SQF Food Safety Audit Edition 8.1
Tone Products - Tone Products, Inc.

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
640982 | 125769

AUDIT RATING
99
Excellent

DECISION DATE
02/22/2021

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
01/29/2022

AUDIT DATES
01/26/2021 - 01/27/2021

EXPIRATION DATE
04/13/2022

ISSUE DATE
02/22/2021

Facility & Scope

Tone Products (43029)
Tone Products, Inc.
2129 N. 15th Ave
Melrose Park, IL 60160
United States

Web Site: http://www.toneproducts.com

Food Sector Categories:
16. Ice, Drink and Beverage Processing
18. Preserved Foods Manufacture
ICT Addendum

Products:
16. Beverage concentrates, bloody mary mix, ready-to-drink cocktail mixers, ready-to-drink cocktail mixers with alcohol
18.Barbecue sauce, dressing, flavoured syrup, marinades, pancake syrup

Scope of Certification:
16. Receiving, mixing, processing, filling, packing, storage and dispatch 18. Receiving, mixing, cooking, filling, packing, storage and dispatch

Certification Body & Audit Team

SGS Systems & Services Certification Pty Ltd

10/585 Blackburn Road
Notting Hill, Victoria, 3168
Australia

CB#: CB-1-SGS
Accreditation Body: JAS-ANZ
Accreditation Number: Z2630103AS

Lead Auditor: Guray, Frank (9341)
Technical Reviewer: Mato, Roy (200391)

Hours Spent on Site: 12
Hours of ICT Activities: 12
Hours Spent Writing Report: 8

Non-Conforming

11.2.13 Cleaning and Sanitation

11.2.13 Provision has been made for the effective cleaning of processing equipment, utensils and protective clothing. Cleaning procedures are in place. Sanitation (ie. Cleaning) can be done during active production, no contamination risks observed with curtains used for minimizing cross contamination. Direct observation and interview of inspector responsible for Pre-operational inspectional checks. Bulk containers are refilled or disposed Chemical containers are disposed of after being emptied. Verbal verification that there has not been any disposal of unused chemicals since the last audit. Review and accepted of the following evidence: SSOP 001 Master Sanitation Schedule[R0], SSOP 005 - Tank and filler cleaning procedure[14-Feb-2018], Line 4 CIP Procedure[05-Jan-2021], Chemical Register[R0], GHS Training - RT[12-Jan-2021], Perasan-A Technical Data[R0], SDS - Perasan A[01-Jan-2019], Production Line Preoperational Inspection - ATP Swab | Filler Wash Record - Previous Allergen, Rinse Type with Soap, Sanitizer, Swab, [11-Sep-2020, 02-Nov-2020, 09-Jul-2020, 08-Jul-2020]. MINOR: Observed 1 spray bottle that was not identified.

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

RESPONSE: MINOR

EVIDENCE: MINOR: Observed 1 spray bottle that was not identified.

ROOT CAUSE: The employee using the sanitizer bottle was/is aware of the requirement that all chemical containers shall be labeled. The employee is tasked every day with sanitizing high-traffic areas and high touch areas as part of our COVID spread mitigation strategy. When the auditor observed him he was spraying a door knob and the area near the hand wash sink. The employee was interviewed and asked why the bottle was not labeled. He said that he shares supplies with the second and third shift cleaning people (someone is assigned to do that job on each shift) and sometimes those people do not return the supplies to the correct place. On this particular day he could not find his labeled spray bottle, so he took a new one.

CORRECTIVE ACTION: 1. The employees performing cleaning of high traffic areas will be assigned their own supplies in a locked cabinet. 2. Unlabeled spray containers will be controlled in the same way as knives, that is to say, if an employee needs one they will have to ask QA or a supervisor. This practice is in place for knives because we need to know immediately when someone has lost their knife. Now, the same policy will apply to spray containers. GMP007 was updated to fully reflect these requirements (changes in yellow.)

VERIFICATION OF CLOSEOUT: Review of response, procedure.

COMPLETION DATE: 02/09/2021 **CLOSEOUT DATE:** 02/11/2021

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Brian Parisi
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** brian@toneproducts.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Frank Guray:Auditor, Brian Parisi:Director of Quality, Jason LaRusso :Director of Operations
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** The facility was occupied in the 1990s and is 155,000 square feet (3 buildings). There are 17 production lines with 3 cold storage and 3 dry storage areas. Production runs 24/5 with start times of 7am, 3pm, and 11 pm. While Juice production runs two shifts. There are 90 Tone employees with 30-40 permanent temps with approximately 1/3 of the total number of employees within each of the shifts. SQF categories include 16: Beverage concentrates, bloody mary mix, ready-to-drink cocktail mixers, ready-to-drink cocktail mixers with alcohol; 18.Barbecue sauce, dressing, flavored syrup, marinades, pancake syrup. Processes include: mixing, processing, cooking, filling, packing, storage and dispatch.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Frank Guray:Auditor, Brian Parisi:Director of Quality, Jason LaRusso :VP of Operations, Will Evon:President, Greg Speny:Operations
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Issue certification pending closure of nonconformity
A	Does this audit include the use of ICT? **RESPONSE:** Yes
B.1	ICT Start date **RESPONSE:** 1/25/2021 12:00:00 AM
B.2	ICT End date **RESPONSE:** 1/26/2021 12:00:00 AM
C	Were there any issues with the use of ICT? If yes, please specify what issues were encountered. **RESPONSE:** No

Section Responses

2.1.1 Food Safety Policy (Mandatory)

2.1.1 Statement includes: "...meets the quality and safety requirements of our customers and relevant regulatory codes..." The statement was posted in the hallway. The statement is signed by Director. The statement is displayed in English, with translations for: Spanish. Review and accepted of the following evidence: FS&Q Policy Statement - Signed by Plant Manager[11-Oct-2019], Food Safety Standards: Introduction and SQF - AP, SV, JP[15-Dec-2020, 30-Nov-2020, 17-Sep-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2 Management Responsibility (Mandatory)

2.1.2 This audit is announced. Both the SQFP and backup are full time employees. The SQFP and backup is Brian / Jason. Review of training systems, verified through records review, interview, and direct observation. Verified through interview. Primary response involves contacting the Supervisor of any issues (or maintenance if a mechanical issue arises.) Adequate resources are available to achieve food safety objectives and to support the development, implementation and maintenance and ongoing improvement of the SQF System. Development effectiveness is demonstrated through the SQFP responsible for document creation / amendment and authorization. Implementation effectiveness is demonstrated through Interview of personnel, and review of documents control for key processes, which includes the management review, internal audit, prerequisite programs, customer feedback. Maintenance effectiveness is determined through review of records and confirmed through interview of employees within the processes. Ongoing Improvement effectiveness is determined through review of management review, Internal Audits. Backups are in place for organization or personnel changes. Designees described within the Job Descriptions Review of blackout dates revealed no production planned for those selected. Review and accepted of the following evidence: Operations Organizational Chart - SQFP reports to President / CEO[14-Sep-2020], SQF Training - BP | Food Safety Standards: Introduction and SQF - MG[26-Dec-2009, 20-Nov-2020], JOB DESCRIPTIONS –Tone Products[11-Oct-2019], Quarterly Report 2020 Quality Assurance Department - Production Error and Defect Data | Customer Complaint Report and Trend Analysis | Corrective Action Plan | Summary of the Quarter's Goals, Objectives, and Corrective Action Plan | Statement of Next Quarter's Goals and Objectives - 6 complaints for Q3, 2 for Q4[01-Oct-2020, 04-Jan-2021, 30-Jun-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2.4 Senior site management shall designate an SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF System, including good manufacturing practices outlined in 2.4.2, and the food safety plan outlined in 2.4.3. ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.1.2.5 The SQF practitioner shall: i. Be employed by the site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code for Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2.7 Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements of the SQF Food Safety Code for Manufacturing, and are informed of their responsibility to report food safety problems to personnel with authority to initiate action.

RESPONSE: COMPLIANT

2.1.2.8 Job descriptions for those responsible for food safety shall be documented and include a provision to cover for the absence of key personnel.

RESPONSE: COMPLIANT

2.1.2.9 Senior site management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3 Management Review (Mandatory)

2.1.3 Management updates are scheduled to be done at least 1 / day. Management reviews are scheduled to be done at least 1 / year. Sr management representative evidence include signoff. Management commitment and policy manual, Internal and external audit findings (list here all external audits that took place since the previous review), Corrective actions and their investigations and resolution, Customer complaints and their resolution and investigation, Hazard and risk management system | HACCP and FQP plan review findings, Follow up items from last year's validation:, Product Identification, Trace, Withdrawal and Recall | Site Security, Crisis Management, and Food Fraud | Identity Preserved Foods (Kosher) | Training and communication | Module 11: GMP for Processing of Food Products Review and accepted of the following evidence: SQF Program Review[01-Dec-2020], Daily HACCP Meeting Record[04-Jan-2021, 04-Dec-2020, 11-Nov-2020].

2.1.3.1 The senior site management shall be responsible for reviewing the SQF System and documenting the review procedure. Reviews shall include: i. The policy manual; ii. Internal and external audit findings; iii. Corrective actions and their investigations and resolution; iv. Customer complaints and their resolution and investigation; v. Hazard and risk management system; and vi. Follow-up action items from previous management review.

RESPONSE: COMPLIANT

2.1.3.2 The SQF practitioner (s) shall update senior site management on a (minimum) monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented. The SQF System in its entirety shall be reviewed at least annually.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.4 Complaint Management (Mandatory)

2.1.4 Complaints of a serious nature have not been received (ie. Those from hospitals, CDC, lawyers) since the last audit. No contradictory evidence observed. Customer feedback procedures are in place. No negative trends regarding customer feedback requiring corrective actions. Customer feedback corrective action elements include 'Nature of Complaint, Observations, Corrective action; Also Root Cause Corrective Action Report[21-Jul-2020]. Review and accepted of the following evidence: Quarterly Report 2020 Quality Assurance Department - Production Error and Defect Data | Customer Complaint Report and Trend Analysis | Corrective Action Plan | Summary of the Quarter's Goals, Objectives, and Corrective Action Plan | Statement of Next Quarter's Goals and Objectives - 6 complaints for Q3, 2 for Q4[01-Oct-2020, 04-Jan-2021, 30-Jun-2020], Nature of Complaint, Observations, Corrective action; Also Root Cause Corrective Action Report[21-Jul-2020], (No Food Safety Complaints since the last audit) - Complaint Investigation Spreadsheet - Spoilage ; The wrong label was used; The customer reported a cocked cap[16-Apr-2020, 10-Jul-2020, 27-Oct-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.5 Crisis Management Planning

2.1.5 Crisis management and planning procedures are in place. The program includes: Crisis Team Members. The senior manager for the CMP is VP of Operations, Plant Manager and QA Manager. Product controls which include identification, isolation, and inspection of product is addressed "...Lead all necessary measures to ensure that crisis response does not compromise product safety or quality...in the control of all finished product, raw materials and packaging supplies. Isolate all affected product and ingredients..." Legal and expert contacts are documented within Director of Operations - "...c. Interaction with legal counsel and government agencies..." - Sr Mgmt will call in case of event. Review, testing, and verification of the crisis management plan is scheduled to be done 1 / year. Event that is ongoing is the COVID pandemic. Product control is addressed within: Maintaining production levels and "...Ensure equipment is thoroughly cleaned and sanitized prior to start-up. Collect environmental swabs and hold equipment that fails ATP swab until a passing swab is collected..." Communication is addressed through Coordination of Regulatory Contacts. Program includes: "...Contact SQFI within 2 hours of onset of food safety crisis should one occur as a result of this crisis or for any reason. See Crisis Management plan FDP005.." No gaps identified during the exercise. Review and accepted of the following evidence: Food Defense Crisis Management Plan[15-Mar-2020], Daily HACCP Meeting[15-Mar-2020], Crisis Management and Product Retrieval - Emergency Contacts – Regulatory Agencies[22-Sep-2015], Verification & Test – Initiated 3/4/2020 and remains in effect until a formal closeout is issued and communicated to all staff[23-Nov-2020], Verification & Test – Initiated 3/4/2020 and remains in effect until a formal closeout is issued and communicated to all staff[23-Nov-2020].

2.1.5.1 A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis.

RESPONSE: COMPLIANT

2.1.5.2 The crisis management plan shall include as a minimum: i. A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure a response does not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations and media.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

2.2.1 The food safety management system is in place and includes all elements. Changes made are to be validated by the SQFP.

2.2.1.1 A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site will use to meet the requirements of the SQF Food Safety Code for Manufacturing, be made available to relevant staff and include: i. A summary of the organization’s food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The scope of certification; iv. A list of the products covered under the scope of certification; v. Food safety procedures, pre-requisite programs, food safety plans; and vi. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

2.2.2 Document control procedures are in place. Amendments to documents and policies are recorded within the Document Registers with Revision Notes. Documents are maintained in the QA Lab / R&D Lab.

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)

2.2.3 Monitoring and record control procedures are in place. Review of various records throughout the process. See specific element for further commentary. Records are maintained for at least 3 years. Review and accepted of the following evidence: Record Retention Test: Batch Ticket Report - CCP, CQP[12-Feb-2019].

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

2.3.1 Product Development and Realization process is in place. There have not been any new products that are not line extensions since the last audit. Review and accepted of the following evidence: Shelf Life Test Report[16-Apr-2020], FORMULA ROUTING SHEET - Digital Signatures[12-Jan-2021, 06-Aug-2020], New Product Hazard Analysis - CCP Requirements, New Ingredient analysis, PRP Review, Allergen Risks[15-Jul-2020, 15-Oct-2020, 12-Jan-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.2 Raw and Packaging Materials

2.3.2 Walkthrough and inspection of raw materials and packaging in storage rooms revealed no issues. Specifications are provided by the supplier. Validation of packaging materials are addressed through letters of guarantees and / or certifications. Review and accepted of the following evidence: Specification / Product Data Sheet / Technical Data[20-Feb-2019, 21-Aug-2017, 12-Aug-2008], Letter of Guarantee[29-Jan-2019, 01-Mar-2018], First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020], Food and Packaging Raw Material Register[R0].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.3 Contract Service Providers

2.3.3 Contract service providers have not been dropped for performance issues since the last audit. No contradictory evidence observed. Providers include SGS and Ajax. Training requirements include Escort and / or GMP Review and accepted of the following evidence: Contract Services Registry - includes SGS[12-Jan-2021].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.4 Contract Manufacturers

2.3.4 N/A. Contract Manufacturing is not managed by this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Contract Manufacturing is not managed by this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Contract Manufacturing is not managed by this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Contract Manufacturing is not managed by this site.

2.3.5 Finished Product Specifications

2.3.5 Review and accepted of the following evidence: Formula Routing Sheet[27-Jul-2020, 19-Feb-2020, 30-Jul-2020], HACCP Finished Goods Register[R0].

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

RESPONSE: COMPLIANT

2.3.5.2 A register of finished product specifications shall be maintained.

RESPONSE: COMPLIANT

2.4.1 Food Legislation (Mandatory)

2.4.1 Regulatory actions have not been taken (ie. Noncompliances, warning letters, Notices of Intended Enforcement, Suspensions, Withdrawals, requests to shutdown, notices involving seizure of product) since the last audit. No contradictory evidence observed. Food Law information is received through the foodsafetynews website. Company is proactive in receiving regulatory / industry information. No regulatory issues detected. Emergency contacts include: foodsafetycrisis@sqfi.com and the certification body with a time line of completion within 24 hours.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

2.4.2 GMPs in place are appropriate for the operations at this site. Review and accepted of the following evidence: GMP Hygiene Requirements [06-Jul-2016].

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)

2.4.3 The HACCP Program has been developed using the Codex method. The team leader is the QA Director. The HACCP Team is multidisciplinary. The food safety plan is effectively implemented and maintained. The entire scope of the operations is included within the food safety plan. Descriptions for product and intended use was present for all products. Food safety hazards include: Microbial growth due to acid/moisture ratio in finished good, microbiological pathogens, Presence of boiler chemicals, metals, or other substances, CCPs include: pH - <4.6 each batch, Thermal Pasteurization Process with hot fill - Process Authority Sets Limits monitored continuously or 200 deg F every batch , Water Activity <0.85 each batch; Juice CCP - Receiving of Concentrates - Seal integrity (all items,) Temperature (Orange Juice bulk) Wash ticket verification (OJ Bulk,) Brix/temperature <40 /color/taste check (OJ Bulk). Controls also include: Sanitation PC, Allergen PC. Review of Annual Verification, also revision information is on separate spreadsheet files. Review and accepted of the following evidence: HACCP Program - with team[25-Oct-2019, 03-Aug-2020], Product Description with identified hazards - Building A, B[08-Aug-2019, 02-Oct-2019, 08-Aug-2019], Flow Chart - Building A, B, C[15-Jul-2019, 15-Jul-2019, 03-Aug-2020], Product Description with identified hazards - Building A | Ingredient Category Hazard Analysis: All Buildings | Hazard Analysis and Preventive Control Determination[23-Oct-2019, 02-Sep-2020, 24-Oct-2020], HACCP Plan Summary[03-Apr-2019], Batch Ticket Report - Brix, pH, Density[09-Sep-2020, 31-Oct-2020, 09-Jul-2020], Daily Mixing Report - Cook CCP, pH, Brix, CQPs[11-Sep-2020, 02-Nov-2020, 09-Jul-2020], 2020 HACCP System Validation - 7 Principles, Sanitation Validation, Glass and Brittle Plastic, Foreign Material Control Program[01-Dec-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.7	The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw material, packaging material, service inputs (e.g. water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation. **RESPONSE:** COMPLIANT
2.4.3.8	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs. **RESPONSE:** COMPLIANT
2.4.3.9	The food safety team shall conduct a hazard analysis for every identified hazard to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT
2.4.3.10	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure. **RESPONSE:** COMPLIANT
2.4.3.11	Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e. a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure. **RESPONSE:** COMPLIANT
2.4.3.12	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard (s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1). **RESPONSE:** COMPLIANT
2.4.3.13	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT
2.4.3.14	The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure. **RESPONSE:** COMPLIANT
2.4.3.15	The documented and approved food safety plan (s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs or other changes affecting product safety occur. **RESPONSE:** COMPLIANT
2.4.3.16	Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5). **RESPONSE:** COMPLIANT
2.4.3.17	Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements. **RESPONSE:** COMPLIANT

2.4.4 Approved Supplier Program (Mandatory)

2.4.4 Suppliers, including those used for emergency purposes, are all approved at this site. There are no sister sites for this facility. No contradictory evidence observed. Suppliers have not been dropped for performance reasons since the last audit. No contradictory evidence observed. Materials are provided by an approved supplier. Monitoring procedures are in place for selection, evaluating, approving, and monitoring suppliers. Approval is done by Matt / Director of Supply Chain. Inbound load security includes the use of a lock (for LTL) or seals. Food fraud vulnerabilities and mitigation plans are assessed within 2.7.2 of this report. Inspection requirements are the same for all inbounds, including those from sister sites. Monitoring is conducted through 100% of all loads inspected Review and accepted of the following evidence: ISO22000[17-Sep-2021], Supplier Approval contact list and register[R0].

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

2.4.5 Nonconforming product and equipment control procedures are in place. Equipment is repaired during the weekend or will shut down a line. Reasons for holds include running out of labels. Expired materials go automatically go on hold. Review of QA Hold Tag - Ages / Out of Code in the system Confirmed hold process effectiveness with the following hold tag found in operations: 'GoCanvas - Anchor Glass Hold - 26 pallets[19-Jan-2021]. HACCP Meetings are used to track equipment sanitation. Equipment is pulled off the production floor, or tagged before use and the line goes down Startup sanitation is used prior to use for equipment requiring repair. Review and accepted of the following evidence: GoCanvas - Anchor Glass Hold - 26 pallets[19-Jan-2021]. N/A. Reblending across production lot codes do not occur at this site. outside of the lot code occur at this site.

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

2.4.6 Rework procedures are in place. Blending between distinct lot codes do not occur at this site. Corrected product rework is recorded on the hold records. Equipment rework is documented within work orders. N/A. Reblending across production lot codes do not occur at this site. outside of the lot code occur at this site. N/A. Rework with regards to product repair only occurs at this site. No blending into different lot codes occur at this site.

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

RESPONSE: COMPLIANT

2.4.6.2 Records of all reworking operations shall be maintained.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Rework with regards to product repair only occurs at this site. No blending into different lot codes occur at this site.

2.4.7 Product Release (Mandatory)

2.4.7 Release procedures are in place. Non-defective product is considered to be released upon completion of packaging. Corrected product release records are documented within the hold records. Product release is done by QA, QA Director or Director of Operations.

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

2.4.8 Environmental monitoring results have not required corrective actions since the last audit. No contradictory evidence observed. Environmental monitoring procedures are in place. Environmental risk is low. Pathogens / Indicator organisms tested for include Salmonella / Listeria. Sites include: Zones 2-4 | 1-2 samples quarterly per sampling point for Listeria and Salmonella. No exemptions have been requested. Review and accepted of the following evidence: Environmental Monitoring Program[20-Jun-2019], Environmental Monitoring Procedure[20-Jun-2019], Environmental COA - Listeria, Salmonella - Done Quarterly | Tone Products Environmental Sampling Program Data[14-Apr-2020, 24-Aug-2020, 31-Dec-2020], Environmental Monitoring Basics - MO | Swabbing (ENV) Review - LH[11-Dec-2020, 11-Dec-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

2.5.1 Validation and effectiveness confirmation procedures are in place. Validation activities is documented through the Internal Audit and Management Reviews. Review and accepted of the following evidence: 2020 HACCP System Validation - 7 Principles, Sanitation Validation, Glass and Brittle Plastic, Foreign Material Control Program[01-Dec-2020], COA - Listeria spp, Salmonella - Lot #0153 - QSRI1 | COA - Listeria, Salmonella, Color, Smell, Flavor, Brix, pH, Bostwick[01-Jun-2020, 08-Jun-2020], Process Review: Traditional Margarita Products[16-Sep-2020].

2.5.1.1 The methods, responsibility and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall ensure that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required result; ii. Critical food safety limits are validated, and re-validated annually; iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and iv. All applicable elements of the SQF Program are implemented and effective.

RESPONSE: COMPLIANT

2.5.1.2 Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

2.5.2 Verification procedures are in place. Review and acceptance of means of verification for the following evidence: Daily Mixing Report - Cook CCP, pH, Brix, CQPs[11-Sep-2020, 02-Nov-2020, 09-Jul-2020], 2020 HACCP System Validation - 7 Principles, Sanitation Validation, Glass and Brittle Plastic, Foreign Material Control Program[01-Dec-2020], SQF Program Review[01-Dec-2020], Production Line Preoperational Inspection - ATP Swab | Filler Wash Record - Previous Allergen, Rinse Type with Soap, Sanitizer, Swab, [11-Sep-2020, 02-Nov-2020, 09-Jul-2020, 08-Jul-2020]. Review and accepted of the following evidence: Master Verification Schedule[17-Sep-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

2.5.3 CCP critical limit deviations have not occurred since the last audit. No contradictory evidence observed. Corrective and Preventative action procedures are in place. Additional corrective action records can be found within the internal audit (if any nonconformities are found) or customer feedback (if any complaints are received and require root cause analysis). Review and accepted of the following evidence: OP001c Root Cause and CA Report[21-Jul-2020, 23-Sep-2020, 12-Oct-2020], Quarterly Report 2020 Quality Assurance Department - Production Error and Defect Data | Customer Complaint Report and Trend Analysis | Corrective Action Plan | Summary of the Quarter's Goals, Objectives, and Corrective Action Plan | Statement of Next Quarter's Goals and Objectives - 6 complaints for Q3, 2 for Q4[01-Oct-2020, 04-Jan-2021, 30-Jun-2020].

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

2.5.4 Procedures are in place. No significant changes to procedures since the last review of the element. Monitoring requirements are documented in various places, including the Food Safety HACCP Programs as CCPs. Product Sampling, Inspection and Analysis for inbound items include: trailer and raw material inspection. Product Sampling, Inspection and Analysis for finished products include: Quality Inspections, visual inspections for trailers and product. Only analytical lab services are done at this site (quality). Review and accepted of the following evidence: CertLab-ANAB-Accreditation-Midwest[26-Feb-2023].

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)

2.5.5 Internal audit procedures are in place. Quarterly System Audit, unless a customer audit, government audit, or SQF audit occurs within that quarter. Site inspections are done monthly. No conflict of interest detected. System Internal audits are done 1 / year. Review and accepted of the following evidence: Internal Audit - JR[31-Mar-2020], Building A GMP Inspection with Corrective Actions[29-Oct-2020, 30-Nov-2020, 30-Dec-2020], Module 2, 9 - SQF Checklist[Q4-2020].

2.5.5.1	The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code for Manufacturing are audited as per the SQF audit checklist or similar tool; ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken; and iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions. **RESPONSE:** COMPLIANT
2.5.5.2	Staff conducting internal audits shall be trained and competent in internal audit procedures. **RESPONSE:** COMPLIANT
2.5.5.3	Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and building/equipment maintenance is compliant to the SQF Food Safety Code for Manufacturing. The site shall: i. Take corrections or corrective and preventative action; and ii. Maintain records of inspections and any corrective action taken. **RESPONSE:** COMPLIANT
2.5.5.4	Where practical staff conducting internal audits shall be independent of the function being audited. **RESPONSE:** COMPLIANT
2.5.5.5	Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained. **RESPONSE:** COMPLIANT
2.6.1	**Product Identification (Mandatory)** 2.6.1 Identification procedures are in place and were confirmed via walkthrough. Review and accepted of the following evidence: Production Schedules[10-Sep-2020, 02-Nov-2020, 09-Jul-2020], First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020].
2.6.1.1	The methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in -progress, process inputs and finished products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure: i. Raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are clearly identified during all stages of receipt, production, storage and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements. **RESPONSE:** COMPLIANT
2.6.1.2	Product identification records shall be maintained. **RESPONSE:** COMPLIANT
2.6.1.3	Product start up and changeover procedures during packing shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label, and that the changeover is inspected and approved by an authorized person. **RESPONSE:** COMPLIANT
2.6.2	**Product Trace (Mandatory)** 2.6.2 Traceability procedures are in place. The traceability exercise is referenced within 2.6.3 for the mock recall program. Traceability link is described as the following: Receiving Log --> BOL --> Line Sheet --> Julian Date and Product #. Review and accepted of the following evidence: First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020], BOL[02-Jan-2020, 21-Oct-2020, 30-Oct-2020], BOL (Stamped Trailer Inspection)[14-Sep-2020, 12-Nov-2020, 16-Jul-2020].
2.6.2.1	The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable to the customer (one up) and provides traceability through the process to the manufacturing supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back); ii. Traceability is maintained where product is reworked; and iii. The effectiveness of the product trace system shall be reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.3). **RESPONSE:** COMPLIANT

2.6.2.2	Records of raw and packaging material receipt and use, and finished product dispatch and destination shall be maintained. **RESPONSE:** COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

2.6.3 Recalls / Withdrawals have not impacted this site since the last audit. No contradictory evidence observed. Withdrawal and Recall procedures are in place. Recall / Withdrawal Root Cause Analysis is addressed within: "...A review committee identified and led by the R/W Coordinator will establish the cause of the problem and will review corrective actions to determine if they are appropriate..." Mock recalls are performed at least 2 / year. Review of Raw Materials Review of Mock Recall for - JPM O3-0009. Conducted 11/17/2020 with 100% in 1:24 min. Finished Product Review of APIJCO70 Lot 043. 2376.46 units tracked with 100% in 1:04. Performance root cause analysis is not required as the company achieved the target. Communique for recall evidence includes: Emergency Contacts (with Local Management and Major Customer Supply Chain Contacts. - 11/16/19. Auditing of communication of food safety events to SQFI and the CB is documented within 2.4.1.3 of this report. Conducted searches for food safety events during the last 12 months (including food safety recalls). No evidence of events observed. Review and accepted of the following evidence: Crisis Management and Product Retrieval | Product Recall Program[22-Sep-2015, 09-Sep-2019].

2.6.3.1	The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall; ii. Describe the management procedures to be implemented including sources of legal, regulatory and expert advice and essential traceability information; and iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; iv. SQFI, the certification body, and the appropriate regulatory authority shall be listed as an essential body and notified in instances of a food safety incident of a public nature, or product recall for any reason. **RESPONSE:** COMPLIANT
2.6.3.2	Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented. **RESPONSE:** COMPLIANT
2.6.3.3	The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually. Testing shall include incoming materials (one back) and finished product (one up). **RESPONSE:** COMPLIANT
2.6.3.4	SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com. **RESPONSE:** COMPLIANT
2.6.3.5	Records of all product withdrawals, recalls and mock recalls shall be maintained. **RESPONSE:** COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

2.7.1 Security breaches (including break-ins, need to contact law enforcement, company infiltration to cause damage to company's image) have not occurred since the last audit. No contradictory evidence observed. Food defense procedures are in place. Sr Site Manager Responsible is the Plant Manager. Sensitive Processing Area Controls include: Incoming Materials and Ingredients. The food defense plan is scheduled to be reviewed and challenged at least 1 time per year. Food defense review is done through the internal audit. Review and accepted of the following evidence: Food Defense and Food Fraud Mitigation Plan - Plant Manager[17-Dec-2020], 2020 Tones Security Letter | * Not done due to the COVID Pandemic,[02-Dec-2020].

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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.2 Food Fraud

2.7.2 Food fraud instances have not been detected since the last audit. No contradictory evidence observed. Food fraud procedures are in place. The food fraud vulnerability assessment and mitigation plan is scheduled to be reviewed and verified at least 1 / year. Review and accepted of the following evidence: FDP 002 Food Defense Plan[17-Dec-2020], Existing Inventory Fraud Mitigation Inspection[10-Mar-2020, 09-Dec-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.8.1 Allergen Management for Food Manufacturing (Mandatory)

2.8.1 Allergen risks in chemicals are monitored by the QA Department Discretionary allergens used at this site include: Wheat, fish, crustaceans, eggs, soy, milk, and treenuts. Additional international discretionary allergens used at this site include: mustard and sulfites. Hand washing protocols are in place to address allergen risks from employee personal effects and meals. Raw material risk analysis is addressed within the Hazard Analysis. Actions used to address allergen adulteration or misbranding include hold process with investigation. Raw materials with allergens are identified by an Allergen Label. Vertical Segregation Storage is implemented at this site. Materials are stored in a way to ensure that materials above it have the same allergens. Horizontal Segregation Storage is implemented at this site. Materials are stored in a way to ensure that enough spacing is in place between materials that may or may not have allergens. Curtains are used to control aerosol risks. Changeover procedures include moving from non-allergen to allergen scheduling. Sanitation and Rapid testing is done for any changeovers going from product with an allergen that is not present in the next production run. Chemical controls include allergen letters, including: Chemical Allergen Risks - Bioblend Letter Allergen Declaration. No above and beyond traceability required for allergen containing items. Review and accepted of the following evidence: Allergen Control Program[11-Feb-2019], QA Dept Monitored - Only order approved with declaration files - Bioblend Letter Allergen Declaration[23-Jan-2019], Food Allergens: REFRESHER - Proper Handling[16-Sep-2020], Allergen System Validation Report - Milk, Seeds, Soy, Fish, Mustard[27-Feb-2020], First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.8.1.3	Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored. **RESPONSE:** COMPLIANT
2.8.1.4	Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided where satisfactory line hygiene and clean-up or segregation is not possible. **RESPONSE:** COMPLIANT
2.8.1.5	Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented. **RESPONSE:** COMPLIANT
2.8.1.6	Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact. **RESPONSE:** COMPLIANT
2.8.1.7	The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured. **RESPONSE:** COMPLIANT
2.8.1.8	The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in-progress and finished product is true to label with regard to allergens. Such measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures. **RESPONSE:** COMPLIANT
2.8.1.9	The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used. **RESPONSE:** COMPLIANT
2.8.1.10	Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable. **RESPONSE:** COMPLIANT
2.8.1.11	Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introducing unintended allergens through supplier, contract manufacturer, employee and visitor activities. **RESPONSE:** COMPLIANT

2.8.2 Allergen Management for Pet Food Manufacturing

2.8.2 N/A. Animal feed, nor pet food is manufactured at this site.

2.8.2.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those inputs and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A list of allergens which is accessible by relevant staff; and iv. The hazards associated with allergens and their control incorporated into the food safety plan. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A. Animal feed, nor pet food is manufactured at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Animal feed, nor pet food is manufactured at this site.

2.8.3 Allergen Management for Manufacturers of Animal Feed

2.8.3 N/A. Animal feed, nor pet food is manufactured at this site. No contradictory evidence observed.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Animal feed, nor pet food is manufactured at this site. No contradictory evidence observed.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Animal feed, nor pet food is manufactured at this site. No contradictory evidence observed.

2.9.1 Training Requirements

2.9.1 Training system is in place. Verified through records review, interview, and direct observation. Topics include: Food Safety Standards: Introduction and SQF, HACCP: Overview, Hand Washing: Effective Techniques, Food Allergens: Introduction. Training is provided for the employees.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

2.9.2 Training program is in place and document. Elements include GMP, Food Safety HACCP, and other necessary elements.

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

RESPONSE: COMPLIANT

2.9.3 Instructions

2.9.3 Language requirements are documented within 2.9.5 of this report. Review and accepted of the following evidence: QA002 Chemical Testing Procedure for WIP and finished goods[01-Jul-2014].

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

RESPONSE: COMPLIANT

2.9.4 HACCP Training Requirements

2.9.4 Review and accepted of the following evidence: HACCP Training - BP[17-Feb-2010], FSPCA Training - BP[26-May-2016].

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

RESPONSE: COMPLIANT

2.9.5 Language

2.9.5 Language spoken at this site is English with translations and interpreters available for Spanish Review and accepted of the following evidence: Reference Card cutouts English and Spanish[R0].

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

RESPONSE: COMPLIANT

2.9.6 Refresher Training

2.9.6 Refresher training is done 1 / year.

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

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

2.9.7 Sampling was done from individuals interviewed within the register to ensure completion. Review of training records within Alchemy. Review and accepted of the following evidence: Food Safety Standards: Introduction and SQF - AP, SV, JP[15-Dec-2020, 30-Nov-2020, 17-Sep-2020], Basic Food Facility Defense - MC[19-Dec-2020].

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

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

11.1.1 Construction activity has not occurred since the last audit. No contradictory evidence observed. External walkthrough of the facility revealed no issues. Review and accepted of the following evidence: FFRM #: XXXXXXXXXX4[31-Dec-2022].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.1 Materials and Surfaces

11.2.1 Product contact surfaces include steel and plastic. Non-product contact surfaces are acceptable within industry expectations.

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

RESPONSE: COMPLIANT

11.2.2 Floors, Drains, and Waste Traps

11.2.2 Floor surfaces include brick. Floors are sloped to the drains, confirmed through direct observation. Drains observed to be clear. N/A. Waste traps, including clarifiers and grease traps, are not used at this site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Waste traps, including clarifiers and grease traps, are not used at this site.

11.2.3 Walls, Partitions, Doors and Ceilings

11.2.3 Visual inspection of internal surfaces (including walls, partitions, ceilings and doors) revealed no issues. They were observed to be clean (and cleanable). No accumulation or junction issues observed. Visual inspection of ducting, conduit and pipes that convey services revealed no issues. Facility is enclosed with a ceiling. Visual inspection of drop ceilings. N/A. Pipes carrying sanitary waste or waste water are not located directly over product lines or storage areas.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Pipes carrying sanitary waste or waste water are not located directly over product lines or storage areas.

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

RESPONSE: COMPLIANT

11.2.3.6 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products.

RESPONSE: COMPLIANT

11.2.3.7 Drop ceilings shall be constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.

RESPONSE: COMPLIANT

11.2.4 Stairs, Catwalks and Platforms

11.2.4 N/A. Platforms, stairs, or catwalks over product (exposed or otherwise) are not present at this site.

11.2.4.1 Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1).

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Platforms, stairs, or catwalks over product (exposed or otherwise) are not present at this site.

11.2.5 Lightings and Light Fittings

11.2.5 Lighting is adequate in processing areas to permit inspection and carry out tasks properly. Visual inspection of light fixtures. Visual inspection of lighting in storage areas.

11.2.5.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.5.3 Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination.

RESPONSE: COMPLIANT

11.2.6 Inspection / Quality Control Area

11.2.6 Visual inspection where monitoring is conducted. Inspection areas include access to hand wash stations and trash containers.

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

11.2.7 All surfaces to the outside are effectively sealed when closed. Visual inspection of external doors for personnel. Visual inspection of ILTs.

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

11.2.8 No off odors or condensation observed at this facility. Visual inspection of fans revealed no sanitary issues.

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

11.2.9 Confirmed equipment, utensils, outerwear was within industry expectations. Equipment and utensil surfaces include plastic, steel utensils. Standard liquid equipment and utensils, no contamination threat observed. Surfaces are smooth and impervious for food contact aspects. Liquid waste is observed to go directly to the drain. Protective clothing used include uniforms or disposable lab coats, observed to be appropriate for food production. Visual inspection of storage hooks for protective clothing. Visual inspection of equipment storage. Review and accepted of the following evidence: GMP007 GMP Sanitary Operation Requirements[04-Dec-2020].

11.2.9.1	Specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented. **RESPONSE:** COMPLIANT
11.2.9.2	Equipment and utensils shall be designed, constructed, installed, operated and maintained to meet any applicable regulatory requirements and not to pose a contamination threat to products. **RESPONSE:** COMPLIANT
11.2.9.3	Benches, tables, conveyors, mixers, mincers, graders and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious and free from cracks or crevices. **RESPONSE:** COMPLIANT
11.2.9.4	Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned as per 11.2.13. Bins used for inedible material shall be clearly identified. **RESPONSE:** COMPLIANT
11.2.9.5	Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system, and to meet local regulatory requirements. **RESPONSE:** COMPLIANT
11.2.9.6	Protective clothing shall be manufactured from material that will not contaminate food and is easily cleaned. **RESPONSE:** COMPLIANT
11.2.9.7	Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities. **RESPONSE:** COMPLIANT
11.2.9.8	All equipment, utensils and protective clothing shall be cleaned after use or at a frequency to control contamination and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination. **RESPONSE:** COMPLIANT

11.2.10 Premises and Equipment Maintenance

11.2.10 Scheduled and requested maintenance procedures are in place. System currently in use is Limbal - transition into this system is in progress. Communication is made to supervision if there are food safety events through radios or line buttons. Grease guns are identified, no misuse observed. No food safety issues observed regarding paint on food contact surfaces / zones. Review and accepted of the following evidence: Sanitation Log (System in transition to a new PM system)[01-Jan-2020], Requested Work Order[04-Jan-2021, 04-Jan-2021].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.11 Calibration

11.2.11 Calibration failures involving food safety and / or regulatory measurements and requiring revisiting product disposition have not occurred since the last audit. No contradictory evidence observed. Calibration procedures are in place. No damage or unauthorized adjustments detected. Systems are in place. Calibration include use of 3rd party certifications. Review and accepted of the following evidence: OP006[12-Oct-2020], Calibration Certificates[16-Dec-2020], pH Calibration Record[11-Sep-2020, 02-Nov-2020, 09-Jul-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.11.6 Calibration records shall be maintained.

RESPONSE: COMPLIANT

11.2.12 Pest Prevention

11.2.12 Bait stations located outside of the building were not inspected due to snowfall. Service is provided by McCloud in Chicago, IL. Review of: Device Map for Device Location information. Visually confirmed devices for the following traps: INT - 14. Review of: Trend Analysis - Mice Rat[Oct-20, Jul-20, Jan-21] for internal rodent trending. Review of: All 3 Buildings - Trend Report - Previous 1 year for external rodent trending. Service includes 2 time(s) per month for internal rodent traps, 2 time(s) per month for external bait stations, 2 time(s) per month for insect traps. Review of: Listing - Service Inspection Report[Dec-20, Sep-20, Jul-20] for frequency compliance. Review of: Open Times & Conditions Resolved This it for corrective actions. Review of: Service Inspection Report for application data. Review of use of pest control chemicals, including: Contrac All Weather Blox , EPA# 12455.79 that targets Mice., Tempo Ultra WP EPA#: 432-1304 that targets Pests, Beetles. Review of: Service Inspection Report[08-Dec-20, 01-Sep-20, 08-Jul-20] for detailed service report reviews. Communication of results are documented by signoff. Review of PCO license for CF, issued by IDPH, number XXX-XXXXX1, expiration date 31-Dec-21. Review of PCO license for SVS, issued by IDPH, number XXX-XXXXX3, expiration date 31-Dec-21. Review of company license for Mc Cloud, issued by IDPH, number XXX-XXXXX1, expiration date 31-Dec-20. N/A. Pest control chemicals are only handled by a 3rd party operator. Empty containers are not reused. Pest control chemicals are not stored on-site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.12.6 Records of all pest control applications shall be maintained.

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Pest control chemicals are only handled by a 3rd party operator. Empty containers are not reused. Pest control chemicals are not stored on-site.

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Pest control chemicals are only handled by a 3rd party operator. Empty containers are not reused. Pest control chemicals are not stored on-site.

11.2.13 Cleaning and Sanitation

11.2.13 Provision has been made for the effective cleaning of processing equipment, utensils and protective clothing. Cleaning procedures are in place. Sanitation (ie. Cleaning) can be done during active production, no contamination risks observed with curtains used for minimizing cross contamination. Direct observation and interview of inspector responsible for Pre-operational inspectional checks. Bulk containers are refilled or disposed Chemical containers are disposed of after being emptied. Verbal verification that there has not been any disposal of unused chemicals since the last audit. Review and accepted of the following evidence: SSOP 001 Master Sanitation Schedule[R0], SSOP 005 - Tank and filler cleaning procedure[14-Feb-2018], Line 4 CIP Procedure[05-Jan-2021], Chemical Register[R0], GHS Training - RT[12-Jan-2021], Perasan-A Technical Data[R0], SDS - Perasan A[01-Jan-2019], Production Line Preoperational Inspection - ATP Swab | Filler Wash Record - Previous Allergen, Rinse Type with Soap, Sanitizer, Swab, [11-Sep-2020, 02-Nov-2020, 09-Jul-2020, 08-Jul-2020]. MINOR: Observed 1 spray bottle that was not identified.

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	Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use; ii. An inventory of all chemicals purchased and used shall be maintained; iii. Detergents and sanitizers are stored as outlined in element 11.6.4; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v. Only trained staff handles sanitizers and detergents. **RESPONSE:** MINOR **EVIDENCE:** MINOR: Observed 1 spray bottle that was not identified. **ROOT CAUSE:** The employee using the sanitizer bottle was/is aware of the requirement that all chemical containers shall be labeled. The employee is tasked every day with sanitizing high-traffic areas and high touch areas as part of our COVID spread mitigation strategy. When the auditor observed him he was spraying a door knob and the area near the hand wash sink. The employee was interviewed and asked why the bottle was not labeled. He said that he shares supplies with the second and third shift cleaning people (someone is assigned to do that job on each shift) and sometimes those people do not return the supplies to the correct place. On this particular day he could not find his labeled spray bottle, so he took a new one. **CORRECTIVE ACTION:** 1. The employees performing cleaning of high traffic areas will be assigned their own supplies in a locked cabinet. 2. Unlabeled spray containers will be controlled in the same way as knives, that is to say, if an employee needs one they will have to ask QA or a supervisor. This practice is in place for knives because we need to know immediately when someone has lost their knife. Now, the same policy will apply to spray containers. GMP007 was updated to fully reflect these requirements (changes in yellow.) **VERIFICATION OF CLOSEOUT:** Review of response, procedure. **COMPLETION DATE:** 02/09/2021 **CLOSEOUT DATE:** 02/11/2021
11.2.13.9	Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained. **RESPONSE:** COMPLIANT
11.2.13.10	The site shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor. **RESPONSE:** COMPLIANT

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

RESPONSE: COMPLIANT

11.3.1 Personnel

11.3.1 Events involving bodily fluid contamination to surfaces, product or packaging have not occurred since the last audit. No contradictory evidence observed. Interview and visual inspection of employees. None were observed to have symptoms. COVID countermeasures include Masks, social distancing. First aid kits are in place, including one found in the maintenance shop. No employees observed with medical conditions, including cuts, sores, or lesions. No employees observed to be smoking, chewing, eating or spitting. Bottled Water is the only beverages permitted in the exposed product area.

11.3.1.1 Personnel who are carriers or are known to have been carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.1.4 Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging or equipment.

RESPONSE: COMPLIANT

11.3.2 Hand Washing

11.3.2 Visual inspection of the hand wash sinks. Observed signs at hand wash stations to remind personnel to wash their hands. Employees observed washing their hands prior to entering the processing area. Employees observed washing their hands prior to putting on gloves. N/A. High risk products are not produced at this site.

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: NOT APPLICABLE

EVIDENCE: N/A. High risk products are not produced at this site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3 Clothing

11.3.3 Protective clothing used include uniforms or lab coats, observed to be appropriate for food production. Visual inspection of foot wear. Additional lab coats are available in the event of excessive soilage. Employees were observed wearing gloves. Review and accepted of the following evidence: Process Hazard Analysis and Preventive Control Determination[24-Sep-2018].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.4 Jewelry and Personal Effects

11.3.4 Other than a plain wedding band, jewelry is not permitted, nor was it seen on any employees.

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

RESPONSE: COMPLIANT

11.3.5 Visitors

11.3.5 All visitors, management and non-production personnel are required to follow the same GMP requirements as production personnel All visitors were required to jewelry GMP requirements as processing employees. Visitors are expected not to have any symptoms. None observed at the time of the audit. Visitors are to enter using the same entrance and exit doors.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.6 Staff Amenities

11.3.6 Lighting is adequate in staff areas.

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

RESPONSE: COMPLIANT

11.3.7 Change Rooms

11.3.7 Uniforms are worn or Lab coats are worn over street clothing. Employee personal Items are stored in lockers. N/A. Showers are not required to be used by employees once they arrive on site.

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: NOT APPLICABLE

EVIDENCE: N/A. Showers are not required to be used by employees once they arrive on site.

11.3.8 Laundry

11.3.8 Clothing is laundered, no excessively soiled uniforms observed being worn.

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

RESPONSE: COMPLIANT

11.3.9 Sanitary Facilities

11.3.9 Sanitary drainage is connected in accordance to regulations. No contradictory evidence observed. Visual inspection of toilet rooms. Properly designed and constructed and separate from processing area. The size appears to be adequate for the number of employees and is kept clean. Hand wash basins are within the sanitary facilities.

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

11.3.10 Visual inspection of lunch room, which was in a different room than food contact or handling zone. Observed to be ventilated and well lit. The lunch room was adequate for the number of employees. Refrigeration and heating facilities were provided for employees. The lunch room was sanitary. Hand wash signs are in place.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

11.4.1 Hair restraints include protection for hair on the head and face (if present). No employees observed with false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish. No hoses were observed to be left on the floor. N/A. Taste sensory evaluations in a food handling/contact zone areas are not done at this facility.

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2; vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food; and vii. Hair restraints are used where product is exposed.

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Taste sensory evaluations in a food handling/contact zone areas are not done at this facility.

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

RESPONSE: COMPLIANT

11.5.1 Water Supply

11.5.1 Water source is municipal. Hot and cold water supply was available and adequate. No water delivery issues observed N/A. Potable water sources are the only ones used at this site. N/A. Water is not stored on site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Potable water sources are the only ones used at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Water is not stored on site.

11.5.2 Water Treatment

11.5.2 N/A. Water treatment (including ozonation, filtration, chlorination) does not occur at this site for food safety purposes to make it potable.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Water treatment (including ozonation, filtration, chlorination) does not occur at this site for food safety purposes to make it potable.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Water treatment (including ozonation, filtration, chlorination) does not occur at this site for food safety purposes to make it potable.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Water treatment (including ozonation, filtration, chlorination) does not occur at this site for food safety purposes to make it potable.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Water treatment (including ozonation, filtration, chlorination) does not occur at this site for food safety purposes to make it potable.

11.5.3 Ice Supply

11.5.3 N/A. Ice is not used at this site for processing purposes.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Ice is not used at this site for processing purposes.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Ice is not used at this site for processing purposes.

11.5.4 Water Quality

11.5.4 Water is tested at least 1 / year. Review and accepted of the following evidence: COA Mixing Room - HPC, Coliform[14-Aug-2020, 25-Jan-2021].

11.5.4.1 Water shall comply with local, national or internationally recognized potable water microbiological and quality standards as required when used for: i. washing, thawing and treating food; ii. handwashing iii. to convey food; iv. as an ingredient or food processing aid; v. cleaning food contact surfaces and equipment; vi. the manufacture of ice; or vii. the manufacture of steam that will come into contact with food or used to heat water that will come in contact with food.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.5 The Quality of Air and Other Gasses

11.5.5 N/A. Compressed air or other gasses are not used on product or product contact surfaces during production at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Compressed air or other gasses are not used on product or product contact surfaces during production at this site.

11.5.5.2 Compressed air systems, and systems used to store or dispense other gases used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Compressed air or other gasses are not used on product or product contact surfaces during production at this site.

11.6.1 Storage and Handling of Goods

11.6.1 Stock rotation procedures are in place. Software and bar code systems are in place. No stock rotation issues. There were no holds due to expiration of shelf life since the last audit. Visual inspection of storage of equipment. Review and accepted of the following evidence: GMP Sanitary Operation Requirements[04-Dec-2020]. N/A. Alternative storage is not done at this site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.1.5 Where goods described in 11.6.2 to 11.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Alternative storage is not done at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Alternative storage is not done at this site.

11.6.2 Cold Storage, Freezing and Chilling of Foods

11.6.2 Walkthrough of refrigerated rooms revealed no warm spots. Direct observation of refrigeration drain lines revealed no issues. Visual inspection of probe placement and current temperature of cold storage areas. Visual inspection revealed no issues within the loading and unloading docks. Review and accepted of the following evidence: Preoperational Inspection Log - Room Temperatures[10-Sep-2020, 02-Nov-2020, 09-Jul-2020].

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

11.6.3 Visual inspection of dry storage. Visual inspection of racking used for packaging. Visual inspection of dry storage pallet jacks.

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

11.6.4 Visual inspection of chemical storage cage. No utensils or packaging stored near chemicals. Visual inspection of chemical storage facilities. No compliance issues observed. Materials are stored away from product and raw materials. N/A. 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 is not used at this site. N/A. Pest control chemicals are only handled by a 3rd party operator. Empty containers are not reused. Pest control chemicals are not stored on-site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. 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 is not used at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Pest control chemicals are only handled by a 3rd party operator. Empty containers are not reused. Pest control chemicals are not stored on-site.

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

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

11.6.5 Visual inspection of dock areas. Direct observation, interview, and records review results are documented within 11.6.6 and 11.6.8.

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

RESPONSE: COMPLIANT

11.6.6 Loading

11.6.6 Loading practices were verified through direct observation and interview. Review and accepted of the following evidence: BOL (Stamped Trailer Inspection)[14-Sep-2020, 12-Nov-2020, 16-Jul-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.7 Transport

11.6.7 N/A. Refrigeration is not required for any finished products at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Refrigeration is not required for any finished products at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Refrigeration is not required for any finished products at this site.

11.6.8 Unloading

11.6.8 Receiving practices were verified through direct observation and interview. Review and accepted of the following evidence: Receiving Log - with COA[02-Jan-2020, 21-Oct-2020, 30-Oct-2020].

11.6.8.1 Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.1 Process Flow

11.7.1 Review of product flow revealed no issues. Review of personnel flow revealed no issues.

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

RESPONSE: COMPLIANT

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

11.7.2 No wet to dry contamination observed.

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

RESPONSE: COMPLIANT

11.7.3 Thawing of Food

11.7.3 N/A. Thawing does not occur at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Thawing does not occur at this site.

11.7.3.2 Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature do not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Thawing using water does not occur at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Thawing using air does not occur at this site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Thawing does not occur at this site.

11.7.4 High Risk Processes

11.7.4 N/A. High risk products are not produced at this site.

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

EVIDENCE: N/A. High risk products are not produced at this site.

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

EVIDENCE: N/A. High risk products are not produced at this site.

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

EVIDENCE: N/A. High risk products are not produced at this site.

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

EVIDENCE: N/A. High risk products are not produced at this site.

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

EVIDENCE: N/A. High risk products are not produced at this site.

11.7.5 Control of Foreign Matter Contamination

11.7.5 Procedures are in place to address foreign matter contamination. Inspections are done through preoperational inspection. Visual inspection of pallets used at this site. No loose metal was observed on equipment or surfaces. Review and accepted of the following evidence: Glass and Fragile Plastic Audit Building A | Building B | Building C[16-Nov-2020, 16-Nov-2020, 16-Nov-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.5.5 Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.5.7 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.11.7.5.8 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.6 Detection of Foreign Objects

11.7.6 Magnets and screen systems are in place. Review and accepted of the following evidence: OP011A - Back Sheets - Color / Smell Taste - Screen Checks[10-Sep-2020, 02-Nov-2020, 09-Jul-2020].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.7 Managing Foreign Matter Contamination Incidents

11.7.7 Foreign matter contamination is managed through the hold process. Review and accepted of the following evidence: Broken Glass Log | Clean up procedure for broken glass[30-Dec-2020, 08-Aug-2016].

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.8.1 Location

11.8.1 N/A. Food Safety On-Site laboratories are not present at this site.

11.8.1.1 On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.9.1 Dry and Liquid Waste Disposal

11.9.1 Programs to address dry and liquid waste are in place. Visual inspection of waste containers revealed no waste overflow. Visual inspection of all trash storage revealed no issues. Review and accepted of the following evidence: DOCUMENT CONTROL AND RECORD RETENTION POLICY - Trademark Materials[15-Mar-2018]. N/A. Inedible waste designated for animal feed is not stored or handled at this site. N/A. Waste traps, including clarifiers and grease traps, are not used at this site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.9.1.6	Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A. Inedible waste designated for animal feed is not stored or handled at this site.
11.9.1.7	Waste held on site prior to disposal shall be stored in a separate storage facility and suitably insect proofed and contained so as not to present a hazard. **RESPONSE:** COMPLIANT
11.9.1.8	Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A. Waste traps, including clarifiers and grease traps, are not used at this site.
11.9.1.9	Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports. **RESPONSE:** COMPLIANT
11.10.1	**Grounds and Roadways** 11.10.1 Visual inspection of external perimeter walkthrough. No issues regarding paths, roadways and loading and unloading areas. No pooling of water observed. Visual inspection of surrounding areas. No issues regarding amenities leading to facility entrances.
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