SQF Food Safety Audit Edition 9
Jensen Meat Company - Jensen Meat Company

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
102819 | 166086

AUDIT RATING
95
Good

DECISION DATE
10/28/2022

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
08/26/2023

AUDIT DATES
09/13/2022 - 09/15/2022

EXPIRATION DATE
11/09/2023

ISSUE DATE
10/28/2022

Facility & Scope

Jensen Meat Company (42989)
Jensen Meat Company
2550 Britannia Blvd
San Diego, CA 92154
United States

Food Sector Categories:
8. Manufactured Meats and Poultry
20. Recipe Meals Manufacturing

Products:
(8) Beef, Pork, Poultry, Lamb (20) Plant Based Products

Scope of Certification:
(8) Beef, Pork, Poultry, Lamb (20) Plant Based Products

Certification Body & Audit Team

Mérieux NutriSciences Certification
401 N Michigan
Suite 1400
Chicago, IL 60611
United States

Web Site: https://www.merieuxnutrisciences.com/

CB#: CB-1-Mérieux
Accreditation Body: JAS-ANZ
Accreditation Number: Z3720906AB

Lead Auditor: Valdez, Ray (201264)
Technical Reviewer: Luttrell, Sandra (132944)

Hours Spent on Site: 26
Hours of ICT Activities: 0
Hours Spent Writing Report: 8

Non-Conforming

2.3.4 Approved Supplier Program (Mandatory)

Minor: The 3rd party of the following ingredient suppliers had the expiry dates indicated below: Konjac flour – 3rd party expiry date on 5/14/22, coconut puree – 3rd party expiry date on 1/30/22, soy protein expiry date on – 2/25/22. Current copies of 3rd party certification audits were sent to JMC during the audit. Letter of Guarantee of primary packaging material use in the plant based was not available during records review. The packaging company sent the LOG on the next day's audit. Supplier Approval Program was reviewed on 8/19/22. SQF Practitioner/QA Team are responsible for the implementation of this program, including: Supplier contact list and collection of all supporting documentation, reviewing supporting documentation for compliance to regulatory standards, performing supplier and raw material risk assessments, coordinating the annual review of the program and ensuring written specifications are in place for raw and finished food products and packaging materials that come in contact with food. JMC requires the following for approving and monitoring food suppliers e.g.: 3rd party audit, COAs, LOG and to fill out an Approved Supplier Questionnaire for annual supplier reassessment or re-evaluation. Raw materials and packaging suppliers shall have food safety programs in place. No raw materials, ingredients, and packaging materials received from other facilities under the same corporate ownership. Supplier audits are not conducted by JMC Food Safety team. Register of raw materials and packaging materials and Approved Suppliers are kept in the QA Manager Computer system and was reviewed on 8/19/22. Third party audits/LOG of the following items was reviewed: Konjac flour – 3rd party expiry on 5/14/22, coconut puree – 3rd party expiry 1/30/22, soy protein expiry date – 2/25/22 and no LOG of the packaging materials,

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

RESPONSE: MINOR

EVIDENCE: Minor: The 3rd party of the following ingredient suppliers had the expiry dates indicated below: Konjac flour – 3rd party expiry date on 5/14/22, coconut puree – 3rd party expiry date on 1/30/22, soy protein expiry date on – 2/25/22. Current copies of 3rd party certification audits were sent to JMC during the audit. Letter of Guarantee of primary packaging material use in the plant based was not available during records review. The packaging company sent the LOG on the next day's audit.

ROOT CAUSE: There was a misunderstanding with our consultant as we understood they were taking care of this for us. We are clear now.

CORRECTIVE ACTION: Documentation has been assigned to Consultare Consulting to trace and gather documents promptly. Onboarding meeting about this was held on 09/20/22. Suppliers are being set up in their system (see picture of dashboard).

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 2.3.4.1. e.g. approved supplier issues.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

2.9.2 Training Program (Mandatory)

Minor: Based on the following observations; the following department or team section recognized the opportunity for refresher training: Several ingredient bins in the mixing room were not labeled and there were no lot numbers for product tracing. The labels of spray bottles use in the raw coloring tables were unreadable. Employee was observed hosing down the floor and the blender equipment with high pressure that resulted in excessive steam water in the plant based processing room. There were exposed products in the area during the audit observation. It was a potential contamination due to aerosol to the exposed products in the area. Numerous preventive maintenance tasks were not performed based on their master preventive maintenance schedules (e.g. monthly/weekly schedules) and there were no comments why these tasks have not been performed according to their schedules. Training program include for maintenance of the SQF Code, food safety, quality, regulatory requirements, customer requirements, employee safety, plant policies, programs and SOPs. JMC Employee Training Program has been designed to increase employee knowledge and ensure staffs or personnel are adequately trained, instructed and supervised in food safety practices which commensurate with their specific responsibilities. Training is on-going or as needed, different training topics monthly and the most recent training was conducted in 8/2022. Training records is maintained in the 3-ring binders and computer system and includes the following: Participant's name, Skills description, Description of the training provided, Date training completed, Trainer or training provider and Verification that the trainee is competent to complete the required tasks.

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

RESPONSE: MINOR

EVIDENCE: Minor: Based on the following observations; the following department or team section recognized the opportunity for refresher training: Several ingredient bins in the mixing room were not labeled and there were no lot numbers for product tracing. The labels of spray bottles use in the raw coloring tables were unreadable. Employee was observed hosing down the floor and the blender equipment with high pressure that resulted in excessive steam water in the plant based processing room. There were exposed products in the area during the audit observation. It was a potential contamination due to aerosol to the exposed products in the area. Numerous preventive maintenance tasks were not performed based on their master preventive maintenance schedules (e.g. monthly/weekly schedules) and there were no comments why these tasks have not been performed according to their schedules.

ROOT CAUSE: Curtains were not put in place. Sleeves were not in use. Sticky Labels were not cleaned properly. Employees were not properly trained on Plex PM

CORRECTIVE ACTION: New easy-peel stickers and plastic wall separators (curtains) have been implemented to segregate the areas best. PM Plex training was conducted

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 2.9.2.1. e.g. training issues.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

9.1.2 Building Materials

Minor: Overhead areas in AU1 and AU2 and final grinder air duct in the grinding room had water condensation and were dripping consistently. There were exposed meat products in the area during the audit plant observation. Condensation may drip into the product being processed and may cause contamination. Actual product contamination was not observed. Overhead beams in the receiving/shipping dock #3 - #10 and evaporator unit #1 had excess water condensation and were dripping. There were numerous boxes and bins of finished products in the area that are ready to be loaded for shipment. Another instance, two areas (by dock # 5 and #3) the condensation was dripping onto the external surface of boxed products that are ready for loading. Condensation was observed did not go through inside the products. Production floors were observed well maintained and sloped to floor drains to allow the effective removal of all overflow or waste water under normal working conditions. There was no pooling water observed in the production areas. No drop ceilings observed in the production room. N/A: There were no stairs and platforms directly above exposed food products surfaces.

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

RESPONSE: MINOR

EVIDENCE: Minor: Overhead areas in AU1 and AU2 and final grinder air duct in the grinding room had water condensation and were dripping consistently. There were exposed meat products in the area during the audit plant observation. Condensation may drip into the product being processed and may cause contamination. Actual product contamination was not observed. Overhead beams in the receiving/shipping dock #3 - #10 and evaporator unit #1 had excess water condensation and were dripping. There were numerous boxes and bins of finished products in the area that are ready to be loaded for shipment. Another instance, two areas (by dock # 5 and #3) the condensation was dripping onto the external surface of boxed products that are ready for loading. Condensation was observed did not go through inside the products.

ROOT CAUSE: Sept 13, 2022 - Warm day outside (86°F from AccuWeather website) vs inside (44.1°F from CL Refrigeration) that day.

CORRECTIVE ACTION: More monitoring/cleaning throughout day, Seal cracks.

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 9.1.2.8 e.g. condensation issues.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

9.1.7 Equipment and Utensils

Minor: Several overhead building structures in the production/grinding room (e.g. evaporator unit's pipe in AU1 and AU2 and ceiling beams) were in poor repair or not completely sealed or caulked. Metal shielding or catch pans of the air vents in the grinding room were not adequate or wide enough if the condensation will be dripping. The facility specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment were reviewed on 5/6/22. It included the scope to all new and used food grade equipment purchase which is intended to be used for the manufacture of food. All equipment must be constructed to ensure effective and efficient cleaning of the equipment over its lifespan. The equipment should be properly designed as to prevent product contamination, including but not limited to bacterial ingress, survival, growth and reproduction on both product and non-product contact surfaces.

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

RESPONSE: MINOR

EVIDENCE: Minor: Several overhead building structures in the production/grinding room (e.g. evaporator unit's pipe in AU1 and AU2 and ceiling beams) were in poor repair or not completely sealed or caulked. Metal shielding or catch pans of the air vents in the grinding room were not adequate or wide enough if the condensation will be dripping.

ROOT CAUSE: Normal Wear and Tear of insulation

CORRECTIVE ACTION: Fixed areas that were in poor repair in AU1 and AU2.

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 9.1.7.2 e.g. overhead structured issues.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

11.7.1 High-Risk Processes

Minor: Plant Based Production Room: The finished product area (the packaging table and cooling tunnel out feed) and raw coloring tables was approximately 3 feet apart and not protected/segregated/no barrier from raw materials or staffs who handles raw materials to ensure cross-contamination is minimized. The employees working in the finished product area and raw coloring tables were observed wearing white smocks. It was not identifiable who is working with raw materials and finished products. Plant Based Production Room is the high risk area in this plant. It is segregated from the raw production room to prevent product contamination. The site uses dedicated employees and to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.

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

RESPONSE: MINOR

EVIDENCE: Minor: Plant Based Production Room: The finished product area (the packaging table and cooling tunnel out feed) and raw coloring tables was approximately 3 feet apart and not protected/segregated/no barrier from raw materials or staffs who handles raw materials to ensure cross-contamination is minimized. The employees working in the finished product area and raw coloring tables were observed wearing white smocks. It was not identifiable who is working with raw materials and finished products.

ROOT CAUSE: Curtains were not put in place. Sleeves were not in use.

CORRECTIVE ACTION: Separators to be used as well as sleeves for employees.

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 9.7.1.1 e.g. barrier issue from finished products and raw products.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Debbie Dardon
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** ddardon@jensenmeat.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Ray Valdez: Lead Auditor, Debbie Dardon: QA Manager, Andres Mendoza: Certification Specialist, Joanna Saad: QA & R & D Coordinator, Jeff Duran: VP of Logistics, Patricia Levigne: VP Sales, Edmundo Garcia: Production Manager, Anthony Crivello: VP Manufacturing, Abel Olivera: CEO, Christopher Irvin: Document Control Specialist, Jaime Fernandez: Sanitation Manager, Isidro Rubio: Maintenance Manager, Javier Casanova: Director of Purchasing, Jose Valencia: VP HR.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** Jensen Meat Company (JMC) is a privately owned company, started their business in Vista, CA in 2009 and moved into San Diego, CA plant in 2013. It is a USDA inspected facility EST#1899 and registered in the State of California. JMC is located in industrial area in Sand Diego, CA. It has approximately 120,000 square feet of process and storage space with additional 30,000 square feet that is under construction. It includes the following: shipping and receiving docks, grinding room, fresh meat processing room, pack up room, packing storage room, dry ingredient storage room, one cooler, a freezer, plant based processing room, cooling tunnel area, oven room and mixing room. JMC employs approximately 450-500 people working two production shifts and one sanitation shift. The products under the scope of this certification were as follows: FSC 8 & 20, (8) Beef, Pork, Poultry, Lamb (20) Plant Based Products. e.g. shrimp, soft shell taco, beef and chicken crumbles and chorizo. The facility has corrected all non-conformances from the previous certification audit.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Ray Valdez: Lead Auditor, Debbie Dardon: QA Manager, Andres Mendoza: Certification Specialist, Joanna Saad: QA & R & D Coordinator, Jeff Duran: VP of Logistics, Patricia Levigne: VP Sales, Edmundo Garcia: Production Manager, Anthony Crivello: VP Manufacturing, Abel Olivera: CEO, Christopher Irvin: Document Control Specialist, Isidro Rubio: Maintenance Manager.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Recommend re-certification upon successful completion of all non-conformances.

Section Responses

2.1.1 Management Responsibility (Mandatory)

Letter of Quality and Food Safety Statement was signed by the CEO on 7/01/22. It was described the operations commitment to providing wholesome, safe food products to ensure customer expectations were met. They were committed to supplying the appropriate resources to support the effective implementation and the continuous improvement of these programs. The statement was provided in English and Spanish which understood by all employees. The statement was posted on the site's main hall way of the interior building. The food safety culture has been established and implemented; it is communicated or relayed to the employees through routine training and meetings. JM reporting structure described who has responsibility of the food safety/quality and how it is communicated to the site's employee. The Senior Management Team (SMT) reviews food safety practices and all applicable requirements of the SQF Code edition 9th at least annually. The review of the SQF System is on-going basis and the most recent review was conducted on 8/1/22. The SMT uses the following resources to achieve food safety objectives and implementation maintenance and on-going improvement of the SQF code edition 9th e.g. HACCP team meetings and training, quality system manuals, internal and external audit findings, corrective actions investigation and resolution. The QA Manager is the designated SQF Practitioners of this facility, oversees the development and implementation and review of the SQF system. The SQF Practitioner is full time employee, completed SQF course on 5/7/08, HACCP course on 12/8/17, PCQI on 3/31/16 and Certified Internal auditing course was completed on 10/28/19. The site uses classroom and hands-on training system (English and Spanish) as training resources for employee's training needs to carry out their specific tasks maintaining food safety. SMT ensures that all staffs 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 through meetings and training. Job descriptions for the staffs responsible for food safety were reviewed and identified the other QA Supervisor to cover for the absence of the SQF Practitioner. The back-up completed the following training on: HACCP – 6/28/21, SQF – 7/7/21, Internal auditing course – 7/4/21 and PCQI – 7/1/21. SMT recently discussed capital budget for the building's structures, additional production areas, overhead structures (e.g. pipes and production floors) to improve the effectiveness of the SQF System to demonstrate continuous improvement. The site identified Federal Holidays (e.g. Christmas and Thanksgiving days) as the blackout dates.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2 Management Review (Mandatory)

Management Review procedures described the annual review of the SQF systems, which was broken down into routine meetings and reviews of the SQF System in its entirety at least annually or as needed e.g. food safety and quality policies, internal audits, review of corrective actions and preventive actions, review of resources, training programs, review of suppliers and quality/food safety objectives and goals. The most recent management review was conducted on 8/5/22 and met the requirements of the SQF code edition 9th. In addition, weekly and monthly Food Safety Team meeting is being conducted to review changes and identifies improvements. Minutes of meetings were reviewed and indicated the management was kept informed of changes, complaints and monitored. The SQF Practitioner updates senior site management on a monthly basis on matters impacting the implementation and maintenance of the SQF System during monthly SMT/Food Safety Team meetings. Records of monthly updates in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3 Complaint Management (Mandatory)

Complaint Management outlines the methods and responsibility for handling and investigating cause and resolution of complaints. Either the Customer Service or Quality Assurance department will receive the complaint details or QA is responsible for investigating and providing feedback, corrective actions, and other pertinent information to the customer. All complaints are to be documented in the Complaint Log and complaints are required to be reviewed and trended monthly by the QA Manager. Customer complaints in the following months were reviewed: 8/2022, 4/2022, 1/2022 and 10/2021. Corrective actions and resolutions were documented in the complaint log. There was no food safety issues, all quality issues. e.g. no interleaf between patties.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

Food Safety System SOP was reviewed on 8/1/22. Food Safety Team is mainly responsible for developing, implementing, maintaining and updating the Food Safety Plan and the associated program. It was documented and maintained a summary of the organization's food safety policies and the methods it will apply to meet the requirements of SQF code were defined. The food safety policy statement and organization chart was signed by the CEO. The lists of products under the scope of this certification are: (8) Beef, Pork, Poultry, Lamb (20) Plant Based Products. Food safety procedures, pre-requisite programs, food safety plans were defined. Food safety plans, Good Manufacturing Practices and other aspects of the SQF System were reviewed on 8/1-5/22.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

The SQF Practitioner/QA Team is responsible for document control and ensuring staff have access to current documents on site. A register of current SQF System documents and amendments to documents are maintained on the 3-ring binders and electronically. Documents were safely stored in the QA Manager's/Team office and readily accessible during the audit. The register was updated on 8/1/22.

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

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

Production/Batch Records were readily accessible, retrievable, securely stored in the QA Team/Manager's office and electronically to prevent damage and deterioration. CCPs/CQPs monitoring records, product release records, receiving/shipping, sanitation/pre-ops inspections and daily production records on 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021 and monthly PM, Environmental Test results, facility/GMP monthly internal audits, sanitation monthly cleaning records in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed. Records were observed legible, no white-out used and suitably authorized by those undertaking monitoring activities. Site's policy on records is to be retained for at least 2 years.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.1 Specification, Formulation and Realization

Specification, Formulation and Realization SOP was reviewed on 8/1/22. The procedures describe the methods and responsibility for designing, developing and converting product concepts to commercial realization including a process capability analysis to ensure the processes are able to consistently supply products that meet customer specifications is performed by the R & D team. The program included product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by site trials, shelf life trials and product testing. Shelf life trials where necessary shall be conducted to establish and validate new product's; handling, storage requirements including the establishment of "use by" or "best before dates"; microbiological criteria (e.g. Listeria, Salmonella, E. coli and Yeast Mold) and consumer preparation, storage and handling requirements. All new products developed for commercial distribution must receive approval by the R & D/SMT. N/A: There was no new product that completely developed since the previous certification audit.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There was no new product that completely developed since the previous certification audit.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

Specifications (Raw and Packaging Materials and Finished Product and Services) SOP were reviewed on 8/1/22. It included that specification for all raw and packaging materials that impact on finished product safety shall be documented and kept current. It is a sourced based on supplier knowledge, past food safety and supplier history. Direct food contact packaging materials must be in compliance with the CFR-Code Title 21 Part 177, USDA and any other regulatory requirements. All raw and packaging materials shall comply with the relevant legislation in the country of manufacture and country of destination, if known. Verification of packaging materials includes e.g. the review of certification or Letter of Guarantee, 3rd party audits, COAs, Organic certificate, Supplier Approval Program, California Proposition 65 Statement and Preventive Control summary. Finished product labels shall be accurate, comply with the relevant legislation, USDA, FDA and be approved by the SQF Practitioner or qualified company personnel. A current register of raw and packaging material specifications and labels are maintained in QA Manager Computer system and it was updated on 8/1/22.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.3 Contract Manufacturers

N/A: This site does not use contract manufacturers.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This site does not use contract manufacturers.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This site does not use contract manufacturers.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This site does not use contract manufacturers.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This site does not use contract manufacturers.

2.3.4 Approved Supplier Program (Mandatory)

Minor: The 3rd party of the following ingredient suppliers had the expiry dates indicated below: Konjac flour – 3rd party expiry date on 5/14/22, coconut puree – 3rd party expiry date on 1/30/22, soy protein expiry date on – 2/25/22. Current copies of 3rd party certification audits were sent to JMC during the audit. Letter of Guarantee of primary packaging material use in the plant based was not available during records review. The packaging company sent the LOG on the next day's audit. Supplier Approval Program was reviewed on 8/19/22. SQF Practitioner/QA Team are responsible for the implementation of this program, including: Supplier contact list and collection of all supporting documentation, reviewing supporting documentation for compliance to regulatory standards, performing supplier and raw material risk assessments, coordinating the annual review of the program and ensuring written specifications are in place for raw and finished food products and packaging materials that come in contact with food. JMC requires the following for approving and monitoring food suppliers e.g.: 3rd party audit, COAs, LOG and to fill out an Approved Supplier Questionnaire for annual supplier reassessment or re-evaluation. Raw materials and packaging suppliers shall have food safety programs in place. No raw materials, ingredients, and packaging materials received from other facilities under the same corporate ownership. Supplier audits are not conducted by JMC Food Safety team. Register of raw materials and packaging materials and Approved Suppliers are kept in the QA Manager Computer system and was reviewed on 8/19/22. Third party audits/LOG of the following items was reviewed: Konjac flour – 3rd party expiry on 5/14/22, coconut puree – 3rd party expiry 1/30/22, soy protein expiry date – 2/25/22 and no LOG of the packaging materials,

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

RESPONSE: MINOR

EVIDENCE: Minor: The 3rd party of the following ingredient suppliers had the expiry dates indicated below: Konjac flour – 3rd party expiry date on 5/14/22, coconut puree – 3rd party expiry date on 1/30/22, soy protein expiry date on – 2/25/22. Current copies of 3rd party certification audits were sent to JMC during the audit. Letter of Guarantee of primary packaging material use in the plant based was not available during records review. The packaging company sent the LOG on the next day's audit.

ROOT CAUSE: There was a misunderstanding with our consultant as we understood they were taking care of this for us. We are clear now.

CORRECTIVE ACTION: Documentation has been assigned to Consultare Consulting to trace and gather documents promptly. Onboarding meeting about this was held on 09/20/22. Suppliers are being set up in their system (see picture of dashboard).

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 2.3.4.1. e.g. approved supplier issues.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.1 Food Legislation (Mandatory)

Food Legislation SOP was reviewed on 8/1/22. It included compliance with the FDA, USDA and all Regulatory Agencies. The QA Manager/SQF Practitioner is responsible managing the regulatory processes and verifying compliance to all applicable regulatory requirements. Food Legislation policy state that the SQFI and the certification body will be notified in writing within twenty-four (24) hours in the event of a regulatory warning. Notification to SQFI is by email to foodsafetycrisis@sqfi.com.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

Good Manufacturing Practices policy was reviewed on 8/1/22. It described and applied the SQF code edition 9th. Good Manufacturing Practices defined how food safety is controlled and assured will be documented and implemented. It included sign in and sign out, plant access, employee hygiene practices, employee health, disease control, sanitation control, plant grounds, pest control, production GMPs and visitor GMPS. It was observed that it was properly implemented.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

JMC had developed and implemented one HACCP/Food Safety Plan in place for the production of (8) Beef, Pork, Poultry, Lamb (20) Plant Based Products. The HACCP plan was reassessed on 3/25/22. The plan was developed using the Codex Alimentarius and was fully implemented. A multi-disciplinary team was used to develop the HACCP plan. The scope of the plan is from receiving, storage, production and to shipping. Product descriptions were in place. The product descriptions included the common name, how it is to be used, packaging type, where it is to be sold, labeling instructions, special distribution control, product classification and products containing allergens or sensitizing materials. The allergens in the meat side are soy and milk and the plant based side are soy, gluten and tree nuts (cashews and coconut). The process flow charts of (8) Beef, Pork, Poultry, Lamb (20) Plant Based Products were verified during the audit observation. It was observed that all process steps were listed or defined on the flow chart as well in the hazard analysis. The meat processing; there was one CCP identified in the process. The CCP is CCP 1 B – product temperature in the final grinder. The critical limit (CL) temperature shall to be at < 44.6 F and monitored every shift and also performs knowledge checking of the product temperature every production batch. The CCPs in the Plant Based are: Cooked Products: Cooking – CL is 165 F or higher, Cooling – 135 F – 70 F – 2 hours and to 41 F within 4 hours and the Raw Products: = Blending Temperature, the CL is< 44.6 F. Plant Based CCPs are monitored every production batch. The scientific references are: Bruce Tompkins and FDA code parameters for the cooking and cooling. The HACCP plan has been effectively implemented. Verification of the CCP monitoring is conducted once per week by the QA team. CCP monitoring records of the following dates were reviewed: 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021. The HACCP plans were reassessed on 3/25/22. Comment Only: Ice is used as ingredient aid in the plant based and it was not listed on the process flow diagram.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4 Product Sampling, Inspection and Analysis

Product Sampling, Inspection and Analysis SOP were reviewed on 8/1/22. It included detailed description of how product should be sampled, tested and analyzed to ensure it complies with customer specifications, legal requirements, food safety and quality. Product sampling is listed as follows: daily sensory evaluations (e.g. color, weight, label, code date and finished product temp) and testing for finished products every production run (e.g. coliform, lactic acid yeast and mold). The site uses external certified lab for micro testing. Finished product test results in 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021 were reviewed. Test results were in compliance to written programs. Records of product inspections and analyses are maintained in the QA Team and Computer System and hard copies on 3-ring binders.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Materials and Product

Non-Conforming Product and Equipment Procedures were reviewed on 8/1/22. The SQF Practitioner/QA Team is responsible for this program. It was established written procedures to follow when placing materials on hold or deemed unsellable. The procedure applied to all materials and products manufactured or maintained at the facility. Hold & Release Disposition Form is to be completed and tag is applied to the product/material. Hold products could only disposed by the QA Manager. Hold log form included date, item name, lot #, quantities, reason for holding, location or room, initiated by, evaluation result, product disposition and authorization. Hold log records in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.6 Product Rework

N/A: There is no product rework in this facility.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no product rework in this facility.

2.4.7 Product Release (Mandatory)

Product Release SOP was reviewed on 8/1/22. The following criteria are reviewed by the QA Team prior to releasing all products to ensure all criteria are met before shipping to customers: e.g. CCP/CQP monitoring logs, allergen label check, lot codes, product temp logs, finished product quality checks, and lab reports (when applicable). Product release records of the following dates were reviewed: 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021. Product release records are maintained in the QA Manager Computer system.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

Environmental Monitoring Program (EMP) was reviewed on 8/1/22. The QA team is responsible for the EMP. The EMP program stated that the target organism is Listeria spp. It described that the frequency of testing samples is twice a month. Test results in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed. There was a Listeria Positive in drain #6 on 8/1/22. The area was retested for three consecutive times on 8/2-4/22 and all test results were negative. EMP described the method to handle elevated or undesirable or positive results. e.g. The area or equipment will be re-cleaned, re-sanitized, re-sampled and re-tested until three consecutive negative test results are obtained.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

Validation and Effectiveness SOP was reviewed on 8/1/22. The SQF Practitioner/QA Team oversees this program. The following items were validated on: 1. Recall Program – 1/7/22 2. GMP – 8/1/22 3. Metal detector 1 & 2– 10/20/21& 9/30/21 4. Backflow device – 9/12/22 5. Scales – 11/11/21 6. Pest Control – 8/2022 7. HACCP/CQP Plan – 3/25/22 8. Sanitation Program – 8/2022 9. Crisis Management – 9/1/22 10. Approved Supplier – 8/19/22 11. Water Potability – 8/1/22 and 3/15/22 12. Food Defense – 8/1/22 13. Food Fraud – 7/1/21

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

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

Verification and Effectiveness SOP were reviewed on 8/1/22. QA Department is responsible for this program. Verification methods were established for the program development and changes of the pre-requisite programs, CCPs/CQPs and other document pertinent to all products and all steps related to their realization and food safety; along with the frequency each will be verified and the corrective actions. Records of daily verification activities of CCPs/CQPs, Product Release and Pre-Ops on 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021 and verification activities of monthly PM, EMP test results, cleaning records and facility GMP audits in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed. Records are maintained in the Computer System and hard copies are in the 3-ring binders.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

Corrective and Preventive Action SOP were reviewed on 8/1/22. QA Team is responsible for this program. Corrective actions on the following were reviewed e.g. 1. Customer complaints in 8/2022, 4/2022, 1/2022 and 10/2021 2. Pre-ops records on 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021 3. Facility internal audits in 8/2022, 4/2022, 1/2022 and 10/2021

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4 Internal Audits and Inspections (Mandatory)

Internal Audits and Inspections SOP were reviewed on 8/1/22. The policy included to provide a guideline for facility, internal food safety and quality audits. The audit team is cross-functional. The site audit processes and procedures to determine the effectiveness of the Food Safety and Quality and to provide objective evidence concerning the need for reduction, elimination and prevention of nonconformities. Facility internal audits and inspections are performed monthly and annually the entire food safety system which includes: Pre-requisite programs, HACCP/Food Safety Plan, critical food quality control, that have been implemented, verification of regulatory requirements, inspections and tests are being conducted as required and the premises, surroundings and equipment are being maintained sanitarily and in good condition. SMT review the audit results to ensure suitability and adequacy and to continuously improve the documented Food Safety and Quality System. Records of internal audits and inspections and corrective actions taken as a result of internal audits in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed. Copies are maintained in the QA Manager Computer System and hard copies on the 3-ring binders.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.1 Product Identification (Mandatory)

Product Identification SOP was reviewed on 8/1/22. The product identification has been implemented to ensure that raw materials, ingredients and packaging materials, and finished products are clearly identified during all stages of receipt, production, storage and dispatch. This site uses supplier/internal lot code and date of receipt for product tracing. Product trace of products manufactured and or distributed by this site that all packages and cases shall contain code markings e.g. best by date or use by date and based on customer requirement. Failure to comply with this procedure may result in customer quality/safety incident, product recalls, withdrawals and inventory errors. Product identification records on the following dates were reviewed: 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

Product Trace SOP was reviewed on 8/1/22. The QA Manager is responsible for product tracing. The auditor chose to trace 83 cases of plant based shrimp, lot #P0033001-7.5, produced on 4/15/22, were shipped on 5/3-5/22, zero left in inventory,(start/end times: 9:50 AM – 10:24 AM), trace was completed in 34 minutes, all ingredients and primary packaging materials/clam shells were all accounted for (e.g. coconut puree- lot#S1902554 , received date on 3/7/22, konjac flour, lot# - S232269, received on 12/20/21, soy protein - lot #S1889475, received on 02/19/22, bag lot#S1896429, received date – 2/28/22. The site’s policy stated that MOCK trace must be completed in 2 hours.

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

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

Product Withdrawal and Recall SOP was reviewed on 8/1/22. It described to ensure JMC had a responsive traceability/withdrawal/recall plan for raw materials, packaging and finished goods that can be traced one up and one back. The recall/withdrawal system is tested at least twice a year and currently meets regulatory and customer requirements. The trace exercise on file reviewed during the audit was dated: 1/7/22= name of product – plant based beef crumbles, 47,222 lbs, lot code – 11/06/21, production date – 11/8/21, distributed or shipped on 11/24/21, 100% of the finished product was traced in 30 minutes. (start/end times: 1:15 PM – 1:45 PM). Records for the investigation and corrective actions of product withdrawal or trace exercise were on file as part of the recall process and maintained. SQFI and Merieux (foodsafetycrisis@sqfi.com and certification@mxns.com) are to be contacted within 24 hours in writing should a recall occur which requires regulatory notification. There was no product recall since the last certification audit in 9/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.4 Crisis Management Planning

Crisis Management Planning SOP was reviewed on 8/1/22. The responsible team is QA/Senior Management (SMT). Specific responsibilities of each team member were described in detail. The site's main goal of this plan is to minimize any disruption in business activity and to quickly resume critical functions reflecting the following priorities: eliminate or minimize threat to food safety, protect the company assets, and resume normal operations as quickly as possible. The crisis management plan was tested on 9/1/22 and the scenario was an ammonia/nitrogen leak test – low oxygen/ evacuation drill in the plant. The investigation report and after action reviews were documented and reviewed during the audit.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

Food Defense Plan was reviewed on 8/1/22. JMC is a USDA inspected facility EST #1899 and also registered with FDA FSMA with expiry date on 12/31/22 and registered in the State of California Department of Public Health. Food Defense Team member responsibilities were documented on the Crisis and Natural Disaster Plan. The facility has the following security measures e.g. 24/7 live cameras in the production plant and outside the building, all access points to the plant and emergency exits are secured. Incoming and outgoing vehicles are inspected for unusual cargo or activity and documented on the inspection log. Truck deliveries will be verified of scheduled deliveries. The food defense plan was reviewed on 8/1/22. The QA team performs monthly audits for the entire facility. Food defense audits in the following months were reviewed: 8/2022, 4/2022, 1/2022 and 10/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.2 Food Fraud (Mandatory)

Food Fraud Mitigation Plan was reviewed on 7/1/21. It described to conduct vulnerability assessment, develop mitigation measures and strategies. All products supplied to JMC are federally inspected and come from facility FDA- compliant. If food fraud involving employees or suppliers is identified or suspected, an investigation will be launched by the Food Fraud Team. If food fraud is uncovered, the team will immediately stop using the raw material in question; they will place a hold on finished product with the suspected item and contact authorities if it was purposeful and for economic gain. Food Fraud Mitigation Plan was reassessed on 7/1/21.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.8.1 Allergen Management (Mandatory)

Allergen Management for Food Manufacturing Program was reviewed on 4/26/22. The allergens in this plant are: milk and soy (meat plant) tree nuts, soy and wheat (plant based). A register of allergens is kept in the SQF Practitioner/QA Manager Computer System. The allergen management program include the identification, management, and labeling of products. Included instructions provided to all relevant staff involved in the receipt or handling of raw materials, work-in progress, finished product on how to identify, handle, store and segregate raw materials containing allergens. All product labels are reviewed daily and or every production run. Product changeover procedures were documented and implemented to eliminate the risk of cross-contact. Scheduling is done to prevent cross-contact of allergens. Allergens are run last to prevent cross-contact. Allergen changeovers records of the following dates were reviewed: 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch rooms, visitors were defined in the allergen management program. Risk assessment of the allergen program was conducted on 2/16/22. No allergen rework in this plant.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.1 Training Requirements

Training Requirements was reviewed on 7/1/21. Training requirements includes e.g: GMPs, Allergen program, Cleaning and Sanitation, Food Safety Plan/HACCP, CCPs/CQPs, Pre-ops, Receiving/Shipping, Warehouse and Inventory Management, Pulling Ingredients, Processing, Packaging, Preventive Maintenance, Food Fraud and Food Defense.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

Minor: Based on the following observations; the following department or team section recognized the opportunity for refresher training: Several ingredient bins in the mixing room were not labeled and there were no lot numbers for product tracing. The labels of spray bottles use in the raw coloring tables were unreadable. Employee was observed hosing down the floor and the blender equipment with high pressure that resulted in excessive steam water in the plant based processing room. There were exposed products in the area during the audit observation. It was a potential contamination due to aerosol to the exposed products in the area. Numerous preventive maintenance tasks were not performed based on their master preventive maintenance schedules (e.g. monthly/weekly schedules) and there were no comments why these tasks have not been performed according to their schedules. Training program include for maintenance of the SQF Code, food safety, quality, regulatory requirements, customer requirements, employee safety, plant policies, programs and SOPs. JMC Employee Training Program has been designed to increase employee knowledge and ensure staffs or personnel are adequately trained, instructed and supervised in food safety practices which commensurate with their specific responsibilities. Training is on-going or as needed, different training topics monthly and the most recent training was conducted in 8/2022. Training records is maintained in the 3-ring binders and computer system and includes the following: Participant's name, Skills description, Description of the training provided, Date training completed, Trainer or training provider and Verification that the trainee is competent to complete the required tasks.

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

RESPONSE: MINOR

EVIDENCE: Minor: Based on the following observations; the following department or team section recognized the opportunity for refresher training: Several ingredient bins in the mixing room were not labeled and there were no lot numbers for product tracing. The labels of spray bottles use in the raw coloring tables were unreadable. Employee was observed hosing down the floor and the blender equipment with high pressure that resulted in excessive steam water in the plant based processing room. There were exposed products in the area during the audit observation. It was a potential contamination due to aerosol to the exposed products in the area. Numerous preventive maintenance tasks were not performed based on their master preventive maintenance schedules (e.g. monthly/weekly schedules) and there were no comments why these tasks have not been performed according to their schedules.

ROOT CAUSE: Curtains were not put in place. Sleeves were not in use. Sticky Labels were not cleaned properly. Employees were not properly trained on Plex PM

CORRECTIVE ACTION: New easy-peel stickers and plastic wall separators (curtains) have been implemented to segregate the areas best. PM Plex training was conducted

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 2.9.2.1. e.g. training issues.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.1.1 Premises Location, Construction, and Housing

JMC is a USDA inspected facility EST#1899 and registered in the State of California. N/A: This is not a slaughterhouse facility.

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

RESPONSE: COMPLIANT

9.1.1.2 Pens, yards, and lairage shall be designed, located, constructed, and maintained to minimize stress, injury, or disease and have minimal impact on the surrounding area and natural resources. Fences, gates, and other surfaces in pens and yards shall be free from paints, dips, sanitizers, and other materials that are likely to cause contamination through ingestion, inhalation, or contact. They shall be designed so that liquid waste can drain away and be collected if required, and that aerial fecal contamination does not contaminate meat products.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.1.1.3 Laneways, races, entrances, exits, and loading/unloading ramps shall be: i. Designed to include consideration of the social behavior and movement of the species; ii. Designed and maintained to prevent potential injury points to the animals; iii. Free from sharp objects that may damage the animals; and iv. Free from chemicals other than those approved by the relevant authority for use on livestock

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.1.2 Building Materials

Minor: Overhead areas in AU1 and AU2 and final grinder air duct in the grinding room had water condensation and were dripping consistently. There were exposed meat products in the area during the audit plant observation. Condensation may drip into the product being processed and may cause contamination. Actual product contamination was not observed. Overhead beams in the receiving/shipping dock #3 - #10 and evaporator unit #1 had excess water condensation and were dripping. There were numerous boxes and bins of finished products in the area that are ready to be loaded for shipment. Another instance, two areas (by dock # 5 and #3) the condensation was dripping onto the external surface of boxed products that are ready for loading. Condensation was observed did not go through inside the products. Production floors were observed well maintained and sloped to floor drains to allow the effective removal of all overflow or waste water under normal working conditions. There was no pooling water observed in the production areas. No drop ceilings observed in the production room. N/A: There were no stairs and platforms directly above exposed food products surfaces.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 9.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.1.2.7 Doors, hatches, and windows and their frames in food processing, handling, or storage areas shall be of a material and construction that meet 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

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

RESPONSE: MINOR

EVIDENCE: Minor: Overhead areas in AU1 and AU2 and final grinder air duct in the grinding room had water condensation and were dripping consistently. There were exposed meat products in the area during the audit plant observation. Condensation may drip into the product being processed and may cause contamination. Actual product contamination was not observed. Overhead beams in the receiving/shipping dock #3 - #10 and evaporator unit #1 had excess water condensation and were dripping. There were numerous boxes and bins of finished products in the area that are ready to be loaded for shipment. Another instance, two areas (by dock # 5 and #3) the condensation was dripping onto the external surface of boxed products that are ready for loading. Condensation was observed did not go through inside the products.

ROOT CAUSE: Sept 13, 2022 - Warm day outside (86°F from AccuWeather website) vs inside (44.1°F from CL Refrigeration) that day.

CORRECTIVE ACTION: More monitoring/cleaning throughout day, Seal cracks.

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 9.1.2.8 e.g. condensation issues.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

9.1.2.9 Stairs, catwalks, and platforms in food processing and handling areas shall be designed and constructed so they do not present a product contamination risk and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 9.2.5).

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There were no stairs and platforms directly above exposed food products surfaces.

9.1.3 Lightings and Light Fittings

Facility lights used in processing/storage areas and packaging storage areas, and all areas where the product is exposed was observed shatterproof and with shatterproof covering.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.1.4 Inspection / Quality Control Area

The Inspection/Quality Control area in the processing areas were observed neat and orderly and had easy access to the hand washing sink.

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

RESPONSE: COMPLIANT

9.1.5 Dust, Insect, and Pest Proofing

Facility receiving and shipping dock doors were observed had adequate sealing around trucks in docking areas. All external windows, ventilation openings, doors and other openings were observed effectively sealed when closed and proofed against dust, vermin and other pests. No poison rodenticide bait stored inside ingredient or product storage areas or processing areas.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.1.6 Ventilation

Adequate ventilation was observed provided in the processing and food handling areas. Fans and exhaust vents were observed insect-proofed.

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

RESPONSE: COMPLIANT

9.1.6.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 9.2.5 to prevent unsanitary conditions.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.1.7 Equipment and Utensils

Minor: Several overhead building structures in the production/grinding room (e.g. evaporator unit's pipe in AU1 and AU2 and ceiling beams) were in poor repair or not completely sealed or caulked. Metal shielding or catch pans of the air vents in the grinding room were not adequate or wide enough if the condensation will be dripping. The facility specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment were reviewed on 5/6/22. It included the scope to all new and used food grade equipment purchase which is intended to be used for the manufacture of food. All equipment must be constructed to ensure effective and efficient cleaning of the equipment over its lifespan. The equipment should be properly designed as to prevent product contamination, including but not limited to bacterial ingress, survival, growth and reproduction on both product and non-product contact surfaces.

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: Minor: Several overhead building structures in the production/grinding room (e.g. evaporator unit's pipe in AU1 and AU2 and ceiling beams) were in poor repair or not completely sealed or caulked. Metal shielding or catch pans of the air vents in the grinding room were not adequate or wide enough if the condensation will be dripping.

ROOT CAUSE: Normal Wear and Tear of insulation

CORRECTIVE ACTION: Fixed areas that were in poor repair in AU1 and AU2.

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 9.1.7.2 e.g. overhead structured issues.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

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

RESPONSE: COMPLIANT

9.1.7.4 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

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

RESPONSE: COMPLIANT

9.1.7.6 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned (refer to 9.2.5.1). Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

9.1.7.7 All equipment and utensils shall be cleaned after use (refer to 9.2.5.1) or at a set and validated frequency to control contamination and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.1.8 Grounds and Roadways

Building's exterior grounds and areas surrounding the premises were maintained to minimize dust and were kept free of waste or accumulated debris so as not to attract pests and vermin. The exterior grounds are monitored routinely and it is included on the facility GMP internal audit. Paths from amenities leading to the facility entrances were effectively sealed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.2.1 Repairs and Maintenance

Premises and Equipment Maintenance (PM) SOP was reviewed on 8/1/22. It defined the methods and responsibilities of maintaining the facility and equipment. All equipment must be maintained in a manner conducive to safe and sanitary production and storage of all products. e.g. cleanable to a microbiological level, made of compatible materials, accessible for inspection, maintenance, cleaning and sanitation, no product or liquid collection, hollow areas, should be hermitically sealed, no niches, sanitary operational performance hygienic design of maintenance and hygienic compatibility with other plant system. The Maintenance Manager is responsible for all aspects of the program. All maintenance and other engineering contractors to work on site are required to be escorted, read and sign the GMPs Policy for visitors, vendors and contractors. Preventive Maintenance Records in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.2.2 Maintenance Staff and Contractors

All maintenance and other engineering contractors to work on site are required to report in the main entrance, be escorted, read and sign the GMPs Policy for visitors, vendors and contractors.

9.2.2.1 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 9.3).

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.2.3 Calibration

Calibration Program was reviewed on 8/1/22. The QA Team is responsible for this program. The site complies with industry and national standard calibration methods. Test equipment used to confirm food safety and quality standards are calibrated with industry standard calibration practices. e.g. scales, metal detector and thermometers. Procedures to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state were defined on the calibration program. The following calibration records were reviewed: 1. Metal detector 1 & 2– 10/20/21& 9/30/21 2. Scales – 11/11/21 3. Cooler – 12/8/21 4. Chemical control – 8/2022 5. Thermometer – 9/12/22 6. Backflow device – 9/12/22 7. Tel- Tru – expiry date – 2/26/23

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.2.3.6 A directory of measuring, test, and inspection equipment that requires calibration and records of the calibration tests shall be maintained.

RESPONSE: COMPLIANT

9.2.4 Pest Prevention

The site uses 3rd party (Lloyd Pest Control) for pest prevention. Pest Control Company provided services for both interior and exterior areas of the facility. The pest control company services the facility at least two times a month. Pest control files included map of pest control devices, the business license expiry date 12/31/23 = insurance = 1/1/23, PCO – certificate expiry date 6/30/23. The pest prevention program described the methods and responsibility for the development, implementation and maintenance of the pest prevention program; record pest sightings and trend frequency of pest activity to target pesticide applications; outline the methods used to prevent pest problems; outline the pest elimination methods; and outline the frequency with which pest status is to be checked. Pest control service reports in the following months were reviewed: 8/2022, 4/2022, 1/2022 and 10/2021. There were no major or rodent/cockroach pest activities reported. Records of all pest control applications were maintained in the pest control log system. Pest control chemicals used had EPA# and were all approved for use in food processing facility. (e.g: Maxforce, All weather blox). N/A: Pest control chemicals were not stored on site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.2.4.5 Pesticides shall be clearly labeled and stored (refer to 9.6.5) if kept on-site

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Pest control chemicals were not stored on site.

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

RESPONSE: COMPLIANT

9.2.5 Cleaning and Sanitation

Cleaning and Sanitation SOPs was reviewed on 8/1/22. Sanitation Manager is responsible overseeing the sanitation program. It included what is to be cleaned; how it is to be cleaned; when it is to be cleaned; who is responsible for the cleaning; and the responsibility and methods used to verify the effectiveness of the cleaning and sanitation program. All cleaning chemicals had Safety Data Sheets (SDS) on file and all approved for use in food processing facility. (e.g. Quat Sanitizer). Pre-operational inspections are conducted by QA Team following cleaning and sanitation prior to start of production from 4:30 AM to 5:00 AM. Monthly cleaning and Pre-Ops records in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed. Verification activities were documented by the Sanitation Lead/Supervisor. N/A: Cleaning in place (CIP) system was not used in this plant.

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

RESPONSE: COMPLIANT

9.2.5.2 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements and purchased in accordance with applicable legislation. The organization shall ensure that detergents and sanitizers are stored as outlined in element 9.6.5 and are handled only by trained staff.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Cleaning in place (CIP) system was not used in this plant.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.3.1 Personnel Welfare

GMP policy stated that no personnel who are known to have been known to be carriers, or are 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 enters storage areas where food is exposed. The site had 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. During the plant observation, there were no personnel observed with exposed cuts, sores or lesions that engaged in handling or processing products or handling primary packaging materials or food contact surfaces.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.3.2 Handwashing

Hand wash station was observed located before the entrance door into main production room and each production room. It was made of stainless steel and hands-free design, paper towel dispensers, hand wash sign, and trash receptacles were provided in the area. Employees were observed consistently washing their hands before going back into the production room.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.3.2.3 Handwashing stations 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.3.3 Clothing and Personal Effects

Employee's uniform or clothing is inspected on a daily basis by the Supervisors to ensure that the clothing/smock and hair policy protects materials, food and food contact surfaces from unintentional microbiological or physical contamination. Also, the site's inspects uniforms of employees during production hours on a monthly basis. The site is using 3rd party laundry services. There were no excessively soiled uniforms observed during the plant observation. Disposable gloves were observed changed after each break, upon re-entry into the processing area and when damaged. Comment Only: Formal clothing risk analysis has not been conducted at this time.

9.3.3.1 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.3.4 Visitors

Visitor policy was described in their GMPs. It described that all visitors shall read, agree and sign the GMP policy before entering any food processing or handling areas, or shall be escorted at all times in food processing and handling and storage areas. It was observed that policy was being enforced or followed.

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

RESPONSE: COMPLIANT

9.3.4.2 All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 9.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.3.5 Staff Amenities (change rooms, toilets, break rooms)

Staff amenities were observed supplied with appropriate lighting and ventilation. Change room is located in the employees' lockers and hall way before the production room. It was provided to enable staff to change into and out of protective clothing as required. Sanitary facilities were observed properly constructed and well- maintained, and located away from processing areas. Sanitary drainage was not connected to drains within processing facility. Hand wash basins were located inside toilet rooms. Employees' lunch room is located away from the food handling areas. The lunch room was observed provided with sufficient amenities at the time of the audit. Hand washing sign was posted at hand washing station. Outside eating area was observed away from the production building and was well maintained.

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

RESPONSE: COMPLIANT

9.3.5.2	Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean. **RESPONSE:** COMPLIANT
9.3.5.3	High-risk change areas shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled. **RESPONSE:** COMPLIANT
9.3.5.4	Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, food contact zones, food, and packaging storage areas. **RESPONSE:** COMPLIANT
9.3.5.5	Where required, a sufficient number of showers shall be provided for use by staff. **RESPONSE:** COMPLIANT
9.3.5.6	Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and vi. Kept clean and tidy. Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas. **RESPONSE:** COMPLIANT
9.3.5.7	Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations. **RESPONSE:** COMPLIANT
9.3.5.8	Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 9.3.2.3. **RESPONSE:** COMPLIANT
9.3.5.9	Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests. **RESPONSE:** COMPLIANT
9.3.5.10	Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for the introduction of contamination, including pests, to the site. **RESPONSE:** COMPLIANT

9.4.1 Staff Engaged in Food Handling and Processing Operations

Personnel entry into processing area was observed through the employees' main access back door only. Door was observed not left open for extended periods when access for waste removal or receiving of product/ingredient/packaging. Packaging material, product, and ingredients were all covered. Waste contained in the bins was removed from the processing area on a regular basis and not left to accumulate. Employees was observed not eating or tasting any product being processed in the food handling/contact zone. There was no tasting or tasting of product observed in the production areas. Hair restraints and beard covers were properly worn. The flow or personnel in food processing and handling areas were observed managed that the potential for product contamination is minimized or controlled.

9.4.1.1	All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging 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; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor. **RESPONSE:** COMPLIANT

9.4.1.2 Personnel working in or visiting food handling or processing operations shall ensure that: i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 9.4.1.4; ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food; iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed. iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.4.2 Animal Husbandry

N/A: Ante-mortem inspection is not conducted in this meat plant. This is not a slaughterhouse.

9.4.2.1 Ante-mortem inspections by a qualified person shall be carried out to ensure animals are free from disease and fit for human consumption.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ante-mortem inspection is not conducted in this meat plant. This is not a slaughterhouse.

9.4.2.2 Animals that are subject to the control of prohibited substances such as veterinary medicine, heavy metals, or pesticides shall be identified and procedures implemented for their segregation and processing.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ante-mortem inspection is not conducted in this meat plant. This is not a slaughterhouse.

9.4.2.3 Animals for slaughter shall have clean water at all times, and clean feed, if held in lairage for extended periods. e flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ante-mortem inspection is not conducted in this meat plant. This is not a slaughterhouse.

9.4.2.4 Employees responsible for the care and management of animals ante-mortem shall be trained and competent in animal handling and welfare. They shall be able to recognize the early signs of distress and disease and ensure pain and stress to animals is minimized.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ante-mortem inspection is not conducted in this meat plant. This is not a slaughterhouse.

9.4.2.5 Animals deemed to be diseased or otherwise unfit for human consumption must be segregated from healthy animals and condemned or otherwise excluded from processing.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ante-mortem inspection is not conducted in this meat plant. This is not a slaughterhouse.

9.4.2.6 The site shall implement measures to prevent cross-contamination of animals for slaughter from agricultural or cleaning chemicals, waste materials, or other materials that could contaminate the animals.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ante-mortem inspection is not conducted in this meat plant. This is not a slaughterhouse.

9.4.3 Slaughtering and Butchering

N/A: This is not a slaughterhouse facility.

9.4.3.1 Only slaughtering methods that are humane and approved for use for a given species by national or international regulations shall be used.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.4.3.2 Where a two-stage process is used, the time interval between stunning and killing shall not exceed regulatory requirements. The use of direct air injection is not permitted.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.4.3.3 The site shall have a pathogen control program that addresses known biological hazards and demonstrates compliance to regulations and customer standards.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.4.3.4 Knives and tools used for skinning shall be cleaned and sterilized between each carcass. Knives and tools that become contaminated shall be cleaned and sterilized prior to use on edible tissue.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.4.3.5 Procedures shall be documented and implemented to maintain the hygienic condition of the carcass and avoid contamination. Fecal matter shall be removed at the slaughter floor and the carcass shall be inspected by an authorized person postmortem for signs of disease or contamination. Where applicable, procedures shall be in place for the grading of carcasses.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.4.3.6 Cooling processes shall have defined time and temperature requirements and be regularly monitored and recorded.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.4.3.7 Procedures shall be in place for the safe and hygienic evisceration and primal cutting of the carcass and the identification of edible and non-edible parts. Edible parts of the carcass shall be processed and stored using clean, sanitized tools and containers and protected from contamination. They shall be covered when not in process.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.4.3.8 All edible parts of the carcass shall be identified through the post-mortem inspection process and traceable back to the animal and date and time of slaughter.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.4.3.9 Slaughter and butchering hygiene shall be regularly monitored for, at minimum, fecal pathogens. Risk-based species-specific microbiological analysis may also be in place.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.5.1 Water Supply

City water from San Diego, CA is being used for cleaning and hand washing. The water is monitored once a year for microbiological indicator of potability by 3rd party certified laboratory. Water potability test result on 8/1/22 and 3/15/22 was coliform absent. N/A: Non-potable water is not used. N/A: This site does not store water.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Non-potable water is not used.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This site does not store water.

9.5.2 Water Treatment

N/A: No water treatment in this facility.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: No water treatment in this facility.

9.5.2.2 Water used as an ingredient in processing or for cleaning and sanitizing equipment shall be tested and, if required, treated to maintain potability (refer to 9.5.2.1).

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: No water treatment in this facility.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: No water treatment in this facility.

9.5.3 Water Quality

City water from San Diego, CA is being used for cleaning and hand washing. The water is monitored once a year for microbiological indicator of potability by 3rd party certified laboratory. Water potability test result on 8/1/22 and 3/15/22 was coliform absent.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.5.4 Ice Supply

N/A: Ice is not use in the meat processing areas.

9.5.4.1 Ice provided for use during processing operations, as a processing aid or an ingredient, shall comply with 9.5.3.1.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ice is not use in the meat processing areas.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ice is not use in the meat processing areas.

9.5.4.3 Ice rooms and receptacles shall be constructed of materials as outlined in element 9.1.2 and designed to minimize contamination of the ice during storage, retrieval, and distribution.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Ice is not use in the meat processing areas.

9.5.5 Air and Other Gasses

Compressed air or other gases (e.g. nitrogen, carbon dioxide) that contacts food are used in line plant based room. It is being tested annually for APC, Yeast Mold. Test results on 7/13/22 were all in compliance (<1 CFU).

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.6.1 Animal Transport

N/A: This is not a slaughterhouse facility.

9.6.1.1 Vehicles used for transport of animals for slaughter shall be fit for purpose and clean before use. Vehicles shall be inspected and a record kept of the inspection.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.6.1.2 Transport times for animals for slaughter shall be kept to a minimum and times recorded.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.6.1.3 Where animals are held for extended periods in pens and yards, adequate supplies of water and fodder shall be provided.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This is not a slaughterhouse facility.

9.6.2 Receipt, Storage, and Handling of Goods

Storage and Handling of Goods SOP was reviewed on 8/1/22. The site document and implemented storage plan that allows for the storage of raw materials, ingredients, packaging materials, equipment, and chemicals. Procedures are in place to ensure that all ingredients, materials, and finished product are utilized within their designated shelf-life (FIFO rotation). No expired products observed during the plant observation. N/A: No temporary storage used on site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: No temporary storage used on site.

9.6.3 Cold Storage, Freezing, and Chilling of Foods

Cooler storage perimeter walls were easily accessible for inspection and cleaning. Cooler temperature is continuously monitored by recording charts and manually checks at least every twice a day during production. Loading and unloading docks were equipped with dock shelters.

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

RESPONSE: COMPLIANT

9.6.3.2 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

Storage rooms were observed used for the storage of dry ingredients, packaging, and other dry goods were observed located away from wet areas and constructed to protect the product from contamination and deterioration.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.6.5 Storage of Hazardous Chemicals and Toxic Substances

All cleaning chemicals used were stored in a separate room to prevent a hazard to staffs and food items. The chemical storage was observed secured and restricted to authorized personnel and equipped with spillage kit. No pesticides, rodenticides, fumigants and insecticides stored on site. All cleaning chemicals in the storage cage were observed properly labeled.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.6.6 Loading, Transport, and Unloading Practices

All products and trailers/trucks were inspected prior to loading and unloading. Trailer condition inspection was recorded on the inspection logs. Refrigerated unit's maintain the product at the required temperature e.g. NMT 45 F. The unit's temperature settings is set to 40 F or below, checked, and recorded before loading, and the product temperature was recorded at regular intervals during loading.

9.6.6.1 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.7.1 High-Risk Processes

N/A: The meat processing rooms do not have kill step in the process.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The meat processing rooms do not have kill step in the process.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The meat processing rooms do not have kill step in the process.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The meat processing rooms do not have kill step in the process.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The meat processing rooms do not have kill step in the process.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The meat processing rooms do not have kill step in the process.

9.7.2 Thawing of Food

N/A: There is no thawing of frozen products in this plant.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no thawing of frozen products in this plant.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no thawing of frozen products in this plant.

9.7.2.3 Provision shall 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: There is no thawing of frozen products in this plant.

9.7.3 Control of Foreign Matter Contamination

Foreign Material and Glass and Brittle Plastic Protocol/Control of Foreign Matter Contamination SOP were reviewed on 7/1/21. It included glass and brittle and plastic control (it is inspected daily or before production and monthly facility GMP audits), metal contaminants control, pallet/wood contaminants control (it is inspected every delivery), tools and machine parts (daily), hand held knives (daily), and other foreign contaminants control daily. The QA team is responsible for this program. Foreign Matter inspection records of the following dates were reviewed: 8/2022, 4/2022, 1/2022 and 10/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.7.4 Detection of Foreign Objects

Detection of Foreign Objects SOP was reviewed on 7/1/21. This site uses metal detectors in the packaging lines prior to release of finished products. Metal detectors are equipped with automatic rejection and belt stop arm. Metal detection test wands/pieces in line 1 were: Fe = 1.5 mm, NFe = 1.5 mm and SS = 2.0 mm. Metal detection test is to be performed before production begins, approximately every hour during production and at the end of production shift. Metal detection records of the following dates were reviewed: 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

9.8.1 Waste Disposal

Waste Management Policy/Trash Disposal was reviewed on 7/1/21. It is the responsibility of the QA/SMT management to assure the areas that they are responsible for have the trash and inedible product handled, stored, and removal properly. This site uses 3rd party for all dry and waste disposals and provides services at least twice a week. Production waste is removed at least once a day or as needed and not builds up in food handling or processing areas. There was no significant or excessive waste accumulation observed at the time of the audit. N/A: There is no trademark use in this plant.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no trademark use in this plant.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

JMC is a USDA inspected facility EST#1899 and registered in the State of California.

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

RESPONSE: COMPLIANT

11.1.2 Building Materials

Production floors were observed well maintained and sloped to floor drains to allow the effective removal of all overflow or waste water under normal working conditions. There was no pooling water observed in the production areas. No drop ceilings observed in the production room. N/A: There were no stairs and platforms directly above exposed food products surfaces.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.3 Lightings and Light Fittings

All lights used in processing/storage areas and packaging storage areas, and all areas where the product is exposed was observed shatterproof and with shatterproof covering.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.4 Inspection/ Quality Control Area

The Inspection/Quality Control area in the processing areas were observed neat and orderly and had easy access to the hand washing sink.

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

RESPONSE: COMPLIANT

11.1.5 Dust, Insect, and Pest Proofing

Facility receiving and shipping dock doors were observed had adequate sealing around trucks in docking areas. All external windows, ventilation openings, doors and other openings were observed effectively sealed when closed and proofed against dust, vermin and other pests. No poison rodenticide bait stored inside ingredient or product storage areas or processing areas.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.6 Ventilation

Adequate ventilation was observed provided in the processing and food handling areas. Fans and exhaust vents were observed insect-proofed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.7 Equipment and Utensils

The facility specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment were reviewed on 5/6/22. It included the scope to all new and used food grade equipment purchase which is intended to be used for the manufacture of food. All equipment must be constructed to ensure effective and efficient cleaning of the equipment over its lifespan. The equipment should be properly designed as to prevent product contamination, including but not limited to bacterial ingress, survival, growth and reproduction on both product and non-product contact surfaces.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.8 Grounds and Roadways

Building's exterior grounds and areas surrounding the premises were maintained to minimize dust and were kept free of waste or accumulated debris so as not to attract pests and vermin. The exterior grounds are monitored routinely and it is included on the facility GMP internal audit. Paths from amenities leading to the facility entrances were effectively sealed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.1 Repairs and Maintenance

Premises and Equipment Maintenance (PM) SOP was reviewed on 8/1/22. It defined the methods and responsibilities of maintaining the facility and equipment. All equipment must be maintained in a manner conducive to safe and sanitary production and storage of all products. e.g. cleanable to a microbiological level, made of compatible materials, accessible for inspection, maintenance, cleaning and sanitation, no product or liquid collection, hollow areas, should be hermitically sealed, no niches, sanitary operational performance hygienic design of maintenance and hygienic compatibility with other plant system. The Maintenance Manager is responsible for all aspects of the program. All maintenance and other engineering contractors to work on site are required to be escorted, read and sign the GMPs Policy for visitors, vendors and contractors. Preventive Maintenance Records in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.2 Maintenance Staff and Contractors

All maintenance and other engineering contractors to work on site are required to be escorted, read and sign the GMPs Policy for visitors, vendors and contractors.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.3 Calibration

Calibration Program was reviewed on 8/1/22. The QA Team is responsible for this program. The site complies with industry and national standard calibration methods. Test equipment used to confirm food safety and quality standards are calibrated with industry standard calibration practices. e.g. scales, metal detector and thermometers. Procedures to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state were defined on the calibration program. The following calibration records were reviewed: 1. Metal detector 1 & 2– 10/20/21& 9/30/21 2. Scales – 11/11/21 3. Cooler – 12/8/21 4. Chemical control – 8/2022 5. Thermometer – 9/12/22 6. Backflow device – 9/12/22 7. Tel- Tru – expiry date – 2/26/23

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.4 Pest Prevention

The site uses 3rd party (Lloyd Pest Control) for pest prevention. Pest Control Company provided services for both interior and exterior areas of the facility. The pest control company services the facility at least two times a month. Pest control files included map of pest control devices, the business license expiry date 12/31/23 = insurance = 1/1/23, PCO – certificate expiry date 6/30/23. The pest prevention program described the methods and responsibility for the development, implementation and maintenance of the pest prevention program; record pest sightings and trend frequency of pest activity to target pesticide applications; outline the methods used to prevent pest problems; outline the pest elimination methods; and outline the frequency with which pest status is to be checked. Pest control service reports in the following months were reviewed: 8/2022, 4/2022, 1/2022 and 10/2021. There were no major or rodent/cockroach pest activities reported. Records of all pest control applications were maintained in the pest control log system. Pest control chemicals used had EPA# and were all approved for use in food processing facility. (e.g: Maxforce, All weather blox). N/A: Pest control chemicals were not stored on site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.5 Cleaning and Sanitation

Cleaning and Sanitation SOPs was reviewed on 8/1/22. Sanitation Manager is responsible overseeing the sanitation program. It included what is to be cleaned; how it is to be cleaned; when it is to be cleaned; who is responsible for the cleaning; and the responsibility and methods used to verify the effectiveness of the cleaning and sanitation program. All cleaning chemicals had Safety Data Sheets (SDS) on file and all approved for use in food processing facility. (e.g. Quat Sanitizer). Pre-operational inspections are conducted by QA Team following cleaning and sanitation prior to start of production from 4:30 AM to 5:00 AM. Monthly cleaning and Pre-Ops records in 8/2022, 4/2022, 1/2022 and 10/2021 were reviewed. Verification activities were documented by the Sanitation Lead/Supervisor. N/A: Cleaning in place (CIP) system was not used in this plant.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Cleaning in place (CIP) system was not used in this plant.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.1 Personnel Welfare

GMP policy stated that no personnel who are known to have been known to be carriers, or are 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 enters storage areas where food is exposed. The site had 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. During the plant observation, there were no personnel observed with exposed cuts, sores or lesions that engaged in handling or processing products or handling primary packaging materials or food contact surfaces.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.2 Handwashing

Hand wash station was observed located before the entrance door into main production room and each production room. It was made of stainless steel and hands-free design, paper towel dispensers, hand wash sign, and trash receptacles were provided in the area. Employees were observed consistently washing their hands before going back into the production room.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3 Clothing and Personal Effects

Employee's uniform or clothing is inspected on a daily basis by the Supervisors to ensure that the clothing/smock and hair policy protects materials, food and food contact surfaces from unintentional microbiological or physical contamination. Also, the site's inspects uniforms of employees during production hours on a monthly basis. The site is using 3rd party laundry services. There were no excessively soiled uniforms observed during the plant observation. Disposable gloves were observed changed after each break, upon re-entry into the processing area and when damaged. Comment Only: Formal clothing risk analysis has not been conducted at this time.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.4 Visitors

Visitor policy was described in their GMPs. It described that all visitors shall read, agree and sign the GMP policy before entering any food processing or handling areas, or shall be escorted at all times in food processing and handling and storage areas. It was observed that policy was being enforced or followed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

Staff amenities were observed supplied with appropriate lighting and ventilation. Change room is located in the employees' lockers and hall way before the production room. It was provided to enable staff to change into and out of protective clothing as required. Sanitary facilities were observed properly constructed and well- maintained, and located away from processing areas. Sanitary drainage was not connected to drains within processing facility. Hand wash basins were located inside toilet rooms. Employees' lunch room is located away from the food handling areas. The lunch room was observed provided with sufficient amenities at the time of the audit. Hand washing sign was posted at hand washing station. Outside eating area was observed away from the production building and was well maintained.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

Personnel entry into processing area was observed through the employees' main access back door only. Door was observed not left open for extended periods when access for waste removal or receiving of product/ingredient/packaging. Packaging material, product, and ingredients were all covered. Waste contained in the bins was removed from the processing area on a regular basis and not left to accumulate. Employees was observed not eating or tasting any product being processed in the food handling/contact zone. There was no tasting or tasting of product observed in the production areas. Hair restraints and beard covers were properly worn. The flow or personnel in food processing and handling areas were observed managed that the potential for product contamination is minimized or controlled.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.1 Water Supply

City water from San Diego, CA is being used for cleaning and hand washing. The water is monitored once a year for microbiological indicator of potability by 3rd party certified laboratory. Water potability test result on 8/1/22 and 3/15/22 was coliform absent. N/A: Non-potable water is not used. N/A: This site does not store water.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Non-potable water is not used.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: This site does not store water.

11.5.2 Water Treatment

N/A: There is no water treatment in this facility.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no water treatment in this facility.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no water treatment in this facility.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no water treatment in this facility.

11.5.3 Water Quality

City water from San Diego, CA is being used for cleaning and hand washing. The water is monitored once a year for microbiological indicator of potability by 3rd party certified laboratory. Water potability test result on 8/1/22 and 3/15/22 was coliform absent.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.4 Ice Supply

Ice is use in the plant based mixing room as processing aid. The water supply was tested on 8/1/22 and test result was coliform absent.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.5 Air and Other Gasses

Compressed air or other gases (e.g. nitrogen, carbon dioxide) that contacts food are used in line plant based room. It is being tested annually for APC, Yeast Mold. Test results on 7/13/22 were all in compliance (<1 CFU).

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.1 Receipt, Storage and Handling of Goods

Storage and Handling of Goods SOP was reviewed on 8/1/22. The site document and implemented storage plan that allows for the storage of raw materials, ingredients, packaging materials, equipment, and chemicals. Procedures are in place to ensure that all ingredients, materials, and finished product are utilized within their designated shelf-life (FIFO rotation). No expired products observed during the plant observation. N/A: No temporary storage used on site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: No temporary storage used on site.

11.6.2 Cold Storage, Freezing and Chilling of Foods

Cooler storage perimeter walls were easily accessible for inspection and cleaning. Cooler temperature is continuously monitored by recording charts and manually checks at least every twice a day during production. Loading and unloading docks were equipped with dock shelters.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

Storage rooms were observed used for the storage of dry ingredients, packaging, and other dry goods were observed located away from wet areas and constructed to protect the product from contamination and deterioration.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

All cleaning chemicals used were stored in a separate room to prevent a hazard to staffs and food items. The chemical storage was observed secured and restricted to authorized personnel and equipped with spillage kit. No pesticides, rodenticides, fumigants and insecticides stored on site. All cleaning chemicals in the storage cage were observed properly labeled.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

All products and trailers/trucks were inspected prior to loading and unloading. Trailer condition inspection was recorded on the inspection logs. Refrigerated unit's maintain the product at the required temperature e.g. NMT 45 F. The cooler unit's temperature settings is set to 40 F or below and freezer trailers are set to 0 F, checked, and recorded before loading, and the product temperature was recorded at regular intervals during loading.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.1 High-Risk Processes

Minor: Plant Based Production Room: The finished product area (the packaging table and cooling tunnel out feed) and raw coloring tables was approximately 3 feet apart and not protected/segregated/no barrier from raw materials or staffs who handles raw materials to ensure cross-contamination is minimized. The employees working in the finished product area and raw coloring tables were observed wearing white smocks. It was not identifiable who is working with raw materials and finished products. Plant Based Production Room is the high risk area in this plant. It is segregated from the raw production room to prevent product contamination. The site uses dedicated employees and to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.

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

RESPONSE: MINOR

EVIDENCE: Minor: Plant Based Production Room: The finished product area (the packaging table and cooling tunnel out feed) and raw coloring tables was approximately 3 feet apart and not protected/segregated/no barrier from raw materials or staffs who handles raw materials to ensure cross-contamination is minimized. The employees working in the finished product area and raw coloring tables were observed wearing white smocks. It was not identifiable who is working with raw materials and finished products.

ROOT CAUSE: Curtains were not put in place. Sleeves were not in use.

CORRECTIVE ACTION: Separators to be used as well as sleeves for employees.

VERIFICATION OF CLOSEOUT: Auditor reviewed CAR/attachment of clause 9.7.1.1 e.g. barrier issue from finished products and raw products.

COMPLETION DATE: 10/07/2022 **CLOSEOUT DATE:** 10/10/2022

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.2 Thawing of Food

N/A: There is no thawing of frozen products in this plant.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no thawing of frozen products in this plant.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no thawing of frozen products in this plant.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: There is no thawing of frozen products in this plant.

11.7.3 Control of Foreign Matter Contamination

Foreign Material and Glass and Brittle Plastic Protocol/Control of Foreign Matter Contamination SOP were reviewed on 7/1/21. It included glass and brittle and plastic control (it is inspected daily or before production and monthly facility GMP audits), metal contaminants control, pallet/wood contaminants control (it is inspected every delivery), tools and machine parts (daily), hand held knives (daily), and other foreign contaminants control daily. The QA team is responsible for this program. Foreign Matter inspection records of the following dates were reviewed: 8/2022, 4/2022, 1/2022 and 10/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.4 Detection of Foreign Objects

Detection of Foreign Objects SOP was reviewed on 7/1/21. This site uses metal detectors in the packaging lines prior to release of finished products. Metal detectors are equipped with automatic rejection and belt stop arm. Metal detection test wands/pieces in line 1 were: Fe = 1.5 mm, NFe = 1.5 mm and SS = 2.0 mm. Metal detection test is to be performed before production begins, approximately every hour during production and at the end of production shift. Metal detection records of the following dates were reviewed: 9/5-7/2022, 4/25-27/2022, 1/25-27/2022 and 10/27-29/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.8.1 Waste Disposal

Waste Management Policy/Trash Disposal was reviewed on 7/1/21. It is the responsibility of the QA/SMT management to assure the areas that they are responsible for have the trash and inedible product handled, stored, and removal properly. This site uses 3rd party for all dry and waste disposals and provides services at least twice a week. Production waste is removed at least once a day or as needed and not builds up in food handling or processing areas. There was no significant or excessive waste accumulation observed at the time of the audit. N/A: There is no trademark use in this plant.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.8.1.3	Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements. **RESPONSE:** COMPLIANT
11.8.1.4	Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin. **RESPONSE:** COMPLIANT
11.8.1.5	Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging. **RESPONSE:** COMPLIANT
11.8.1.6	Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A: There is no trademark use in this plant.
11.8.1.7	Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health. **RESPONSE:** COMPLIANT
11.8.1.8	Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards. **RESPONSE:** COMPLIANT
11.8.1.9	Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards. **RESPONSE:** COMPLIANT
11.8.1.10	Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports. **RESPONSE:** COMPLIANT