control, and waste management. Contract arrangements for and pest control were reviewed during the audit and found to be satisfactory.</p>

2.3.3.1	<p>Specifications for contract services that have an impact on product safety shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of all contract personnel.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.3.2	<p>A register of all contract service specifications shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.4	<p><b>Contract Manufacturers</b></p> <p>The site does not use contract manufacturers. N/A</p>
2.3.4.1	<p>The methods and responsibility for ensuring all agreements relating to food safety and customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p>
2.3.4.2	<p>The site shall: i. Verify compliance with the SQF Food Safety Code for Manufacturing and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the site or other third-party agency to confirm compliance to the SQF Food Safety Code for Manufacturing and agreed arrangements; and ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p>
2.3.4.3	<p>Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p>
2.3.5	<p><b>Finished Product Specifications</b></p> <p>Finished product specifications are current, documented in 2.3.5 Specifications for Finished Product (11/1/2018) and approved by the site's customers. Specifications include chemical and microbial limits, labeling and packaging requirements. A register of all current finished product specifications is maintained. Finished product specifications for Strawberry flavor (product code #2007912) was reviewed during the audit and contained the required information.</p>
2.3.5.1	<p>Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include: i. Microbiological and chemical limits; and ii. Labeling and packaging requirements.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.3.5.2	<p>A register of finished product specifications shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.4.1	<p><b>Food Legislation (Mandatory)</b></p> <p>The site is FSMA ready. As a private label company, customer requirements include regulatory requirements such as nutritional labeling. The site has a documented procedure, 2.4.1 Food legislation (11/1/2018), to keep updated about changes in relevant legislation, technical developments and industry codes of practice and SQFP is responsible. The site has a written provision that AIB, the certification body, and SQFI will be notified within 24 hours if a food safety event requiring public notification occurs.</p>
2.4.1.1	<p>The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of use or sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.4.1.2	<p>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.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.4.1.3	<p>SQFI and the certification body shall be notified in writing within twenty-four (24) hours in the event of a regulatory warning. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.</p> <p><b>RESPONSE:</b> COMPLIANT</p>

## 2.4.2 Good Manufacturing Practices (Mandatory)

The property, buildings and equipment are located, constructed and designed to ensure food is manufactured in a safe, hygienic environment. The site has written and implemented those Good Manufacturing Practices applicable to the scope of this certification. These food safety pre-requisite programs are found in 2.4.2 Food safety Fundamentals (11/1/2018). The effectiveness of the pre-requisite programs has been verified based on a schedule, which is found in Food Safety Manual.

- 2.4.2.1** The site shall ensure the Good Manufacturing Practices described in modules 3, 4, 9, 10 or 11 (as applicable) of this Food Safety Code are applied, or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.3 Food Safety Plan (Mandatory)

One Food Safety Plan has been developed, implemented and maintained by the site with two CCPs which are oven temperature (temperature is different per customers) and metal detection. They are kept on file in Food Safety Manual and maintained by SQF Practitioner. The Food Safety Plan has been prepared in accordance with the 12 steps identified in the Codex Alimentarius Commission HACCP guidelines. A multi-disciplinary Food Safety Team has been identified and trained, with documentation found in Food Safety Manual. The Plan includes a list of all products in the scope of the certification, a complete product description, intended product use (including vulnerable populations) and flow diagrams for each process including all input and output steps in the process. The process flow has been verified by the site per visual inspection by HACCP team. The food safety team has analyzed all hazards reasonably likely to occur including physical, chemical and microbiological hazards for each process step, ingredient and packaging. Control measures are in place to eliminate or reduce the food safety risk to acceptable levels. The HACCP plan is verified as part of the SQF System and reviewed annually or when changes occur, by the food safety team with the last review date on May 15, 2020. National regulatory requirements for the site also require food safety requirements (FSMA complaint Food Safety Plan), allergen content, labeling, and nutritional labeling, which were observed to be implemented.

- 2.4.3.1** A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. Feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

**RESPONSE:** COMPLIANT

- 2.4.3.2** The food safety plan shall be effectively implemented, maintained and outline the means by which the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

2.4.3.7	<p>The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw material, packaging material, service inputs (e.g. water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.8	<p>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.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.9	<p>The food safety team shall conduct a hazard analysis for every identified hazard to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.10	<p>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.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.11	<p>Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e. a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.12	<p>For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard (s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.13	<p>The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.14	<p>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.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.15	<p>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.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.16	<p>Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.4.3.17	<p>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.</p> <p><b>RESPONSE: COMPLIANT</b></p>

#### 2.4.4 Approved Supplier Program (Mandatory)

The site has a written supplier approval policy 2.4.4 Approved Supplier Program, which has been implemented and covers the procedures for approving suppliers of raw materials, ingredients, packaging materials and services. The policy includes a review of the specifications of products, the supplier's food safety controls, procedures for granting and monitoring approved suppliers, the level of risk of products to the site and details of requirements for Certificate of Conformance, Certificates of Analysis and testing. Approved supplier performance and status is reviewed using approved supplier performance. The procedures for emergency use of non-approved suppliers have been documented. It was observed that the food defense plan contains methods to secure incoming products from sabotage, the food fraud vulnerability assessment identifies threats to incoming product substitution, mislabeling and dilution, and the food fraud mitigation plan demonstrates these threats are controlled. A register is maintained of all current approved suppliers, which was reviewed during the audit and found to be acceptable. Raw materials: oat, wheat, and barley found in the storage warehouse were verified to have come from suppliers on the Approved Supplier List. Supplier audits are based on risk; The site does not have high risk suppliers, therefore, no supplier audit is required.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

**2.4.4.9** Supplier audits shall be based on risk and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

**RESPONSE:** COMPLIANT

**2.4.4.10** A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained.

**RESPONSE:** COMPLIANT

## 2.4.5 Non-conforming Product or Equipment

The site has written procedures for withholding non-conforming products, raw materials, work-in-progress, ingredients, packaging and equipment in document in 2.4.5 Non-Conforming Products (11/1/2018). The program was found to be properly implemented in the facility. Methods to segregate, identify, handle and dispose of product include downgraded to trash and were observed to minimize any inadvertent use. Nonconforming products or equipment is identified, segregated or disposed of, with records maintained by SQF Practitioner for products and maintenance manager for equipment. Nonconforming product log was reviewed. Relevant staff is aware of the site's Hold policy, as evidenced by interviews with Plant Manager/Shipping & Receiving /Maintenance, Office Manager and QA Manager/SQFP.

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

**RESPONSE:** COMPLIANT

- 2.4.5.2** Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.

**RESPONSE:** COMPLIANT

## 2.4.6 Product Rework

Product is not reworked, recouped or recycled. N/A

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

**RESPONSE:** NOT APPLICABLE

- 2.4.6.2** Records of all reworking operations shall be maintained.

**RESPONSE:** NOT APPLICABLE

## 2.4.7 Product Release (Mandatory)

The site has written procedures 2.4.7 Product Sampling Inspection and Release (11/1/2018), implemented for releasing finished products. These release procedures include ensuring that all product inspections and analyses have been verified and documented by authorized personnel to show that all food safety and quality controls have been met. A review of records for product releases for Brownie bites during the audit showed they had been conducted per procedures.

- 2.4.7.1** The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released: i. By authorized personnel; and ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

**RESPONSE:** COMPLIANT

- 2.4.7.2** Records of all product release shall be maintained.

**RESPONSE:** COMPLIANT

## 2.4.8 Environmental Monitoring

The site has implemented a risk-based environmental monitoring program, which is described in the document called 2.4.8 Environmental Monitoring Program (11/1/2018). The sampling and testing program includes Listeria, Salmonella and ATP swab. Records reviewed for November 2020. The site has documented corrective action procedures when unsatisfactory trends were found.

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

**RESPONSE:** COMPLIANT

2.4.8.2	<p>The responsibility and methods for the environmental monitoring program shall be documented and implemented.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.4.8.3	<p>An environmental sampling and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.4.8.4	<p>Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.5.1	<p><b>Validation and Effectiveness (Mandatory)</b></p> <p>The methods, responsibilities and criteria for ensuring the effectiveness of Good Manufacturing Practices, critical food safety limits and all other applicable elements of the SQF System have been documented and implemented. These methods are in form 2.5.1 Verification schedule and validation, effectiveness (11/1/2018) and were found to ensure that each has been implemented effectively. Methods to ensure that procedure or process changes are still effective in controlling food safety are in place and documented in form 2.5.1 Verification schedule and validation effectiveness (11/1/2018) and 2.4.2 Prerequisite program verification and validation (7/26/2011).</p>
2.5.1.1	<p>The methods, responsibility and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall ensure that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required result; ii. Critical food safety limits are validated, and re-validated annually; iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and iv. All applicable elements of the SQF Program are implemented and effective.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.5.1.2	<p>Records of all validation activities shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.5.2	<p><b>Verification Activities (Mandatory)</b></p> <p>The site has established a verification schedule, dated 7/26/2018, outlining the verification steps, procedures and responsibilities for each verification activity. The schedule is found in 2.4.2 Prerequisite program verification and validation (7/26/2011) and maintained by the SQF Practitioner. The procedures for verifying Good Manufacturing Practices, critical control points, other food safety controls and regulatory compliance include utilizing authorized personnel to verify all monitoring activities. Records of verification of monitoring activities reviews were as follows: Preventive Control Monitoring Log (1/22/2020) 170F for 5 sec minimum, and metal detectors are checked hourly. Glass, plastic and ceramics form (daily) 1/22/2020 Strawberry, COF form (1/22/2020) – Moisture and Water Activity. Oat Cocoa Chips 2.0 o z. Moisture, water activity, Seal integrity, weight. Cinnamon Crisp. Moisture, water activity, Seal integrity, weight. Berry Apple. Moisture, water activity, Seal integrity, weight. Cherry WG. Moisture, water activity, Seal integrity, weight. French Toast. Moisture, water activity, Seal integrity, weight. Employee/Facility Good Manufacturing Program Inspections Checklist (1/22/2020) Mixing room cleaning (1/22/2020) Break Room Cleaning Procedures (1/22/2020) Packing room cleaning procedures (daily) Scale calibration form (1/22/2020) Material Transfer form (weekly) 1/22/2020) Storage Conditions Form (weekly) Cleaning and sanitizing Product Zone ATP (wrote down before).</p>
2.5.2.1	<p>A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity shall be prepared and implemented.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.5.2.2	<p>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.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.5.2.3	<p>Records of the verification of monitoring activities shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>

### 2.5.3 Corrective and Preventative Action (Mandatory)

The site's Corrective and Preventative Action program is written in 2.5.3 Corrective and Preventive Actions (1/1/2019). It describes the methods and responsibilities for investigating, resolving and managing corrective actions. The identification of root causes and resolutions to deviations of critical control limits are documented. Records of investigations and corrective actions were reviewed for Corrective Action Reports; #012019 CPA Report (1/7/2019) broken glass dial Line #2 Wire Cut machine. These were found to have reviews, investigations, corrective and preventative actions and resolutions were documented.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 2.5.4 Product Sampling, Inspection and Analysis

The site's procedures and criteria for sampling, inspecting and analyzing raw materials, work-in-progress and finished product have been documented and implemented in 2.4.7 Product Sampling, Inspection & Release (11/1/2018). Certificates of Analysis are required for all incoming materials. The site Moisture and Water Activity, which do not require proficiency test. Any samples requiring chemical and/or microbial testing per customer requests are sent out to the preapproved accredited third party laboratory.

- 2.5.4.1** The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work-in-progress shall be documented and implemented. The methods applied shall ensure: i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements; ii. Inspections are conducted to ensure raw materials, work in process and finished products comply with the relevant specification, regulatory requirements and are true to label; and iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods.

**RESPONSE:** COMPLIANT

- 2.5.4.2** On-site personnel that conduct environmental or product testing shall participate in an applicable proficiency testing program at least annually to ensure accuracy of results.

**RESPONSE:** COMPLIANT

- 2.5.4.3** Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard and shall be included on the site's contract service specifications register (refer to 2.3.3.1).

**RESPONSE:** COMPLIANT

- 2.5.4.4** Records of all inspections and analyses shall be maintained.

**RESPONSE:** COMPLIANT

### 2.5.5 Internal Audits and Inspections (Mandatory)

The site's procedure for scheduling and conducting internal audits to assess the effectiveness of the SQF system has been documented and implemented per document 2.5.5 Internal Audit (11/1/2018). The Internal Audit Program is maintained by SQF Practitioner. Facility and equipment inspections are conducted regularly to ensure Good Manufacturing Practices are followed, which is documented in FM 2.5.5 Internal audits and inspections (1/1/2019). All applicable SQF Code requirements, using the SQF checklist or a similar tool, are part of the internal audit program. The frequency of the audits is communicated to management; SQF Practitioner is responsible to see that corrective actions are implemented and verified. Personnel conducting audits have been properly trained and where practical, audit areas independent of their function. Records of internal audits in the facility conducted such as Monthly GMP audits (March and December, 2020), Daily GMP Checks (1/22/2020 – 12/20/2020), Preop inspections (1/22/2020– 12/20/2020) were sampled and reviewed during the audit.

- 2.5.5.1** The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code for Manufacturing are audited as per the SQF audit checklist or similar tool; ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken; and iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions.

**RESPONSE:** COMPLIANT



2.5.5.2	Staff conducting internal audits shall be trained and competent in internal audit procedures. <b>RESPONSE: COMPLIANT</b>
2.5.5.3	Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and building/equipment maintenance is compliant to the SQF Food Safety Code for Manufacturing. The site shall: i. Take corrections or corrective and preventative action; and ii. Maintain records of inspections and any corrective action taken. <b>RESPONSE: COMPLIANT</b>
2.5.5.4	Where practical staff conducting internal audits shall be independent of the function being audited. <b>RESPONSE: COMPLIANT</b>
2.5.5.5	Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained. <b>RESPONSE: COMPLIANT</b>
<b>2.6.1</b>	<b>Product Identification (Mandatory)</b> A policy defining how products are identified from receipt through production and shipping has been documented in 2.6.1 Product Coding and Traceability (11/1/2018). The site's identification system ensures all raw materials, ingredients, packaging materials, work-in-progress, process inputs and finished goods are clearly identified at all stages of their process. Items are marked at receipt by shipping staff. Product identification records were reviewed during the audit for Brownie bites and demonstrated the products were properly identified throughout the process. Product startup/changeover procedures during packing ensure that the correct product goes into the correct package with the correct label. A changeover is done after the daily production and cleaning is completed.
2.6.1.1	The methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in-progress, process inputs and finished products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure: i. Raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are clearly identified during all stages of receipt, production, storage and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements. <b>RESPONSE: COMPLIANT</b>
2.6.1.2	Product identification records shall be maintained. <b>RESPONSE: COMPLIANT</b>
2.6.1.3	Product start up and changeover procedures during packing shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label, and that the changeover is inspected and approved by an authorized person. <b>RESPONSE: COMPLIANT</b>
<b>2.6.2</b>	<b>Product Trace (Mandatory)</b> A policy defines the methods and responsibilities for tracing product to the customer (one up) and from vendors of raw materials and packaging (one back). This is written in 2.6.1 Product Coding and Traceability (11/1/2018). The effectiveness of the trace system is conducted at least annually, as part of the product withdrawal and recall program. Records of the receipt, use and dispatch of finished product are maintained. The site does not rework.
2.6.2.1	The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable to the customer (one up) and provides traceability through the process to the manufacturing supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back); ii. Traceability is maintained where product is reworked; and iii. The effectiveness of the product trace system shall be reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.3). <b>RESPONSE: COMPLIANT</b>
2.6.2.2	Records of raw and packaging material receipt and use, and finished product dispatch and destination shall be maintained. <b>RESPONSE: COMPLIANT</b>

## 2.6.3 Product Withdrawal and Recall (Mandatory)

The site has a documented procedure, 2.6.3 RECALL PROCEDURE (11/1/2018), defining the methods and responsibilities for withdrawing and recalling product if necessary. A recall team has been designated and is led by President and QA Manager. The withdrawal policy includes the requirement to investigate a recall and determine the root cause of a recall/withdrawal with a corrective action. It also includes a communication plan to notify customers, consumers, regulatory authorities and other essential bodies. This includes SQFI and AIB, the Certification Body, who must be notified within 24 hours in writing of any food safety event requiring public notification. Investigation into the root cause of any product recall, mock recall or product withdrawal, with actions taken, was observed to be documented. Mock trace exercises are completed at least once a year, one step forward and one step back, to verify the effectiveness of the system. Records were reviewed of the recall plan and summaries of the second trace exercises of the year performed for Strawberry Flavor, Lot # 2007912, (total received in pounds total 209, used 30, inventory 179) on 9/25/2020. 100% was recovered in 35 minutes. Production record for Strawberry Pancake, (8/15/2020), Shipping form (of FG) 9/18/2020, 7/21/2020, and 9/22/2020. The mock trace exercise records reviewed showed the Product Withdrawal and Recall procedures were tested back one step and forward one step with acceptable accountability. There was no recalls or market withdrawals during the last twelve months.

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

**RESPONSE: COMPLIANT**

- 2.6.3.2** Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.

**RESPONSE: COMPLIANT**

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

**RESPONSE: COMPLIANT**

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

**RESPONSE: COMPLIANT**

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

**RESPONSE: COMPLIANT**

## 2.7.1 Food Defense Plan (Mandatory)

The site has a Food Defense Policy 2.7.1 Food Defense (11/1/2018), in which the procedures, responsibilities and criteria for preventing deliberate food adulteration have been documented and implemented. A food defense protocol includes the name of the senior manager responsible for food defense, President, methods to allow access to the site only for authorized personnel, designated access points, the secured storage of materials and hazardous chemicals and the control of access to contractors and visitors. The Food Defense Plan was last tested and challenged (1/20/2020) using a food defense assessment form.

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

**RESPONSE: COMPLIANT**

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

**RESPONSE: COMPLIANT**

2.7.1.3	<p>The food defense plan shall be reviewed and challenged at least annually.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.7.1.4	<p>Records of reviews of the food defense plan shall be maintained.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.7.2	<p><b>Food Fraud</b></p> <p>The site has conducted a Food Fraud Vulnerability Assessment, found in document 2.7.2 Food Fraud Vulnerability Assessment Harvest Bakery (1/9/2019), which includes the site's susceptibility to fraudulent economic gain, including product substitution, mislabeling, counterfeiting and dilution that could impact food safety. The site has developed a Food Fraud Mitigation Plan using Food Fraud Vulnerability Assessment method (BRC method) on 1/9/2019 to address the control of the identified food fraud vulnerabilities.</p>
2.7.2.1	<p>The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.7.2.2	<p>A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.7.2.3	<p>The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.7.2.4	<p>Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.8.1	<p><b>Allergen Management for Food Manufacturing (Mandatory)</b></p> <p>The site's Allergen Management Policy to control allergens and prevent contamination of other products is found in document 2.8.1 Allergen Control Procedure (11/1/2018) and is the responsibility of SQF Practitioner. Allergen of concern in this operation was wheat flour, eggs, dairy (milk powder and butter), soy (for one customer, every 3 or 4 months), and walnuts (not often). A risk analysis was observed to be in place for allergens including raw materials, ingredients and processing aids such as food grade lubricants. Workplace allergens from locations such as lunch rooms, locker rooms and vending machines were found to be part of the allergen program. The operation was found to have a product identification system that includes clear identification and labeling of products to meet regulatory requirements when made on production lines used for allergenic products. Proper procedures for cleaning of food contact surfaces, including periodic validation of cleaning methods by protein-specific testing, were found to be in place. The product trace system ensures the complete trace of allergen ingredients including any rework containing allergens. The site has procedures in place, found in document 2.8.1 Allergen Control Procedure (11/1/2018), to control the accuracy of finished product labels, including labels of allergenic products. Allergenic products in storage were observed during the audit to be properly labeled and stored separately to prevent cross contact. Allergen validation test records were reviewed as follows: Production schedule is set up to prevent running allergen product ahead of non-allergen product. After allergen products, full cleaning, visual and ATP swab are conducted followed by regular allergen swab.</p>
2.8.1.1	<p>The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A register of allergens which is applicable in the country of manufacture and the country (ies) of destination if known; iv. A list of allergens which is accessible by relevant staff. v. The hazards associated with allergens and their control incorporated into the food safety plan. vi. A management plan for control of identified allergens. The allergen management program shall include the identification, management, and labelling of products containing gluten, where applicable.</p> <p><b>RESPONSE: COMPLIANT</b></p>
2.8.1.2	<p>Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in progress, rework or finished product on how to identify, handle, store and segregate raw materials containing allergens.</p> <p><b>RESPONSE: COMPLIANT</b></p>

2.8.1.3	Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored. <b>RESPONSE:</b> COMPLIANT
2.8.1.4	Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided where satisfactory line hygiene and clean-up or segregation is not possible. <b>RESPONSE:</b> COMPLIANT
2.8.1.5	Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented. <b>RESPONSE:</b> 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. <b>RESPONSE:</b> COMPLIANT
2.8.1.7	The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured. <b>RESPONSE:</b> COMPLIANT
2.8.1.8	The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in-progress and finished product is true to label with regard to allergens. Such measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures. <b>RESPONSE:</b> COMPLIANT
2.8.1.9	The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used. <b>RESPONSE:</b> COMPLIANT
2.8.1.10	Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable. <b>RESPONSE:</b> COMPLIANT
2.8.1.11	Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introducing unintended allergens through supplier, contract manufacturer, employee and visitor activities. <b>RESPONSE:</b> COMPLIANT
2.8.2	<b>Allergen Management for Pet Food Manufacturing</b> The site does not manufacture pet food. N/A
2.8.2.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those inputs and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A list of allergens which is accessible by relevant staff; and iv. The hazards associated with allergens and their control incorporated into the food safety plan. <b>RESPONSE:</b> NOT APPLICABLE <b>EVIDENCE:</b> The site does not manufacture pet food. N/A

2.8.2.2	<p>Product labeling, in accordance with regulatory requirements, shall include allergens where risks from cross-contact have been identified.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p> <p><b>EVIDENCE:</b> The site does not manufacture pet food. N/A</p>
2.8.3	<p><b>Allergen Management for Manufacturers of Animal Feed</b></p> <p>The site does not manufacture pet food. N/A</p>
2.8.3.1	<p>Sites that exclusively manufacture animal feed and do not manufacture, handle or store food or pet food products are not required to implement an allergen management plan unless required by regulation or customer requirement.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p>
2.8.3.2	<p>Where an allergen management plan is required by regulation or customer specification, the requirements of 2.8.2 shall apply.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p>
2.9.1	<p><b>Training Requirements</b></p> <p>Appropriate training is provided for all plant personnel for all tasks to ensure the effective implementation of the SQF system. Training programs are the assigned responsibility of SQF Practitioner. The effectiveness of the facility's training program was evidenced by interviews with plant employees and review of the Monthly GMP Inspection Report (March &amp; April 2020).</p>
2.9.1.1	<p>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.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.9.1.2	<p>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.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.9.2	<p><b>Training Program (Mandatory)</b></p> <p>The site has implemented a training program, entitled 2.9.1 Training Procedure (11/1/2018), which covers the necessary competencies for plant personnel. This program requires training to be conducted in Company food safety policies and procedures, GMP including regulatory compliances, GMP, HACCP, biosecurity, chemical control, hazard communication, foodborne pathogens, allergen, emergency preparedness and job specific duties to ensure regulatory, food safety and all other requirements of the SQF System are met. This training program is administered by SQF Practitioner.</p>
2.9.2.1	<p>An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Developing and applying Good Manufacturing Practices; ii. Applying food regulatory requirements; iii. Steps identified by the hazard analysis and/or other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety; and iv. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF System.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.9.3	<p><b>Instructions</b></p> <p>Work instructions have been written explaining how tasks critical to maintaining food safety are performed. Records of work instruction training were reviewed for metal detector (11.7.5 Foreign Material Control as an on-board training for QA Tech &amp; Moisture Analyzer training (on-line) for QA Tech.</p>
2.9.3.1	<p>Instructions shall be available in the languages relevant to the staff, explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety, and process efficiency are to be performed.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.9.4	<p><b>HACCP Training Requirements</b></p> <p>HACCP training for personnel involved in the development and maintaining the food safety plan is administered. The last training occurred on January 5, 2021. All employees training records dated January 5, 2021 was reviewed and found no discrepancies.</p>

2.9.4.1	<p>HACCP training shall be provided for staff involved in developing and maintaining food safety plans.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.9.5	<p><b>Language</b></p> <p>Periodic refresher training needs have been identified in the Training Program. From a review of refresher training records covering GMP including regulatory compliances, GMP, HACCP, biosecurity, chemical control, hazard communication, foodborne pathogens, allergen, emergency preparedness and interviews with employees, it was evident the proper refresher training has been conducted to ensure food safety, quality and the SQF system are maintained. Specific refresher training topics are covered on annual basis.</p>
2.9.5.1	<p>Training materials and the delivery of training shall be provided in language understood by staff.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.9.6	<p><b>Refresher Training</b></p> <p>A training skills register is maintained by the SQF Practitioner and during the review was found to have a listing of the trainee, trainer, the description of the training, the date of training and verification by supervision that the training was completed. The site verifies the effectiveness of training by quiz and internal audit. Plant employees interviewed were found to have current training records on the register.</p>
2.9.6.1	<p>The training program shall include provision for identifying and implementing the refresher training needs of the organization.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
2.9.7	<p><b>Training Skills Register</b></p> <p>The site's buildings, property and surroundings were observed during the audit to not pose a food safety risk to products. Measures have been established to maintain a suitable external environment and the facility performs external inspections as part of their internal audit program. The last external inspection was performed during the April Monthly Inspection and reviewed by management. The site maintains the required approvals by relevant authorities, as evidenced by FDA facility registration whi expires October 5, 2021 and Business License from the State which expires (7/1/2021) for their ongoing operations.</p>
2.9.7.1	<p>A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Supervisor's verification that the training was completed, and that the trainee is competent to complete the required tasks.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.1.1	<p><b>Premises Location and Approval</b></p> <p>The place is surrounded by green areas. A bakery plant and a parts, motor manufacturer are located about 200 meters from the plant. All this does not represent a risk for the Food Safety of the Site. There is a Food Establishment Registration N. 2454-5589 by the Illinois Business Authorization dated with expiration date July 1, 2021.</p>
11.1.1.1	<p>The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.1.1.2	<p>The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.2.1	<p><b>Materials and Surfaces</b></p> <p>Product contact surfaces, surfaces not in contact with food and storage areas are constructed of suitable materials including stainless steel. They were observed during the audit to be properly maintained so that food safety is not compromised.</p>
11.2.1.1	<p>Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage, and cold storage areas shall be constructed of materials that will not contribute a food safety risk.</p> <p><b>RESPONSE:</b> COMPLIANT</p>

### 11.2.2 Floors, Drains, and Waste Traps

Floors are constructed of smooth and dense impact resistant material and properly graded for effective drainage of overflow or waste water. Waste trap system was located at the mixing room away from food handling areas. Waste water during the audit was observed to be properly discharged. Drains were observed to be located and constructed for ease of cleaning and inspection. 11.2.2.1 -- Major -- Multiple long cracks were noticed on the floor surfaces of the facility. The cracks were observed in the dock area, warehouse, packing room and the mixing room.

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

**RESPONSE:** MINOR

**EVIDENCE:** Multiple long cracks were noticed on the floor surfaces of the facility. The cracks were observed in the dock area, warehouse, packing room and the mixing room.

**ROOT CAUSE:** It has been our intention to seal the remaining cracks in 2021. We have sealed most of the packing room and the mixing room. This was done last year. We will continue sealing cracks this spring.

**CORRECTIVE ACTION:** Cracks throughout the facility will be sealed this spring. Outside temperatures will not allow this to be done now. Spring 2021

**VERIFICATION OF CLOSEOUT:** The auditor approve the corrective actions. The facility will seal all cracks when the weather warms up.

**COMPLETION DATE:** 02/16/2021    **CLOSEOUT DATE:** 03/11/2021

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 11.2.3 Walls, Partitions, Doors and Ceilings

Wall to wall and wall to floor junctures were observed to be sealed and free of debris. Ducting, piping and conduit conveying services were observed to be properly designed and installed to prevent contamination and for ease of cleaning. Overhead cleaning was found to be part of the master cleaning schedule. Overhead waste water pipe installations did not pose a hazard of contamination to food, materials or food contact surfaces. Doors, windows and frames in product areas were observed to be properly constructed of materials with the same functional requirements as internal walls and partitions. The ceilings in all food processing and handling areas are constructed of insulated metal sheet, which are easily cleaned and prevent product contamination.

**11.2.3.1** Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light-colored finish and shall be kept clean (refer to 11.2.13.1).

**RESPONSE:** COMPLIANT

**11.2.3.2** Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

**RESPONSE:** COMPLIANT

**11.2.3.3** Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed to prevent the contamination of food, ingredients and food contact surfaces and allow ease of cleaning.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

11.2.3.5	<p>Doors, hatches and windows and their frames in food processing, handling or storage areas shall be of a material and construction which meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction and windows shall be made of shatterproof glass or similar material.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.2.3.6	<p>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.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p> <p><b>EVIDENCE:</b> No drop ceiling.</p>
11.2.3.7	<p>Drop ceilings shall be constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.2.4	<p><b>Stairs, Catwalks and Platforms</b></p> <p>Stairs, catwalks and platforms were observed during facility tours to be constructed and designed so that food contamination is avoided, and with no open grates above exposed product surfaces.</p>
11.2.4.1	<p>Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1).</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.2.5	<p><b>Lightings and Light Fittings</b></p> <p>Lighting was of the appropriate intensity for employees to carry out their tasks efficiently. All lighting is either covered or is shatter-proof. 11.2.5.2 -- Minor -- Most plastic or glass fixtures were in good condition and protected from breakage. The exception was in the freezer, one bulb shield out of the three present was cracked and was not recorded in the self inspection audit. No exposed product near the cracked shield. In addition, there were pieces missing from the cracked shield.</p>
11.2.5.1	<p>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.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.2.5.2	<p>Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program.</p> <p><b>RESPONSE:</b> MINOR</p> <p><b>EVIDENCE:</b> Most plastic or glass fixtures were in good condition and protected from breakage. The exception was in the freezer, one bulb shield out of the three present was cracked and was not recorded in the self inspection audit. No exposed product near the cracked shield. In addition, there were pieces missing from the cracked shield.</p> <p><b>ROOT CAUSE:</b> This was missed during daily inspections of the freezer.</p> <p><b>CORRECTIVE ACTION:</b> Light shield has been replaced. During daily inspection it was not noted that the shield was broken. Will highlight area on freezer inspection so this is not missed again.</p> <p><b>VERIFICATION OF CLOSEOUT:</b> The cracked light shield was repaired.</p> <p><b>COMPLETION DATE:</b> 02/16/2021    <b>CLOSEOUT DATE:</b> 03/11/2021</p>
11.2.5.3	<p>Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination.</p> <p><b>RESPONSE:</b> COMPLIANT</p>



### 11.2.6 Inspection / Quality Control Area

The processing and packaging areas where material and product inspections occur have adequate work space, stainless steel tables and lighting to allow staff to perform thorough material inspections. The inspection areas on the production floor have stainless steel tables with adequate space and lighting. Hand wash stations have been installed at obvious and convenient locations in the process areas and the lab.

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

**RESPONSE:** COMPLIANT

**11.2.6.2** The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to hand washing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

**RESPONSE:** COMPLIANT

### 11.2.7 Dust, Insect, and Pest Proofing

External windows, doors and other openings were observed during facility tours to be properly sealed to prevent any pest infestation or dust coming into the facility. External personnel doors were observed to be self-closing and sealed to prevent dust and pest ingress. All external doors and dock doors were sealed to prevent infestation. Electric insect devices, and interior and exterior rodent stations are located so the product is not at risk for contamination. Rodenticide bait is only used on the outside of the facility.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 11.2.8 Ventilation

There was an oven air exhaust vent installed. Ventilation equipment was seen to be adequately cleaned, insect proofed and located to not pose a risk of contamination. Otherwise, the site does not have any make up air or ventilation system installed.

**11.2.8.1** Adequate ventilation shall be provided in enclosed processing and food handling areas.

**RESPONSE:** COMPLIANT

**11.2.8.2** All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.12, to prevent unsanitary conditions.

**RESPONSE:** COMPLIANT

**11.2.8.3** Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features: i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over the cooker(s); ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk; and iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.

**RESPONSE:** COMPLIANT

### 11.2.9 Equipment, Utensils, and Protective Clothing

Specifications for the site's equipment, utensils and protective clothing, and purchase procedures for equipment are documented in 11.2.9.1 in the Standard Operating Procedures (11/1/2018) Section: Equipment Sourcing and Commissioning and GMP program and were seen to be appropriately implemented. Equipment and utensils, including tables, conveyors, bins and containers are designed, constructed and installed to meet regulatory requirements and prevent risks of contamination of the product. These items were found to be cleaned and stored properly after use to prevent cross contamination. Equipment surfaces were observed to be smooth, impervious and free from cracks and crevices. Containers and bins are made of non-toxic materials and were labeled or color-coded, for appropriate use with either edible or non-edible materials. There was no waste water discharge observed. Protective clothing meets documented specifications, is easily cleaned, and is made of material that will not contaminate food. Employees store protective clothing on racks adjacent to access points when going on breaks. All equipment, utensils and protective clothing are cleaned at appropriate frequencies and are properly stored to prevent contamination. 11.2.9.2 -- Minor -- The white seal on the mixer lid was observed damaged and with missing pieces on the left end. The white seal is a food grade material; however, its within close proximity of product (above the mixing bowl). There were no detector for the white seal. 11.2.9.8 -- Minor -- Old, dried product residue were observed stuck to the work bench/table in the mixing room. There were raw material containers stored underneath the table and were left opened occasionally during production. The table is to wipe down daily and thoroughly cleaned monthly.

**11.2.9.1** Specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** MINOR

**EVIDENCE:** The white seal on the mixer lid was observed damaged and with missing pieces on the left end. The white seal is a food grade material FDA approved as verified by the auditor; however, its within proximity of product (above the mixing bowl) and no apparent detector for the white seal if it falls in the process flow.

**ROOT CAUSE:** Added mixer seal to the daily morning walk through. Oversight by QA Manager not having this on the daily inspection sheet.

**CORRECTIVE ACTION:** Mixer lid seal has been replaced with food grade FDA approved material. Replacement seal has been ordered. Purchase order is attached.

**VERIFICATION OF CLOSEOUT:** The facility added the seal to daily walk through. The CAPA is approved.

**COMPLETION DATE:** 02/16/2021 **CLOSEOUT DATE:** 03/11/2021

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

**RESPONSE:** COMPLIANT

**11.2.9.4** Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned as per 11.2.13. Bins used for inedible material shall be clearly identified.

**RESPONSE:** COMPLIANT

**11.2.9.5** Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system, and to meet local regulatory requirements.

**RESPONSE:** COMPLIANT

**11.2.9.6** Protective clothing shall be manufactured from material that will not contaminate food and is easily cleaned.

**RESPONSE:** COMPLIANT

**11.2.9.7** Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.

**RESPONSE:** COMPLIANT

- 11.2.9.8** All equipment, utensils and protective clothing shall be cleaned after use or at a frequency to control contamination and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

**RESPONSE:** MINOR

**EVIDENCE:** Old, dried product residue were observed stuck to the work bench/table in the mixing room. There were raw material containers stored underneath the table and were left opened occasionally during production. The table is to wipe down daily and thoroughly cleaned monthly.

**ROOT CAUSE:** While the table is cleaned on a daily basis the underside was missed during daily cleaning. Will follow up with employee involved as appropriate.

**CORRECTIVE ACTION:** Cleaned underside of the workbench/table. Cleaning the table is on the daily mixing room cleaning sheet. Will add underside to the form.

**VERIFICATION OF CLOSEOUT:** The table was added to the cleaning schedule. CAPA is approved.

**COMPLETION DATE:** 02/16/2021 **CLOSEOUT DATE:** 03/11/2021

## 11.2.10 Premises and Equipment Maintenance

The site has a program that defines the responsibilities for the maintenance and repair of all plant equipment and buildings. There is a schedule of planned Preventive Maintenance, and PM tasks are documented in 11.2.10 Equipment Maintenance and Calibration (11/1/2018). Maintenance personnel are trained in good manufacturing practices and food safety. When repairs and maintenance are complete, maintenance personnel remove all tools and debris and notify a supervisor. Appropriate cleaning and pre-operational inspections are carried out before resumption of operations, documented in Daily Pre-Op Inspection. This was reviewed during the audit and found to be complete. Maintenance and engineering contractors on site are trained in the site's food safety and hygiene procedures by means of GMP training or they are escorted at all times while on site. Periodic inspections are completed to ensure loose parts and other materials are not potential contaminants. Temporary repairs, if required, are appropriate, included in the cleaning program and have a plan for their removal. Machinery, conveyors and other equipment over or near food or food contact surfaces are lubricated with food grade materials. The food grade lubricants were noted to be properly labeled and stored separately in maintenance Food Grade Lube Storage. Paint is not used on food contact surfaces and any paint in processing areas was noted to be in good condition with no observed flaking. PM Records reviewed areas follows: Carton Makers (1/7/2021), Cooling tunnel (09/08/2020, every six months PM), Wrappers (12/23/2020 every 4 months PM), Disc Cutter (11/14/2020. Every six months PM) and Conveyors (9/08/2020, every 6 month PM).

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

<b>11.2.10.7</b>	<p>The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.10.8</b>	<p>Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.10.9</b>	<p>Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed and a pre-operational inspection conducted prior to the commencement of site operations.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.10.10</b>	<p>Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.10.11</b>	<p>Paint used in a food handling or contact zone shall be suitable for use, in good condition and shall not be used on any product contact surface.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.11</b>	<p><b>Calibration</b></p> <p>A policy defines the methods and responsibilities for calibrating measuring, testing and inspection equipment, and has been implemented. The facility has developed a calibration schedule for all devices listed. This documentation is located in 11.2.10 Equipment Maintenance and Calibration (11/1/2018). The frequency of calibrations is based on the manufacturer's recommendations or customer requirements. The policy includes the procedures to address the disposition of any affected product should inspection equipment be found to be out of calibration, written in 11.2.10 Equipment Maintenance and Calibration (11/1/2018). Inspection and testing equipment is protected from damage or unauthorized use by training. Equipment is calibrated against national or international standards. The procedures to address the disposition of any affected product should inspection equipment be found to be out of calibration, written in Out of Calibration Procedure Doc. Inspection and testing equipment is protected from damage or unauthorized use by training. Equipment is calibrated against national or international standards. Calibration records were reviewed for metal detectors (June 5, 2020), and Thermometer (1/17/2020, 2/4/2020 and 3/4/2020).</p>
<b>11.2.11.1</b>	<p>The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite programs and food safety plans, or to demonstrate compliance with customer specifications shall be documented and implemented. Software used for such activities shall be validated as appropriate.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.11.2</b>	<p>Procedures shall be documented and implemented to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.11.3</b>	<p>Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.11.4</b>	<p>Equipment shall be calibrated against national or international reference standards and methods or to accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.11.5</b>	<p>Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
<b>11.2.11.6</b>	<p>Calibration records shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>

### 11.2.12 Pest Prevention

A policy, 11.2.12 Pest Control Procedure (11/1/2018), defines the site's program for pest prevention and the appropriate follow up to pest prevention issues that may occur. The program was observed during the audit to be effectively implemented. The premises were free of waste and debris as observed during the interior and exterior tours. No pest activity was identified or noted during tours, that presented a risk for product contamination and corrective action and record keeping procedures are in place should this occur. A Pest Contractor has been contracted for pest prevention and an updated scope of service dated 4/15/2004 defines the methods of pest prevention, the frequency of interior and exterior inspections and targeted pests. A current site map, dated 6/11/2020 is accurate showing the location of 25 external and 53 internal devices. A pesticide application log gives details and dates of all chemical usage. Licenses of the Pest Control Company licence expires 12/31/2021 from local authorities are current and indicate employees are trained and competent. A list of chemicals used by the Pest Contractor is found in Pest Prevention Program Binder and includes SDS information. Inspection activity reports are signed by a management representative after visits and were reviewed and found to be completed as scheduled. Any observations or issues noted by the Pest Contractor are addressed and documented by the site. The trending of the pest activity frequency is documented in Pest Prevention Program Binder.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

- 11.2.12.6** Records of all pest control applications shall be maintained.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

- 11.2.12.8** Pest contractors shall be: i. Licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.3) which will include and maintain a site map indicating the location of bait stations traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and vi. Provide a written report of their findings and the inspections and treatments applied.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 11.2.13 Cleaning and Sanitation

The site has a Cleaning and Sanitation Program, 11.2.13 Cleaning and Sanitation (11/1/2018) that describes the methods and responsibilities for cleaning of processing equipment, the environment, storage areas, bathrooms and break rooms. Sanitation Standard Operating Procedures are written and include what is cleaned, chemical usage (concentrations, etc.), cleaning methods and who is responsible. A master sanitation plan includes all areas of the facility with frequencies and responsibilities for deep cleaning. A review of the plan for January to December 2018 showed cleaning tasks were completed as scheduled. There is a suitable area for cleaning containers, knives, cutting boards and other utensils that does not cause a food product contamination. The site does not have CIP system. The site is running One shift (7 AM to 3:30 PM) five days a week, and there is daily pre-op inspection. End of day cleaning and sanitation was verified by production plant manager and QA. Other records reviewed are: Employee/Facility Good Manufacturing Program Inspections Checklist (March 1, 2019 -January 1, 2021), Mixing room cleaning (Daily), Break Room Cleaning Procedures (March 1, 2019 -January 1, 2021), Packing room cleaning procedures (March 1, 2019 -January 1, 2021). Cleaning materials are stored securely and properly labeled with SDS information available to all employees. Chemicals Dawn detergent, Lysol daily cleaner, Dawn Heavy duty detergent and Mr. Red Degreaser were observed to be included on a list of approved chemicals, labeled consistent with regulations and had SDS on hand. Dispensed cleaning chemicals were properly stored and identified. Cleaning chemicals are not mixed on-site. All employees are properly trained in cleaning methods and the safe use of chemicals. The last chemical handling training was conducted during the refresher training on January 5, 2021.

- 11.2.13.1** The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Methods used to confirm the correct concentrations of detergents and sanitizers, and vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

11.2.13.8	<p>Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use; ii. An inventory of all chemicals purchased and used shall be maintained; iii. Detergents and sanitizers are stored as outlined in element 11.6.4; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v. Only trained staff handles sanitizers and detergents.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.2.13.9	<p>Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.2.13.10	<p>The site shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.2.13.11	<p>A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.1	<p><b>Personnel</b></p> <p>A Personal Hygiene and Practice (1/1/2019) policy for all employees has been documented and implemented. Employees are prohibited from working in food handling or open food storage areas who are suffering from, or who are or were carriers of, an infectious disease that may be passed through food. The site has documented measures to prevent contact of product materials with bodily fluids and respond appropriately to any bodily fluid spillage. The policy includes the prohibition of any food handling activity for persons with exposed cuts, sores or lesions and requires that minor cuts or abrasions be covered with a waterproof, metal detectable, colored bandage or dressing. The Personal Hygiene and Practice (1/1/2019) policy prohibits smoking, eating, drinking except for water under acceptable, controlled conditions or spitting in the facility. Smoking is prohibited in all areas of the site except for the designated areas outside the building. Employee interviews confirmed that employees are trained in good manufacturing practices and are knowledgeable of the requirements.</p>
11.3.1.1	<p>Personnel who are carriers or are known to have been carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.1.2	<p>The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids from open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury which causes spillage of bodily fluid, a properly trained employee shall ensure that all affected areas including handling and processing areas have been adequately cleaned and that all materials and products have been quarantined and disposed of.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.1.3	<p>Personnel with exposed cuts, sores or lesions shall not engage in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.1.4	<p>Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging or equipment.</p> <p><b>RESPONSE:</b> COMPLIANT</p>

### 11.3.2 Hand Washing

A policy covering hand washing requirements has been documented and implemented. Hand wash basins are located at appropriate employee access points to processing areas. Hand wash sinks are made of non-corrosive materials and supplied with tempered potable water. Soap in a fixed dispenser, paper towels and waste containers are available. Signs are posted reminding employees to wash their hands before returning to work. Signs are posted at hand wash station and in bathrooms. Employees are required to wash hands when wearing gloves. Interviews conducted with employees during the audit demonstrated that employees understand the hand washing requirements. Employees were observed to wash their hands properly during the audit and to use proper glove procedures. 11.3.2.5 -- Minor -- Personnel and auditor did not wash hands prior to entering product handling area during the tour of the facility. Equipment, utensils were touched during the tour.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** MINOR

**EVIDENCE:** Personnel and auditor did not wash hands prior to entering product handling area during the tour of the facility. Equipment, utensils were touched during the tour.

**ROOT CAUSE:** Overlooked by the Qa Manager and Office Manager.

**CORRECTIVE ACTION:** Added a handwashing sign to the entrance of the mixing room. Did a facility audit of all entrances going into food handling and processing areas to make sure the proper signs are in place.

**VERIFICATION OF CLOSEOUT:** CAPA is approved.

**COMPLETION DATE:** 02/16/2021 **CLOSEOUT DATE:** 03/11/2021

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

**RESPONSE:** COMPLIANT

### 11.3.3 Clothing

A policy, based on a documented risk assessment, found in 11.3.1 Clothing ( 1/1/2019), defines the site's clothing requirements and been implemented. Clothing including shoes are required to be clean at the commencement of the shift and changed or replaced if excessively soiled. Disposable gloves and aprons are to be changed when soiled or damaged. Employees were observed to comply with the clothing requirements of the facility. Non-disposable gloves and aprons were observed to be cleaned and properly stored per site policies.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT



11.3.3.3	<p>Clothing, including shoes, shall be clean at the commencement of each shift and maintained in a serviceable condition.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.3.4	<p>Excessively soiled uniforms shall be changed or replaced where they present a product contamination risk.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.3.5	<p>Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or designated sealed containers in personnel lockers and not on packaging, ingredients, product or equipment.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.4	<p><b>Jewelry and Personal Effects</b></p> <p>A policy defining jewelry use has been written in GMP policy and implemented (11.3.1). Jewelry and other loose objects are prohibited in food processing and handling areas. Employees were observed to comply with the jewelry policy during the audit tours. Plain bands are allowed by the facility's policy.</p>
11.3.4.1	<p>Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and prescribed medical alert bracelets can be permitted, however the site will need to consider their customer requirements and the applicable food legislation.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.5	<p><b>Visitors</b></p> <p>A policy defining visitor and contractor requirements found in Visitor Policy has been documented and implemented. The policy requires that visitors be trained in hygiene and food safety requirements before entering food processing or handling areas, or that they be continually escorted while in those locations. The requirements for visitors in those areas include the proper use of access points, hand wash requirements, suitable protective clothing and footwear, removal of jewelry or other loose objects, and an absence of visible signs of illness.</p>
11.3.5.1	<p>All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.5.2	<p>All visitors shall be required to remove jewelry and other loose objects.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.5.3	<p>Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.5.4	<p>Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all hand washing and personnel practice requirements.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.5.5	<p>All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing or handling areas or shall be escorted at all times in food processing, handling and storage areas.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.3.6	<p><b>Staff Amenities</b></p> <p>Employee bathrooms and break rooms were observed to be appropriately lit and ventilated and available for all personnel at the facility.</p>
11.3.6.1	<p>Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and processing of product.</p> <p><b>RESPONSE:</b> COMPLIANT</p>

### 11.3.7 Change Rooms

There are facilities for employees to change into and out of protective clothing. Provisions have been made for storage of street clothing and personal items and are separate from processing and storage areas. Change rooms are provided for employees.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 11.3.8 Laundry

Laundrying of uniforms is conducted by an outside contractor. N/A

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

**RESPONSE:** NOT APPLICABLE

### 11.3.9 Sanitary Facilities

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

**11.3.9.1** Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and vi. Kept clean and tidy.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 11.3.10 Lunch Rooms

Lunch rooms that are properly separated from production are available, well lit, properly ventilated and are appropriately sized for the number of facility employees. Lunch rooms include hot and cold potable water, food storage areas, refrigerators with hand and utensil washing capabilities. Signs reminding employees to wash their hands before returning to work were observed at the exit to lunch rooms. Lunch rooms were observed to be clean and well-maintained during the audit tours.

11.3.10.1	<p>Separate lunch-room facilities shall be provided away from a food contact/handling zone.</p> <p><b>RESPONSE: COMPLIANT</b></p>
11.3.10.2	<p>Lunch-room facilities shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities enabling them to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.</p> <p><b>RESPONSE: COMPLIANT</b></p>
11.3.10.3	<p>Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for introduction of contamination including pests to the site.</p> <p><b>RESPONSE: COMPLIANT</b></p>
11.3.10.4	<p>Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in lunch-rooms, at lunch-room exits and in outside eating areas if applicable.</p> <p><b>RESPONSE: COMPLIANT</b></p>
11.4.1	<p><b>Staff Engaged in Food Handling and Processing Operations</b></p> <p>Food handling procedures for all employees are documented and implemented. Personnel are required to access the processing areas through personnel doors only and doors were observed closed. False fingernails or fingernail polish, long nails, false or extended eyelashes are prohibited and no violations were noted. Hair restraints were observed to be worn where the product is exposed. Ingredients were in appropriate, labeled containers and kept off the floor. Sensory evaluations were conducted in designated areas that were well lit and appropriately equipped for that purpose and personnel conducting sensory evaluations are trained and maintain high hygienic standards. Wash down hoses were observed to be properly stored on racks when not in use.</p>
11.4.1.1	<p>All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2; vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food; and vii. Hair restraints are used where product is exposed.</p> <p><b>RESPONSE: COMPLIANT</b></p>
11.4.1.2	<p>In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the site shall implement proper controls and procedures to ensure: i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel only; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; and v. Equipment used for sensory evaluations is sanitized, maintained and stored separate from processing equipment.</p> <p><b>RESPONSE: COMPLIANT</b></p>
11.4.1.3	<p>All wash down hoses shall be stored on hose racks after use and not left on the floor.</p> <p><b>RESPONSE: COMPLIANT</b></p>
11.5.1	<p><b>Water Supply</b></p> <p>Potable water is sourced for use in the facility for processing and cleaning the premises and equipment. Potable water is supplied from the City of LaSalle, IL. It was determined that there was adequate hot and cold water for cleaning and processing. Back flow preventers are installed on water lines. Back flow devices are tested annually by the State approved Inspector, and the last test was conducted on 3/12/2020. Hose stations, taps and other water sources are designed to prevent back flow or back siphonage.</p>
11.5.1.1	<p>Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment.</p> <p><b>RESPONSE: COMPLIANT</b></p>

11.5.1.2	Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment. <b>RESPONSE:</b> COMPLIANT
11.5.1.3	The delivery of water within the premises shall ensure potable water is not contaminated. <b>RESPONSE:</b> COMPLIANT
11.5.1.4	The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent back flow or back siphonage. <b>RESPONSE:</b> NOT APPLICABLE <b>EVIDENCE:</b> Non-potable water is not used at this site. N/A
11.5.1.5	Where water is stored on site, storage facilities shall be adequately designed, constructed and maintained to prevent contamination. <b>RESPONSE:</b> NOT APPLICABLE <b>EVIDENCE:</b> Water is not stored on site. N/A
11.5.2	<b>Water Treatment</b> Water is not required to be treated at the facility. N/A
11.5.2.1	Water treatment methods, equipment and materials, if required, shall be designed, installed and operated to ensure water receives an effective treatment. <b>RESPONSE:</b> NOT APPLICABLE
11.5.2.2	Water treatment equipment shall be monitored regularly to ensure it remains serviceable. <b>RESPONSE:</b> NOT APPLICABLE
11.5.2.3	Treated water shall be regularly monitored to ensure it meets the indicators specified. <b>RESPONSE:</b> NOT APPLICABLE
11.5.2.4	Water used in as an ingredient in processing, or in cleaning and sanitizing equipment, shall be tested, and if required, treated to maintain potability (refer to 11.5.2.1). <b>RESPONSE:</b> NOT APPLICABLE
11.5.3	<b>Ice Supply</b> Ice is not used at the facility. N/A
11.5.3.1	Ice provided for use during processing operations or as a processing aid or an ingredient shall comply with 11.5.4.1. <b>RESPONSE:</b> NOT APPLICABLE
11.5.3.2	Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution. <b>RESPONSE:</b> NOT APPLICABLE
11.5.4	<b>Water Quality</b> Water used in cleaning or handwashing is monitored periodically for potability by the site. Samples from inside the facility are sent to an outside lab for analysis. Based on risk, the site's testing frequency is set at a minimum frequency of once a quarter. The last potability test was conducted on February 3, 2021 by a approved third party laboratory.
11.5.4.1	Water shall comply with local, national or internationally recognized potable water microbiological and quality standards as required when used for: i. washing, thawing and treating food; ii. handwashing iii. to convey food; iv. as an ingredient or food processing aid; v. cleaning food contact surfaces and equipment; vi. the manufacture of ice; or vii. the manufacture of steam that will come into contact with food or used to heat water that will come in contact with food. <b>RESPONSE:</b> COMPLIANT

11.5.4.2	Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning, or from within the site. The frequency of analysis shall be risk-based, and at a minimum annually. <b>RESPONSE:</b> COMPLIANT
11.5.4.3	Water and ice shall be analyzed using reference standards and methods. <b>RESPONSE:</b> COMPLIANT
11.5.5	<b>The Quality of Air and Other Gasses</b> At the time of audit, compressed air was not set up to touch any food or food contact surfaces. N/A
11.5.5.1	Compressed air or other gases (e.g. nitrogen, carbon dioxide) that contacts food or food contact surfaces shall be clean and present no risk to food safety. <b>RESPONSE:</b> NOT APPLICABLE
11.5.5.2	Compressed air systems, and systems used to store or dispense other gases used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. <b>RESPONSE:</b> NOT APPLICABLE
11.6.1	<b>Storage and Handling of Goods</b> The site has implemented effective documented storage plan(s) for the storage of raw materials, ingredients, packaging, equipment and chemicals. For example, the GMP and 11.6 Shipping Receiving and Storage Procedure (11/1/2018) were reviewed during the audit and found to be acceptable. Stock rotation, based on First In First Out except for the bin, which is emptied and cleaned at least once a year has been implemented by the site to ensure that all materials are used within their designated shelf-life.
11.6.1.1	The site shall document and implement an effective storage plan that allows for the safe, hygienic storage of raw materials (i.e. frozen, chilled, and ambient), ingredients, packaging materials, equipment, and chemicals. <b>RESPONSE:</b> COMPLIANT
11.6.1.2	The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented. <b>RESPONSE:</b> COMPLIANT
11.6.1.3	Procedures shall be in place to ensure that all ingredients, materials, work-in-progress, rework, and finished product are utilized within their designated shelf-life. <b>RESPONSE:</b> COMPLIANT
11.6.1.4	Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. <b>RESPONSE:</b> COMPLIANT
11.6.1.5	Where goods described in 11.6.2 to 11.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety. <b>RESPONSE:</b> NOT APPLICABLE <b>EVIDENCE:</b> Temporary or overflow conditions are not used by the site. N/A
11.6.1.6	Records shall be available to validate alternate or temporary control measures for the storage of raw materials, ingredients, packaging materials, equipment, chemicals, or finished products. <b>RESPONSE:</b> NOT APPLICABLE <b>EVIDENCE:</b> The site has not used alternate storage or temporary control measures over the timeframe being audited. N/A

### 11.6.2 Cold Storage, Freezing and Chilling of Foods

Freezers and cold storage areas are designed and constructed to allow for hygienic and efficient refrigeration. It appeared to be sufficient capacity for the facilities requirements and sufficient space for periodic cleaning. The condensate lines were connected directly to the plant drainage system. Temperature monitoring devices are located at the warmest part of the refrigerators/freezers, and temperatures are periodically monitored and recorded. Temperature monitoring for Freezer dated, form dated November 23, 2020 was reviewed and met required targets. Refrigeration equipment is maintained on the plant's preventive maintenance schedule, and work was last completed as scheduled. An outside contractor maintains the refrigeration equipment.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

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

- 11.6.3.1** Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Any hazardous chemicals, such as cleaning chemicals, were observed to be properly stored and labeled and did not appear to present a hazard to personnel or food products. No processing utensils or packaging were stored next to chemicals. Pesticides are not stored on site. Chemical storage areas were observed to be locked and had instructions on handling hazardous chemicals, an up-to-date inventory of all chemicals, available first aid and spill containment equipment. Daily supplies of chemicals were properly stored. All stored chemicals have current SDS information on file at the facility. SDS and the label declaration and/or documented approval for the chemical's intended use were reviewed for Dawn detergent, Lysol daily cleaner, Dawn Heavy duty detergent and Mr. Red Degreaser.

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

**RESPONSE:** COMPLIANT

11.6.4.2	Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances. <b>RESPONSE: COMPLIANT</b>
11.6.4.3	Daily supplies of chemicals used for continuous sanitizing of water or as a processing aid, or for emergency cleaning of food processing equipment or surfaces in food contact zones, may be stored within or in close proximity to a processing area provided that access to the chemical storage facility is restricted to authorized personnel. <b>RESPONSE: COMPLIANT</b>
11.6.4.4	Pesticides, rodenticides, fumigants and insecticides shall be stored separate from sanitizers and detergents. All chemicals shall be stored in their original containers, or in clearly labelled and suitable secondary containers if allowed by applicable legislation. <b>RESPONSE: COMPLIANT</b>
11.6.4.5	Hazardous chemical and toxic substance storage facilities shall: i. Be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals; ii. Be adequately ventilated; iii. Be provided with appropriate signage indicating the area is a hazardous storage area; iv. Be secure and lockable to restrict access only to those personnel with formal training in the handling and use of hazardous chemicals and toxic substances; v. Have instructions on the safe handling of hazardous chemicals and toxic substances readily accessible to staff; vi. Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility; vii. Have suitable first aid equipment and protective clothing available close to the storage area; viii. In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and ix. Be equipped with spillage kits and cleaning equipment. <b>RESPONSE: COMPLIANT</b>
11.6.5	<b>Loading, Transport, and Unloading Practices</b> A policy defining the practices for loading, unloading and storage of food products has been documented in 11.6 Shipping Receiving and Storage Procedure (11/1/2018) and implemented. It was observed during the audit tours that food is unloaded, stored and loaded under conditions that prevent cross contamination.
11.6.5.1	The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported and unloaded under conditions suitable to prevent cross-contamination. <b>RESPONSE: COMPLIANT</b>
11.6.6	<b>Loading</b> The site's policy requires that all trailers be inspected for cleanliness, infestation, odors, damage, etc. before loading and that vehicles be secured from tampering by use of seal or other agreed method. Documentation was reviewed for 1/04/2021, 1/18/2021, and 1/18/2021. It was observed during the audit tours that loading practices do not expose products to detrimental conditions. Trailers and vehicles used for transport were observed to be properly secured from tampering by a seal, when it is FCL shipping .
11.6.6.1	Vehicles (e.g. trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product. <b>RESPONSE: COMPLIANT</b>
11.6.6.2	Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity during loading and transport. <b>RESPONSE: COMPLIANT</b>
11.6.6.3	Vehicles (e.g. trucks/vans/containers) shall be secured from tampering using a seal or other agreed upon and acceptable device or system. <b>RESPONSE: COMPLIANT</b>
11.6.7	<b>Transport</b> The site's products are not required to be refrigerated. N/A
11.6.7.1	Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and product temperatures recorded at regular intervals during loading as appropriate. <b>RESPONSE: NOT APPLICABLE</b>

11.6.7.2	<p>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.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p>
11.6.8	<p><b>Unloading</b></p> <p>Butter is the only item comes in reefer container (not refrigerated). Reefer unit temperatures are monitored and recorded before opening the trailer doors. Product temperatures are recorded at appropriate intervals during the unloading. Temperatures were reviewed by plant manager/shipper/receiver and found to be properly recorded.</p>
11.6.8.1	<p>Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.6.8.2	<p>Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.1	<p><b>Process Flow</b></p> <p>The process flow was observed to be logical, with a continuous flow and designed to prevent cross contamination. It was observed during audit tours that the flow of employees is such that any cross contamination is minimal.</p>
11.7.1.1	<p>The process flow shall be designed to prevent cross-contamination and organized so there is a continuous flow of product through the process. The flow of personnel shall be managed such that the potential for contamination is minimized.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.2	<p><b>Receipt of Raw and Packaging Materials and Ingredients</b></p> <p>Dry ingredients and packaging were observed to be stored separately from unprocessed raw materials or frozen ingredient, butter. Not only for the temperature but also for the allergen cross contact prevention.</p>
11.7.2.1	<p>Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross-contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross-contamination.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.3	<p><b>Thawing of Food</b></p> <p>Butters are thawed in the refrigerator.</p>
11.7.3.1	<p>Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.3.2	<p>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.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p> <p><b>EVIDENCE:</b> The facility does not conduct water thawing of products. N/A</p>
11.7.3.3	<p>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.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p> <p><b>EVIDENCE:</b> The facility does not conduct air thawing of products. N/A</p>
11.7.3.4	<p>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.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p>



#### 11.7.4 High Risk Processes

The site does not produce high risk products. N/A

- 11.7.4.1** The processing of high risk food shall be conducted under controlled conditions such that sensitive areas in which high risk food has undergone a “kill” step, a “food safety intervention” or is subject to post process handling, are protected/segregated from other processes, raw materials or staff who handle raw materials to ensure cross-contamination is minimized.  
**RESPONSE:** NOT APPLICABLE
- 11.7.4.2** Areas in which high risk processes are conducted shall only be serviced by staff dedicated to that function.  
**RESPONSE:** NOT APPLICABLE
- 11.7.4.3** Staff access points shall be located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.  
**RESPONSE:** NOT APPLICABLE
- 11.7.4.4** Staff engaged in high risk areas shall change into clean clothing or temporary protective outerwear when entering high risk areas.  
**RESPONSE:** NOT APPLICABLE
- 11.7.4.5** Product transfer points shall be located and designed so as not to compromise high risk segregation and to minimize the risk of cross-contamination.  
**RESPONSE:** NOT APPLICABLE

#### 11.7.5 Control of Foreign Matter Contamination

Policy 11.7.5 Physical hazard Control Procedure (11/1/2018) defines the methods and responsibilities to prevent foreign material contamination. The policy's implementation was demonstrated by pre-operational inspections and regularly scheduled maintenance inspections that are conducted and documented for the condition of equipment and any potential contaminants. A glass register has been documented with glass, brittle plastic and ceramic sources included in all areas of the plant. The glass register is current as of 5/7/2019. Periodic inspections with documentation are made of these areas to ensure breakage has not occurred, and items are not missing or moved. The last three inspections conducted on 5/3, 6, 7/2019 were reviewed and found to be completed as scheduled (daily). Wood pallets were clean and in good condition, and the facility has a policy prohibiting and/or controlling wooden utensils in processing /food handling areas. The site has documented a knife policy, and knives are controlled, cleaned and required to be in good condition. Periodic maintenance inspections include looking for loose objects and potential contaminants from overheads.

- 11.7.5.1** The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff.  
**RESPONSE:** COMPLIANT
- 11.7.5.2** Inspections shall be performed to ensure plant and equipment remain in good condition, equipment has not become detached or deteriorated and is free from potential contaminants.  
**RESPONSE:** COMPLIANT
- 11.7.5.3** All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location.  
**RESPONSE:** COMPLIANT
- 11.7.5.4** Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing /contact zones.  
**RESPONSE:** COMPLIANT
- 11.7.5.5** Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register.  
**RESPONSE:** COMPLIANT
- 11.7.5.6** Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.  
**RESPONSE:** COMPLIANT

11.7.5.7	<p>Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.11.7.5.8 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.5.8	<p>Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.5.9	<p>Knives and cutting instruments used in processing and packaging operations shall be controlled and kept clean and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.6	<p><b>Detection of Foreign Objects</b></p> <p>A policy defining the methods and responsibilities for the use of foreign material detection and removal devices has been documented and implemented. The device used in the facility is metal detector. Metal detector is routinely monitored, validated and verified by operations personnel. Demonstration and documentation of the devices were observed during the audit tours. Interview with QA who is responsible for the monitoring indicated they were knowledgeable and understood what to do if the devices failed when tested with known samples. Device was observed to reject defective product physically and isolate product. Records reviewed demonstrated the site was verifying the functioning of these devices, documenting any objects rejected or removed by them and implementing corrective actions.</p>
11.7.6.1	<p>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.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p> <p><b>EVIDENCE:</b> The facility did not use screens, sieves, filters or other technologies to remove or detect foreign matter. Foreign material detection is done only by metal detector.</p>
11.7.6.2	<p>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.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.6.3	<p>Records shall be maintained of the inspection of foreign object detection devices and of any products rejected or removed by them. Records shall include any corrective actions resulting from the inspections.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.7	<p><b>Managing Foreign Matter Contamination Incidents</b></p> <p>The site's policy requires that any product affected by foreign material contamination be isolated, inspected, reworked or disposed o f. The glass policy requires that a thorough cleanup and inspection (including of cleaning equipment and footwear) occur if a glass breakage were to occur. A responsible person, SQF Practitioner, is required to inspect the affected area before the restarting of production.</p>
11.7.7.1	<p>In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.7.7.2	<p>In circumstances where glass or similar material breakage occurs, the affected area is to be isolated, cleaned and thoroughly inspected (including cleaning equipment and footwear) and cleared by a suitably responsible person prior to the commencement of operations.</p> <p><b>RESPONSE:</b> COMPLIANT</p>
11.8.1	<p><b>Location</b></p> <p>The facility does not have a non-site chemical or microbiological laboratory that may pose a risk to product safety. N/A</p>
11.8.1.1	<p>On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.</p> <p><b>RESPONSE:</b> NOT APPLICABLE</p>

11.8.1.2	Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory wastewater outlet shall as a minimum be down stream of drains that service food processing and handling areas. <b>RESPONSE:</b> NOT APPLICABLE
11.8.1.3	Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel. <b>RESPONSE:</b> NOT APPLICABLE
11.9.1	<b>Dry and Liquid Waste Disposal</b> <p>A policy defining the methods and responsibilities for handling dry, wet and liquid waste has been documented and implemented, is found in 11.9 Waste Disposal (11/1/2018). Waste was observed to be removed on a scheduled basis and is documented on pre-operational inspections and internal audits conducted by the plant. Waste containers, hoppers, bins and storage areas on the interior and exterior of the facility were observed to be well-maintained and clean. Solid waste from processing was observed to be properly disposed of. Waste water is discharged to plant drains and collected for disposal to the municipality's waste water system. A documented procedure 11.9 Waste Disposal (11/1/2018) is in place to ensure controlled disposal of trademarked materials where required, including a review of any contracted disposal services. Inedible waste designated for animal feed is handled and stored so as not to pose a risk to the animal or to further processing.</p>
11.9.1.1	The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented. <b>RESPONSE:</b> COMPLIANT
11.9.1.2	Waste shall be removed on a regular basis and not build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken. <b>RESPONSE:</b> COMPLIANT
11.9.1.3	Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition, cleaned and sanitized regularly so as not to attract pests and other vermin. <b>RESPONSE:</b> COMPLIANT
11.9.1.4	Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging. <b>RESPONSE:</b> COMPLIANT
11.9.1.5	Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance. <b>RESPONSE:</b> COMPLIANT
11.9.1.6	Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing. <b>RESPONSE:</b> COMPLIANT
11.9.1.7	Waste held on site prior to disposal shall be stored in a separate storage facility and suitably insect proofed and contained so as not to present a hazard. <b>RESPONSE:</b> COMPLIANT
11.9.1.8	Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard. <b>RESPONSE:</b> COMPLIANT
11.9.1.9	Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports. <b>RESPONSE:</b> COMPLIANT

### 11.10.1 Grounds and Roadways

The grounds and surrounding areas were observed to minimize dust and be free of any waste so pests are not attracted. Paths, roadways and dock areas were seen to be adequately and properly drained and well maintained, so they do not present a hazard. Walkways from the parking lot and other employee amenities were paved or effectively sealed.

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

**RESPONSE:** COMPLIANT

**11.10.1.2** The grounds and area surrounding the premises shall be maintained to minimize dust and kept free of waste, accumulated debris or standing water so as not to attract pests and vermin.

**RESPONSE:** COMPLIANT

**11.10.1.3** Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises.

**RESPONSE:** COMPLIANT

**11.10.1.4** Paths, roadways, loading and unloading areas shall be adequately drained to prevent ponding of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

**RESPONSE:** COMPLIANT

**11.10.1.5** Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises.

**RESPONSE:** COMPLIANT

**11.10.1.6** Paths from amenities leading to site entrances are required to be effectively sealed.

**RESPONSE:** COMPLIANT