

SQF Food Safety Audit Edition 9 Virginia Produce Company, Inc.

Summary

AUDIT DECISION CERTIFICATION NUMBER

CERTIFIED 9595 | 176262

DECISION DATE AUDIT TYPE

05/09/23 **UNANNOUNCED**

RECERTIFICATION DATE AUDIT DATES

04/14/24 04/06/23 - 04/07/23

EXPIRATION DATE ISSUE DATE 06/28/24 05/09/23

AUDIT RATING

Excellent

Facility & Scope

Virginia Produce Company, Inc.

PO Box 40 Hillsville, VA 24343 **United States**

Food Sector Categories:

4. Fresh Produce, Grain, and Nut Packhouse **Operations**

14. Fruit, Vegetable, and Nut Processing, and **Fruit Juices**

25. Repackaging of Products Not Manufactured On Site

Products:

Apples, Beans, Cabbage, Corn, Cukes, Eggplant, Gourds, Lemons, Onions, Parsnips, Pepper, Potato, Pumpkin, Squash, Strawberry, Tomato, Watermelon, Zucchini

Scope of Certification:

Primary Plant Production, Food Manufacturing

Certification Body & Audit Team

EAGLE Food Registrations, Inc.

40 N. Main Street Suite 1880 Dayton, OH, 45423, **United States**

CB#: CB-1-Eagle

Accreditation Body: ANSI Accreditation Number: 894

Lead Auditor: Blaine Holmberg (123273) **Technical Reviewer:** Lisa Crawford (424990)

Other Members:

N/A

Hours Spent on Site: 20 Hours of ICT Activites: 0

Hours Spent Writing Report: 8

10.2.3 Maintenance Personnel and Contractors

Maintenance staff and contractors follow company GMP policies. Preventative maintenance schedules and work orders are prepared to cover equipment, the buildings and facility grounds.

Minor: The work orders have statements for removing tools and debris and post maintenance sanitation but these are not being documented.

10.2.3.3 Maintenance personnel 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. Maintenance, operations, and/or sanitation shall sign-off on communications.

RESPONSE: MINOR

EVIDENCE: The work orders have statements for removing tools and debris and post maintenance sanitation but these are not being documented.

ROOT CAUSE: The Maintenance Manager is also the Sanitation Manager and although he was ensuring that tools and debris were removed from the work site and that any necessary sanitation was completed after the work was completed, he was not documenting it on the work order forms.

CORRECTIVE ACTION: The Maintenance/Sanitation Manager was retrained on how to properly fill out the work orders. The work order document was also updated add a signature and date line for the reviewer to sign off on. Also, two members of the maintenance staff were trained on properly completing work orders.

VERIFICATION OF CLOSEOUT: auditor reviewed and approved

COMPLETION DATE: 04/11/2023 **CLOSEOUT DATE**: 05/03/2023

2.7.1 Food Defense Plan (Mandatory)

Food Defense Plan (2.7 reviewed 3/8/2023) outlines methods and responsibilities for food defense. Procedures address requirements of code. The plant has access control, locked external doors, monitored entrances and seals of shipping vehicles. Plant Manager is responsible for product defense. The food defense plan is reviewed and challenged at least annually, last tested on 6/15/2022. An undercover detective was hired to try to get into the facility and was successful. Employees were retrained on food defense and an electronic door locking system was installed.

Minor: An external door going into production was unlocked during the exterior inspection. The door is equipped with a magnet key fob lock, but it was not functioning.

- **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: MINOR

EVIDENCE: An external door going into production was unlocked during the exterior inspection. The door is equipped with a magnet key fob lock, but it was not functioning.

ROOT CAUSE: The door striker plate was not positioned correctly or close enough to the magnetic lock to allow the magnet to lock the door. In addition, there was moisture in the door lock control that was causing the lock to malfunction. The magnetic lock was armed but was not engaging consistently to keep the door locked.

CORRECTIVE ACTION: Email from Johnson Controls with information about Technician's arrival time on 4/11/23. Email confirmation from 4/6/23 from Johnson Controls of maintenance appointment set for 4/11/23. On 4/6/23 Johnson Controls, the third party that manages our security, was called and a maintenance appointment was setup for 4/11/23 to work on the door. On 4/11/23 the technician adjusted the striker plate and replaced the door exit switch. He also put sealant in the switch housing to keep moisture out. The door now locks and unlocks properly. Email from Johnson Controls indicating the completion of the work order on 4/11/23.

VERIFICATION OF CLOSEOUT: auditor reviewed and approved

COMPLETION DATE: 04/28/2023 **CLOSEOUT DATE**: 05/03/2023

11.3.2 Handwashing

Employees are instructed to wash their hands before starting and/or returning to work. Observation of employees during the audit noted adherence to the facility hand wash policy. Hand wash sinks are located at the employee entrances, in the bath rooms and break rooms. All hand wash basins are constructed of stainless steel or non-corrodible materials. Hand wash basins are supplied with water, liquid soap, paper towels and a waste container. Signs are available at all wash stations which are legible and prominently displayed in English and Spanish. Gloves are used over clean hands.

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

RESPONSE: MINOR

EVIDENCE: Clean gloves were in open bins directly under a new clock in computer.

ROOT CAUSE: The new time clock had been recently installed and the bins containing the clean gloves where inadvertently put back under the time clock.

CORRECTIVE ACTION: New bins with lids were ordered and the clean gloves put in them. They were also moved to the other side of the table so they are not under the time clock.

VERIFICATION OF CLOSEOUT: auditor reviewed and approved

COMPLETION DATE: 04/28/2023 **CLOSEOUT DATE**: 05/03/2023

11.7.4 Detection of Foreign Objects

All corn is run through metal detectors after being sealed in primary packaging. Metal detectors are checked hourly with 2mm Fe, 2mm NFe, and 4mm SS. Items are placed on hold if any foreign matter contamination is observed. Final disposition will be determined by upper management. The glass and brittle plastic procedure details the procedures to use in the event of glass breakage. The procedure required isolation of the area until cleaning and inspection to assure removal.

Minor: One metal detector was not properly rejecting all products into the reject bin during the metal detector checks observed in the initial audit walkthrough. The timing was immediately adjusted to reject product more accurately into the bin. All tests were properly detecting the test balls and the light and alarm were properly functioning.

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: MINOR

EVIDENCE: One metal detector was not properly rejecting all products into the reject bin during the metal detector checks observed in the initial audit walkthrough. The timing was immediately adjusted to reject product more accurately into the bin. All tests were properly detecting the test balls and the light and alarm were properly functioning.

ROOT CAUSE: The employee testing the metal detector was turning off the air supply to the plunger before doing the tests. He did this to prevent the test balls from being damaged when they were ejected into to the locked bin.

CORRECTIVE ACTION: The employee (Nathan Edwards, Repack Manager) who performs the tests was retrained to keep the air on so the plunger is properly tested. The test balls will be placed inside the packed item so they are not loose and do not get damaged when the plunger ejects them into the locked bin. Two other repack employees were trained on the testing process as well to serve as back ups to the Repack Manager.

VERIFICATION OF CLOSEOUT: auditor reviewed and approved

COMPLETION DATE: 04/28/2023 **CLOSEOUT DATE**: 05/03/2023

Section Responses

Audit Statement	Audit
SQF Practitioner Name	Name the designated SQF Practitioner
	RESPONSE: BRIAN HAWKS

SQF

Email of the designated SQF Practitioner

Practitioner Email

RESPONSE: BRIAN.HAWKS@VAPRODUCE.COM

Opening Meeting

People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas)

RESPONSE: KEVIN BEAMER: PRESIDENT/COO, JENNIFER HAWKS: VICE PRESIDENT, MATTHEW BEAMER: WAREHOUSE MANAGER, CODY EDWARDS: SHIPPING/RECEIVING MANAGER, NIKKI EDWARDS: ASSISTANT FOOD SAFETY MANAGER / BACKUP SQF PRACTITIONER, BRIAN HAWKS: FOOD SAFETY MANAGER / SQF PRACTITIONER, BLAINE HOLMBERG: AUDITOR

Facility Description

Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details

RESPONSE: THIS IS AN UNANNOUNCED SQF RECERTIFICATION AUDIT. THE FACILITY REPACKS A VARIETY OF FRESH FRUITS AND VEGETABLES INCLUDING: APPLES, BEANS, CABBAGE, CITRUS, CORN, CUCUMBERS, EGGPLANT, ONIONS, PEPPERS, PUMPKINS, SQUASH, STRAWBERRIES, SWEET POTATOES, TOMATOES, WATERMELON. THEY ALSO RUN CORN THROUGH A PROCESS OF TRIMMING, CUTTING, HUSKING, AND PACKING INTO TRAYS. THE COMPANY HAS BEEN IN BUSINESS SINCE 2005 AND MOVED INTO THIS FACILITY IN 2014. THE FACILITY IS 139,000 SQ.FT. TOTAL. THERE ARE ABOUT 150 TOTAL EMPLOYEES WORKING STAGGERED SHIFTS 5 TO 6 DAYS A WEEK, TYIPICALLY 6 AM TO 3 PM, CLEANING CREW FROM 4 PM TO 9 PM, AND SANITATION FROM 9 PM TO 5 AM.

Closing Meeting

People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas)

RESPONSE: MOIR BEAMER: CEO, KEVIN BEAMER: PRESIDENT/COO, JENNIFER HAWKS: VICE PRESIDENT, NATHAN EDWARDS: REPACK MANAGER, MIKE KINZER: MAINTENANCE MANAGER, MATTHEW BEAMER: WAREHOUSE MANAGER, CODY EDWARDS: SHIPPING/RECEIVING MANAGER, NIKKI EDWARDS: ASSISTANT FOOD SAFETY MANAGER / BACKUP SQF PRACTITIONER, BRIAN HAWKS: FOOD SAFETY MANAGER / SQF PRACTITIONER, BLAINE HOLMBERG: AUDITOR

Auditor Recommendat

ion

Auditor Recommendation

RESPONSE: ISSUE NEW CERTIFICATE AUDIT ONCE DEFICIENCIES ARE CORRECTED IN THE ALLOTTED TIME

2.1.1 Management Responsibility (Mandatory)

Policy Statement is available in English and Spanish, and includes the methods of meeting the requirements. The company policy includes a commitment to establish and review food safety objectives. It is signed by the President and is effectively communicated to all staff in training and posted at production entrance. Food safety objectives include: encourage and maintaining food safety culture with additional training - 5 additional employees completed HACCP training; reduce customer complaints 5% with a best reduction in 2022 was down 1.64%; 100% of employees trained in GMPs - all employees were trained in February 2023; and pass SQF audit with an excellent rating. All objectives are tracked and reviewed during monthly management meetings full analysis and review in annual meeting on 2/22/2023. The SQF Practitioner is the Food Safety Manager, Brian Hawks, who has HACCP training from 1/9/2023. The backup practitioner is the Assistant Food Safety Manager, Nikki Edwards, who has HACCP training from 2/2/2020 and advanced HACCP training from 4/18/2020. The Practitioners are full time employees. The senior management supported the documented procedures, training, policy improvements and capital improvements to ensure the food safety practices were adopted and maintained. A new corn cutting line was installed last year. Another corn cutting line was installed last week and going into production over the next few weeks once the new metal detector is properly functioning. A door entry system was installed with key fob entries and door monitoring.

- **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

EVIDENCE:

- **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

EVIDENCE:

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

EVIDENCE:

- **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

EVIDENCE:

- **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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

2.1.2 Management Review (Mandatory)

Management Review procedures (2.1.4 reviewed 3/8/2023) documents management reviews. The entire SQF system is reviewed by upper management at least annually. The system was last reviewed on 3/8/2023. The SQF Practitioner is responsible for validating the food safety plan. If there are any changes to the food safety fundamentals or food safety plan, they are reviewed and validated by the management team including the SQF Practitioner. They also conduct management meetings at least monthly.

- **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

EVIDENCE:

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

EVIDENCE:

2.1.3 Complaint Management (Mandatory)

The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities are documented in 2.1.5 revised on 3/8/2023. The SQF Practitioner handles customer complaints. The department manager to which the complaint is assigned performs an investigation and develops a corrective action. The facility's SQF Practitioners make the final decision on the resolution of the complaint. They have not received any food safety complaints in the past year. Any complaints involve quality issues with fresh produce such as decay, color.

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

EVIDENCE:

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

EVIDENCE:

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)

The food safety manual is documented. Hazard Analysis was performed based on food safety risk. There is a organizational chart, scope statement/list of products. The scope is within Food Sector category.

- **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

EVIDENCE:

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

EVIDENCE:

2.2.2 Document Control (Mandatory)

The facility's written Document Control Procedure (2.2.1 revised 3/8/2023) outlines the SQF practitioners are responsible for each department specific programs and policies. The programs are required to be assessed at least once per year. Documents are stored and controlled by the SQF practitioner. Company uses an electronic storage and document sharing program for accessibility.

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

EVIDENCE:

2.2.3 Records (Mandatory)

The facility's written Records Control Procedure outlines a Records Retention Schedule detailing the records will be maintained for a minimum of 2 years. Records are readily accessible, retrievable, securely stored electronically. Records were observed to be signed and dated by those completing the work.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

2.3.1 Specification, Formulation and Realization

No products are developed, the company only packs fresh produce. All products follow the two HACCP plans for repack and corn cutting and packing. Most fresh produce is labeled with a pack date, some customers have established sell by dates for specific products.

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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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.

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

All product purchased is fresh produce from approved farms and brokers. USDA standards are used for specifications. Food contact packaging is purchased from approved suppliers. Letters of guarantee, specifications, COAs, and 3rd party audits are kept on file from food contact packaging suppliers. Contract Service Provider procedure (2.3.3 reviewed 3/8/2023) details the training documents, specifications and a full description of the services provided to and from contract service providers. Contract Service Provider register is documented including contractors such as pest control, certification body and consulting. Product specifications are available for all products. Auditor reviewed spec sheets for squash, zucchini, peppers, tomatoes, and corn.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

- **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

EVIDENCE:

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

No contract manufacturers are used.

2.3.4 Approved Supplier Program (Mandatory)

Records of raw and packaging materials are maintained in the company electronic database and from approved suppliers. The auditor reviewed records for incoming goods from 2022 and 2023. The supplier approval program is the responsibility of management and the review was performed by the HACCP team. It included an annual review of performance and acceptable testing results. The facility's QA team reviews the suppliers on an annual basis. A register of approved suppliers is maintained electronically. An Approved Supplier register was observed detailing all the suppliers management has approved. It was last reviewed on 3/8/2023. They receive letters of guarantee, spec sheets, 3rd party audits and SDS for raw materials and packaging. Auditor reviewed supplier approval documents were up to date for suppliers for fruits and vegetables (SQF cert expires 7/10/2023, Primus GFS cert exp 12/8/2023, Global GAP cert exp 2/28/2024); Foam tray - NSF GMP audit from 2/23/2023 and letter of guarantee from 1/3/2023; corrugated packaging LOG from 5/12/2022.

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

A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained.

Code Amendment #2

Approved supplier registers shall include supplier contact details. All approved and emergency suppliers shall be registered.

RESPONSE: COMPLIANT

EVIDENCE:

- **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:
 - 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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

2.4.1 Food Legislation (Mandatory)

The SQF Practitioner is responsible for keeping informed of relevant changes to legislation through professional organizations, publications, regulatory email updates, continuing education, webinars. SQFI and the certification body will be notified in writing (email is preferred) within 24 hours of identification of a food safety event that requires public notification. This is specified in SQF 2.4.1.

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

EVIDENCE:

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

EVIDENCE:

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)

All employees and visitors are required to follow GMPS. Employees are trained on GMPs upon initial hire and at least annually, last documented in June 2022. Visitors are required to read and agree to GMPs before entering the facility and are escorted when in product areas. GMPs were observed to be followed during the audit.

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

EVIDENCE:

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

EVIDENCE:

2.4.3 Food Safety Plan (Mandatory)

The food safety plan has been developed following the 12-step HACCP method and has been effectively implemented. The food safety team consists of multiple employees including SQF Practitioner, Plant Manager, Production Assistant/Internal Auditor, QC Supervisors, Shipping Manager. They have also updated the HACCP plan to include preventative controls. The hazard analysis has been conducted on the products made and includes all processes identified in the flow chart. There are 2 HACCP plans for repack of fresh produce and another for cutting, husking, washing, and packing corn. There are no CCPs are identified for repack. Two CCPs are identified for corn: chlorine testing of the wash step and metal detection. Chlorine is tested hourly for free chlorine and pH. Critical limits are > 1 ppm free chlorine and pH between 6.5 to 8. Metal detectors are checked hourly with 2mm Fe, 2mm NFe, and 4mm SS. The HACCP plan is validated at least annually, last on 3/9/2023.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

2.4.4 Product Sampling, Inspection and Analysis

Methods for product sampling, inspection and analysis are documented in 2.5.4. All finished products are inspected during packaging and verified by QA. Employees are trained for each product to meet customer specifications. Finished products are visually inspected to meet specifications during packing.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.5 Non-conforming Materials and Product

Non-conforming & Rework Control (2.4.6 revised 3/8/2023) outlines the methods and responsibilities for handling non-conforming products. Any facility management team member can place products on hold due to non-conformity issues. Non-conforming products are put on hold, segregated and cannot be shipped. The Management team perform final release on all hold products. Auditor reviewed Hold log from 2022 and 2023 and corrective actions for non-conforming product.

- **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

EVIDENCE:

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

EVIDENCE:

2.4.6 Product Rework

Traceability is maintained for any repacked product. All products are scanned into the digital inventory system.

- **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: COMPLIANT

EVIDENCE:

2.4.7 Product Release (Mandatory)

All products are approved and released. All production checks are documented prior to product release. Finished Product Release Form must be completed and signed by QA for products to be approved to ship. The form includes: label verification, sell by date, temperature, quality visual inspection.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

2.4.8 Environmental Monitoring

The facility is swabbed for environmental pathogens (Listeria and Salmonella) in at least 2 rotating locations in each Zone 2, 3, and 4 quarterly. Auditor reviewed lab results from 3/15/2023 and 12/5/2022. If any positives are found, corrective action procedures are followed including recleaning and reswabbing. Corrective actions for environmental swab results are conducted which include recleaning and reswabbing. They have not found any positive results since implementing the system in June 2022.

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

EVIDENCE:

- **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

EVIDENCE:

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

EVIDENCE:

2.5.1 Validation and Effectiveness (Mandatory)

Internal Verification & Validation Procedure SQF 2.5.1 states the SQF Practitioner is responsible for monitoring the verification and validation activities performed in the facility. Each department manager or supervisor is responsible for that departments verification and validation of its procedures. The entire SQF system is validated by section throughout the year by the SQF Practitioner. The frequency and methods used to validate and verify food safety fundamentals, critical limits, and other food safety controls identified in food safety plans are documented in form 2.5.1 reviewed 3/8/2023. Records are maintained by the SQF Practitioner in the SQF Manual. Records were reviewed from 2022 and 2023.

- **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

EVIDENCE:

2.5.2 Verification Activities (Mandatory)

Internal Verification and Validation Schedule (reviewed 3/8/2023) is complete, current and outlines the frequency of each program. The methods, responsibility and criteria for verifying the effectiveness of monitoring pre-requisite programs and HACCP program is defined in 2.5.4 reviewed 3/8/2023. Records are maintained by the SQF Practitioner and stored in the SQF Practitioners office and on the shared server. Records were reviewed from 2022 and 2023.

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

EVIDENCE:

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

EVIDENCE:

2.5.3 Corrective and Preventative Action (Mandatory)

Corrective Action Procedure (2.5.5 reviewed 3/8/2023) details root cause analysis and resolution of non-conforming products and the responsibility is of the SQF Practitioner. The facility documents their corrective actions as part of the audits. The auditor reviewed a corrective actions (Corrective Action Response forms) from 2022 and 2023 for internal audits and non-conforming product.

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

EVIDENCE:

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

EVIDENCE:

2.5.4 Internal Audits and Inspections (Mandatory)

Internal Audits (2.5.7 reviewed 3/8/2023) addresses responsibility and methods of the internal audit process. SQF system is audited at least once each calendar year and is the responsibility of the plant manager and food safety coordinator. The internal audits are conducted effectively verify the SQF system and any findings are addressed with corrective actions. The SQF Practitioner and backup have received internal audit training and they conduct audits independent of their function. Internal audit training certificate reviewed from 6/13/2022. Monthly facility inspections were reviewed from 2022 and 2023.

- 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.

EVIDENCE:

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

EVIDENCE:

- 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

EVIDENCE:

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

EVIDENCE:

2.6.1 Product Identification (Mandatory)

Product Identification (2.6.1 reviewed 3/8/2023) addresses methods and responsibility (SQF Practitioner) for product identification at all stages. Correct labels are applied to all products with approved copies of labels attached to each finished product packet to ensure they match customer specs. Records of product identification are maintained on file and on the recorded production records. The auditor reviewed records from 2022 and 2023.

- **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

EVIDENCE:

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

EVIDENCE:

2.6.2 Product Trace (Mandatory)

Product Identification-Trace-Withdrawal and Recall (SQF 2.6.2 reviewed 3/8/2023) outlines responsibilities and methods for recalls and withdrawals. Mock recalls and traceability exercises are conducted at least annually. The traceability exercises are conducted one up and one back by the management team.

A traceability exercise was conducted during the audit on 4/6/2023. Auditor selected Yellow Corn (PO# 105398) received on 3/8/2023 with a total of 970 cases (48 ct) (28 pallets). This corn was processed on 3/8 and 3/9/2023 including cutting, husking, packing into tray packs. Total product produced from this lot was 778 full finished cases of finished products (about 80% loss to cutting/trimming/husking which is normal for this product). All 778 cases were shipped to one customer on multiple shipments on 3/8 and 3/9/2023. All product was traced in less than 10 minutes using the digital inventory system.

Another trace exercise was conducted as part of a mock recall by the management team on 3/7/2023. Management team selected a customer sales order with a mock recall scenario of a customer complaining about rotting cucumbers. Sales Order # 208041 (36 ct cucumber super selects) shipped to one customer on 1/7/2023 with a total of 80 cases. This incoming lot was traced back to PO# 105100 received on 1/6/2023 with a total of 800 cases (36 ct) They were repacked into trays on 1/6/2023 producing a total of 814 cases and 6 of those 814 were dumped for quality sort out, so 808 cases of finished product packed for sale. All 808 cases were shipped on multiple shipments from 1/6 through 1/10/2023 and none remaining in inventory.

- **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

EVIDENCE:

2.6.3 Product Withdrawal and Recall (Mandatory)

Requirement to inform SQFI and the certification body was addressed in procedure 2.6.3. The plant manager is assigned as the Crisis manager who responsible for handling any product crisis. Product Identification-Trace-Withdrawal and Recall states investigation to determine root cause of a recall shall be undertaken and action documented. Recall system is tested at least annually as stated in 2.6.3 Mock Recall Requirement Protocol. Records of a mock recall are on file and were reviewed from 3/7/2023.

- **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.

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

2.6.4 Crisis Management Planning

The Crisis Management Plan (2.1.5 reviewed 3/8/2023) is outlined for threats, methods and responsibility for coping with a crisis. All elements are included within the plan, which included training of a crisis management team; controls implemented to ensure a response to a crisis does not compromise product safety; measures to isolate and identify product affected by a response to a crisis; the preparation and maintenance of a current crisis alert contact list; the responsibility for internal communications and communicating with authorities, external organizations and media. Senior Management are responsible for overseeing the team. The crisis management plan is tested at least annually, last tested on 6/16/2022 for a compressor failure causing refrigeration units to go down. In this situation, product would be moved to a facility less than a mile away with extra cooler space.

- 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.

EVIDENCE:

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

EVIDENCE:

2.7.1 Food Defense Plan (Mandatory)

Food Defense Plan (2.7 reviewed 3/8/2023) outlines methods and responsibilities for food defense. Procedures address requirements of code. The plant has access control, locked external doors, monitored entrances and seals of shipping vehicles. Plant Manager is responsible for product defense. The food defense plan is reviewed and challenged at least annually, last tested on 6/15/2022. An undercover detective was hired to try to get into the facility and was successful. Employees were retrained on food defense and an electronic door locking system was installed.

Minor: An external door going into production was unlocked during the exterior inspection. The door is equipped with a magnet key fob lock, but it was not functioning.

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: MINOR

EVIDENCE: An external door going into production was unlocked during the exterior inspection. The door is equipped with a magnet key fob lock, but it was not functioning.

ROOT CAUSE: The door striker plate was not positioned correctly or close enough to the magnetic lock to allow the magnet to lock the door. In addition, there was moisture in the door lock control that was causing the lock to malfunction. The magnetic lock was armed but was not engaging consistently to keep the door locked.

CORRECTIVE ACTION: Email from Johnson Controls with information about Technician's arrival time on 4/11/23. Email confirmation from 4/6/23 from Johnson Controls of maintenance appointment set for 4/11/23. On 4/6/23 Johnson Controls, the third party that manages our security, was called and a maintenance appointment was setup for 4/11/23 to work on the door. On 4/11/23 the technician adjusted the striker plate and replaced the door exit switch. He also put sealant in the switch housing to keep moisture out. The door now locks and unlocks properly. Email from Johnson Controls indicating the completion of the work order on 4/11/23.

VERIFICATION OF CLOSEOUT: auditor reviewed and approved

COMPLETION DATE: 04/28/2023 **CLOSEOUT DATE**: 05/03/2023

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

EVIDENCE:

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)

Methods and responsibilities for identifying food fraud are documented in 2.7.2, reviewed 3/8/2023. A vulnerability assessment was initially conducted by management on 5/24/2022. It was determined that the facility is low risk for food fraud as they only handle fresh produce. The food fraud vulnerability assessment is reviewed and verified at least annually, last on 3/8/2023.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

2.8.1 Allergen Management (Mandatory)

Responsibility and methods for controlling allergens are outlined in 2.8.2 reviewed 3/8/2023. No major allergens are handled at this facility. All employees are trained at least annually on allergen awareness, last in February 2023. Employees are required to remove smocks before entering break rooms and wash hands after lunch to prevent any allergen contamination.

- **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.

EVIDENCE:

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

EVIDENCE:

2.9.1 Training Requirements

Policy 2.9 reviewed 3/8/2023, addresses requirements of employee training. Competencies and methods are detailed in the training documentation.

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

EVIDENCE:

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

EVIDENCE:

2.9.2 Training Program (Mandatory)

Work instructions are documented for the incoming product inspection, hold policy, cleaning, preventative maintenance and all other tasks that assured product safety. The facility performs all training information in English and Spanish. All refresher training is performed at least annually. Auditor observed annual SQF refresher training in February 2023, Food Safety, SQF, GMPs, pre-ops from 6/16/2022, CCP training on 6/14/2022, proper usage of hair/beard nets on 6/2/2022. Training is documented on training logs. The register includes the participant name, description of training, trainer, date of training, skills description and competency verification.

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

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

- **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

EVIDENCE:

10.1.1 Premise Exterior

The facility is located in an industrial area of Hillsville, VA. The surrounding area is well maintained. The site is approved with proper licensing. Auditor reviewed Virginia Department of Agriculture and Consumer Services, Food Manufacturer Permit expires 6/30/2023, FDA registration expires 12/31/2024.

10.1.1.1 The location and construction of the premises and building shall ensure that:

i. Adjacent and adjoining buildings, operations, and land use do not interfere with safe and hygienic operations; and

ii.Relevant regulatory authority approval has been obtained and is on file.

RESPONSE: COMPLIANT

10.1.1.2 The methods and responsibilities applied to maintain a suitable exterior environment shall be documented and implemented. These include:

i. Effective, periodic monitoring and/or inspection of the premises, the surrounding areas, storage facilities, machinery, and equipment;

ii.Controls to ensure that the exterior is kept free of waste and/or accumulated debris to prevent the attraction of pests and vermin;

iii.Paths, roadways, loading and unloading areas are adequately drained and maintained; and iv.Records of inspections and correction actions are maintained.

RESPONSE: COMPLIANT

EVIDENCE:

10.1.2 Building Interior

Surfaces are properly constructed. Product (stainless steel) and non-product contact surfaces are constructed of materials that do not pose a product safety risk. Floors are properly constructed and graded. There is no waste trap. Walls, ceilings, partitions and doors are properly constructed and maintained. Stairs and catwalks are properly constructed and maintained. The lights throughout the facility were shatter proof. The lighting was sufficient throughout. Inspection areas are provided and suitable with proper lighting.

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

RESPONSE: COMPLIANT

EVIDENCE:

10.1.2.2 Drains and waste/material trap systems shall be constructed and located so that they can be easily cleaned and not present a hazard to products.

RESPONSE: COMPLIANT

EVIDENCE:

10.1.2.3 Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have even, smooth light-colored finishes, be impervious to liquids, and shall be kept clean (refer to 10.2.5).

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

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

RESPONSE: COMPLIANT

EVIDENCE:

10.1.2.4 Ducting, conduit, and pipes that convey 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 (refer to 10.3.2).

EVIDENCE:

10.1.2.5 Adequate ventilation shall be provided in enclosed product handling and storage areas and meet commodity-specific regulations where applicable. All ventilation equipment and devices shall be adequately cleaned per the cleaning and sanitation program.

RESPONSE: COMPLIANT

EVIDENCE:

10.1.2.6 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.

RESPONSE: COMPLIANT

EVIDENCE:

10.1.2.7 Doors, hatches, and windows and their frames in food handling or storage areas shall be of a material and construction that meets the same functional requirements 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

EVIDENCE:

10.1.2.8 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 10.3.2).

RESPONSE: COMPLIANT

EVIDENCE:

10.1.2.9 The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/packed (refer to 2.4.4 for internal lab requirements). 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

EVIDENCE:

10.1.2.10 Lighting and light fixtures in product handling areas, inspection stations, ingredient/ input and packaging storage areas, and all areas where the product is exposed shall be:

i.Of appropriate intensity to enable personnel to carry out tasks efficiently and effectively; and ii.Shatterproof, manufactured with a shatterproof covering, or fitted with protective covers. Where fixtures cannot be recessed, including in warehouses, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

EVIDENCE:

10.1.3 Dust, Insect, and Pest Proofing

All doors and windows are adequately sealed to protect against dust and pest contamination. Rodent traps are located away from the processing areas and do not pose a risk to the products. Bait stations are located along the exterior perimeters only.

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

RESPONSE: COMPLIANT

EVIDENCE:

10.1.3.2 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 entry 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

EVIDENCE:

10.1.3.3 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 operating equipment.

Poison rodenticide bait shall not be used inside packing rooms, product storage areas, or food handling areas.

RESPONSE: COMPLIANT

EVIDENCE:

10.2.1 Equipment and Utensils

Food processing equipment, utensils and clothing are properly designed and maintained. All trash containers are labeled.

10.2.1.1 The methods and responsibility for purchasing and specifications development for equipment and utensils shall be documented and implemented. The methods shall ensure that equipment and utensils:

i. Are designed, constructed, installed, and operated so as not to pose a threat to products; and ii. Meet any applicable regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.2.1.3 Benches, tables, conveyors, shellers, graders, packers, and other mechanical equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious, and free from cracks or crevices.

RESPONSE: COMPLIANT

EVIDENCE:

10.2.1.4 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned per the cleaning and sanitation program. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

EVIDENCE:

10.2.1.5 All equipment and utensils shall be cleaned after use and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

EVIDENCE:

10.2.1.6 Vehicles and/or other devices used to transport and move products 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

EVIDENCE:

10.2.2 Equipment Maintenance and Repair

Maintenance procedures and responsibilities are outlined in 11.2.9 reviewed 3/8/2023. Preventative maintenance checks from 2022 and 2023 were reviewed including daily, weekly, bi-weekly, monthly checks of equipment and the facility. Equipment failures are documented on Work Order forms. Maintenance staff and contractors follow company GMP policies. Temporary repairs are not allowed. Food grade lubricant is used on all food processing equipment.

10.2.2.1 The methods and responsibility for the maintenance and repair of equipment and buildings and facilities shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination. The methods shall include procedures to ensure:

i.Routine preventive maintenance of facilities and equipment in any food handling or storage area is performed according to a maintenance control schedule;

ii. Preventive maintenance and repair of items identified as impacting food safety controls and practices are prioritized for completion according to defined schedules or immediately when they are not properly functioning; and

iii.Records are maintained for all preventive maintenance and equipment failure/immediate repair activities and corrective actions.

The maintenance schedule shall cover buildings, equipment, and other areas of the premises critical to the maintenance of product safety and quality.

RESPONSE: COMPLIANT

EVIDENCE:

10.2.2.2 The maintenance supervisor and/or site supervisor shall be informed when repairs or maintenance are undertaken in product handling or storage areas and when the 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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

10.2.3 Maintenance Personnel and Contractors

Maintenance staff and contractors follow company GMP policies. Preventative maintenance schedules and work orders are prepared to cover equipment, the buildings and facility grounds.

Minor: The work orders have statements for removing tools and debris and post maintenance sanitation but these are not being documented.

10.2.3.1 Maintenance personnel and contractors shall comply with the site's personnel and operational hygiene requirements (refer to 10.5).

RESPONSE: COMPLIANT

EVIDENCE:

10.2.3.2 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

EVIDENCE:

10.2.3.3 Maintenance personnel 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. Maintenance, operations, and/or sanitation shall sign-off on communications.

RESPONSE: MINOR

EVIDENCE: The work orders have statements for removing tools and debris and post maintenance sanitation but these are not being documented.

ROOT CAUSE: The Maintenance Manager is also the Sanitation Manager and although he was ensuring that tools and debris were removed from the work site and that any necessary sanitation was completed after the work was completed, he was not documenting it on the work order forms.

CORRECTIVE ACTION: The Maintenance/Sanitation Manager was retrained on how to properly fill out the work orders. The work order document was also updated add a signature and date line for the reviewer to sign off on. Also, two members of the maintenance staff were trained on properly completing work orders.

VERIFICATION OF CLOSEOUT: auditor reviewed and approved

COMPLETION DATE: 04/11/2023 **CLOSEOUT DATE**: 05/03/2023

10.2.4 Calibration

The methods and responsibility for the Calibration Protocol (11.2.11 reviewed 3/8/2023) are defined. The methods and responsibility for addressing disposition of potentially affected product is detailed under procedure 11.2.11. Hold procedure is followed. All equipment is calibrated against reference standards as stated in 11.2.11. Auditor observed calibration records: cooler thermometers (verified with NIST certified thermometer weekly and documented on Thermometer Calibration Log), NIST certified thermometer (issued 1/10/2023), scales (calibrated by 3rd party 2/8/2023), metal detectors (checked hourly during production with standards and validated by the manufacturer at least annually, last on 2/14/2023).

10.2.4.1 The methods and responsibility for calibration and re-calibration of measuring, testing, and inspection equipment used for monitoring activities outlined in Good Operating Practices, food safety plans, and other process controls or to demonstrate compliance with customer specifications shall be documented and implemented. The procedures shall ensure:

i. alibration is performed according to regulatory requirements and/or the equipment manufacturer's recommended schedule;

ii.Calibrated measuring, testing, and inspection equipment is protected from damage and unauthorized adjustment;

iii. Affected product is handled according to non-conforming product procedures when equipment is found to be out of calibration;

iv. Software used for calibration activities is effective and appropriate; and v. Records of calibration activities are maintained.

RESPONSE: COMPLIANT

EVIDENCE:

10.2.4.2 Equipment shall be calibrated against manufacturer, 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

EVIDENCE:

10.3.1 Pest Prevention

The Integrated Pest Management (11.2.11 reviewed 3/8/2023) details the methods and responsibility for integrated pest management within the facility. Pest inspections are performed by Strikeforce Pest Prevention Elimination monthly and all records are kept in a binder in the SQF Practitioner's office. Pest control management plan is maintained and includes a labeled site map, approved chemical labels and SDS, inspection reports, and proper licensing. Inspections are conducted by technicians licensed by Virginia Department of Agriculture and Consumer Services, Office of Pesticide Services, Pesticide Applicator Certificate expires 6/30/2023 and Pesticide Business License expires 3/31/2024. Inspection reports are left with the site by the technician after each inspection. Auditor observed pest findings logs and PCO recommendations from 2023. Annual site assessment / IPM Review was last conducted on 2/14/2023 and included system review and recommendations; and trend analysis from 10/19/2022. Fumigants are stored in a separate building, locked and only accessible to the employee who is licensed for pesticide handling.

10.3.1.1 The methods and responsibility for pest prevention shall be documented and effectively implemented. The pest prevention program shall:

i.Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program;

ii.Record pest sightings and trend the frequency of pest activity so as 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 bait stations set on a site map;

vii.List the chemicals used. They are required to be approved by the relevant authority, and their Safety Data Sheets (SDS) made available;

viii.Outline the methods used to make personnel 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 personnel 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

EVIDENCE:

10.3.1.2 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. Maintain a site map indicating the location of bait stations, traps, and other applicable pest control/monitoring devices; and v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments.

RESPONSE: COMPLIANT

EVIDENCE:

10.3.1.3 Inspections for pest activity shall be conducted on a regular basis by trained 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 pest activity inspections and pest control devices shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

10.3.1.4 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

EVIDENCE:

10.3.1.5 No domestic animals shall be permitted on the site in food handling or storage areas

EVIDENCE:

10.3.2 Cleaning and Sanitation

Sanitation procedures have been developed and maintained for specific areas. The procedures detail what, how and who is responsible for cleaning each area. Processing equipment and protective clothing are properly cleaned. Verification of sanitation is performed through daily pre-operational inspections. Auditor reviewed cleaning records and pre-op inspection forms from 2022 and 2023. Approved chemicals are purchased from an approved supplier, SDS and inventory are maintained. The chemicals are stored in a locked room separated from production. All chemical containers are properly labeled and properly disposed of when empty.

10.3.2.1 The methods and responsibility for cleaning of the product handling equipment and environment shall be documented and implemented. Cleaning procedures and schedules shall include:

i.A list of equipment, utensils, and storage areas that require periodic cleaning;

ii.Instructions on how cleaning is performed for the various areas and equipment;

iii. The frequency of when cleaning is to be completed;

iv.Personnel responsible and the methods used to verify the effectiveness of the cleaning and sanitation program (e.g., validation of procedures, concentration of detergents and sanitizers); and v.Records of cleaning activities and effectiveness reviews/inspections are maintained.

RESPONSE: COMPLIANT

EVIDENCE:

10.3.2.2 Detergents and sanitizers shall be suitable for use in a food handling 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 properly stored as per the storage program;

iv.Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v.Only trained personnel handle sanitizers and detergents.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.3.2.4 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils. Racks and containers for storing cleaned utensils and protective clothing shall be clearly identified and maintained in a manner that prevents contamination of products, equipment, or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

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

Pre-operational inspections shall be conducted by qualified personnel and records maintained.

RESPONSE: COMPLIANT

EVIDENCE:

10.3.2.6 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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.4.1 Personnel Practices

Employees are trained on infectious disease concerns in their GMP refresher training and during their new hire training. During the audit, there were no employees observed in production areas who showed signs of infectious diseases. Employees are trained on exposed cuts and lesions in their GMP refresher training and during their new hire training. During the audit, there were no employees observed in the production areas who showed signs of having open wounds or lesions. Use of tobacco, eating, drinking or smoking is not allowed in the production areas. A lunch room is available to employees for eating and drinking. The facility does not allow the use of jewelry except medic alert jewelry and plain wedding bands. There was no observation of employees wearing jewelry.

10.4.1.1 A documented and implemented procedure for personal hygiene and personnel practices shall ensure that personnel engaged in the handling of product use appropriate personal hygiene practices. The procedure shall include instructions that:

i.Jewelry and other loose objects that pose a threat to the safety of the product are not worn or taken into any product handling or storage operations.

ii. Fingernail polish, artificial nails, and long nails are not permitted where product is handled with bare hands; iii. False eyelashes and eyelash extensions are not permitted;

iv. Hair restraints are used where product is exposed; and

v.Smoking, chewing, eating, drinking (except for water which shall be available to all personnel), or spitting are not permitted in any packing or storage areas.

Note: The wearing of plain bands with no stones or jewelry accepted for religious or cultural reasons and prescribed medical alert bracelets can be permitted; however, the site will need to consider its customer requirements and the applicable food legislation.

Personnel and visitor practices, including all those listed in 10.4.1, shall be routinely monitored for compliance, and any resulting corrective actions implemented and recorded for personnel who violate food safety practices.

Code Amendment #1

A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.1.2 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 packhouse operations.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.1.3 Procedures and responsibilities shall be in place that specify the handling of product and/or product contact surfaces that have been in contact with or exposed to blood or other bodily fluids.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.1.4 Personnel with exposed cuts, sores, or lesions shall not be engaged in handling product or product contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a suitable waterproof and colored dressing.

RESPONSE: COMPLIANT

10.4.2 Sanitary Facilities and Handwashing

Employees are instructed to wash their hands before starting and/or returning to work. Observation of employees during the audit noted adherence to the facility hand wash policy. Hand wash sinks are located at the employee entrances, in the bath rooms and break rooms. All hand wash basins are constructed of stainless steel or non-corrodible materials. Hand wash basins are supplied with water, liquid soap, paper towels and a waste container. Signs are available at all wash stations which are legible and prominently displayed in English and Spanish. Gloves are used over clean hands.

10.4.2.1 Toilet and handwashing facilities shall be provided and designed, constructed, and located in a manner that minimizes the potential risk for product contamination. The following shall be considered:

i. There shall be sufficient toilet facilities for the maximum number of personnel, and they shall be constructed so they can be easily cleaned and maintained;

ii. Handwash basins with clean and potable water, hand soap, disposable towels or effective hand drying devices, waste bins, and a tank that captures used handwash water for disposal (if not connected to drains) shall be provided inside or adjacent to toilet facilities and in accessible locations throughout food handling areas as required;

iii. Signage in appropriate languages shall be provided adjacent to handwash basins instructing personnel to wash their hands after each toilet visit;

iv.Racks for protective clothing used by personnel and visitors shall be provided; and v.Toilet and wash stations shall be maintained in clean and sanitary conditions.

Tools/equipment used for cleaning toilet rooms shall not be used to clean operational areas.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.2.2 Personnel shall have clean hands, and hands shall be washed by all personnel, contractors, and visitors:

i.On entering food handling areas, and before putting on gloves;

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 products, or contaminated material.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.2.3 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 as per regulations.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.3 Protective Clothing

Clothing worn by staff is properly maintained, clean and did not pose a risk to the product. Disposable gloves are used over clean hands.

10.4.3.1 Protective clothing (e.g., uniforms and smocks) shall not pose a food safety threat or be a risk to product contamination. Protective clothing shall be:

i.Manufactured from material that can be effectively maintained, stored, and laundered after use or at a frequency that does not create risks of cross-contact with products. Excessively soiled uniforms shall be changed or replaced where they become a product contamination risk; and

ii. Temporarily stored on racks, when personnel leave operating areas or use toilet facilities and the clothing can be easily removed (e.g., smocks and aprons).

RESPONSE: COMPLIANT

EVIDENCE:

10.4.3.2 Where applicable, clothing (i.e., any outer garment), including footwear, shall be in good condition, cleaned, and worn to protect product from the risk of contamination.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.3.3 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area, and when damaged.

Non-disposable aprons and gloves shall be cleaned and sanitized as required and, when not in use, stored on racks provided in the processing area or designated sealed containers in personnel lockers and not on packaging, ingredients, product, or equipment.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.4 Visitors

Visitors are required to sign-in at the visitor's entrance. Visitors are also required to read and sign the GMP requirements prior to entering the facility. Appropriate clothing and footwear are covered in the requirements. All visitors are required to follow the employee GMP and clothing requirements.

10.4.4.1 All visitors, including management, shall be required to adhere to site personnel practices and specifically:

i.Remove jewelry and other loose objects as per 10.4.1.1;

ii. Wash hands as per 10.4.2.2;

iii. Wear suitable clothing and footwear when entering any operational or food handling area; and iv. Enter and exit food handling areas through the proper entrance points.

RESPONSE: COMPLIANT

EVIDENCE:

10.4.4.2 Visitors who are exhibiting visible signs of illness or have been in recent direct contact with other sites, animals, or produce shall be prohibited from entering any growing or product handling or harvesting operation.

RESPONSE: COMPLIANT

10.4.5 Personnel Amenities (change rooms, toilets, lunchrooms/breakrooms)

Staff amenities have sufficient lighting and ventilation to accommodate the maximum number of plant personnel. Change rooms are not required. Lockers are provided for storing personal items. Showers are not required. Toilets are adequate in number for the maximum number of staff. Toilets are constructed so that they can be easily maintained and are tidy and clean. They are located in the offices separate from the processing areas. Hand wash sinks are provided inside each rest room. The hand washing sinks are designed and constructed as per section 11.3.2.2. The lunch room is located in a separate building by the employee entrance, separated from the processing areas. It is equipped with refrigerators, microwaves and sink. It was observed to be well lit, maintained and clean. The outside eating area is also well maintained and covered. Hand wash signs are posted in English and Spanish.

- **10.4.5.1** Staff facilities shall be supplied with appropriate lighting and ventilation and provided to enable staff and visitors to:
 - i. Change into and out of protective clothing, if applicable;

ii. Store street clothing, footwear, and personal items separate from food handling, packing, and storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

- **10.4.5.2** Separate lunchroom and/or breakroom facilities shall be provided away from product contact/handling zones. Lunchrooms/breakrooms shall be:
 - i. Ventilated and well lit;
 - ii. Provided with adequate tables and seating to accommodate the maximum number of personnel 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 personnel to store or heat food and prepare non-alcoholic beverages if required; and

v.Kept clean and free from waste materials and pests.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.5.1 Product Handling and Packaging Operations

Plant personnel were observed only entering or exiting the facility through the designated employee entrances. Employees have been instructed to keep exterior doors closed when not in use. During the audit, all exterior doors in the production areas were observed to be maintained closed by plant personnel. There were no employees observed wearing false fingernails or fingernail polish in the processing areas of the facility. Trash containers were observed to be properly identified and emptied at a regular frequency. Wash down hoses are properly stored on racks.

- **10.5.1.1** All personnel engaged in any food handling operations shall ensure that products and materials are handled and stored to prevent damage or product contamination. They shall comply with the following operational practices:
 - i. No eating or tasting any product in the food handling/contact zone, except as noted in element 10.5.1.2;
 - ii. Entry into operational areas is only through the personnel access doors;
 - iii. All doors are kept closed. Doors are not open for extended periods when access is required for waste removal, or receiving and/or shipping of products, ingredients, or packaging.
 - iv. Packaging, product, and ingredients are kept in appropriate containers as required and off the floor;
 - v. Waste is contained in the bins identified for this purpose, removed from operational areas regularly, and not left to accumulate; and
 - vi. All wash down and compressed air hoses are stored on hose racks after use and not left on the floor.

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.5.1.3 The flow of personnel in food handling areas shall be managed so that the potential for contamination is minimized.

RESPONSE: COMPLIANT

EVIDENCE:

10.5.1.4 Personnel practices and activities, including those listed in 10.5, shall be routinely monitored for compliance, and any resulting corrective actions implemented and recorded for personnel who violate food safety practices.

RESPONSE: COMPLIANT

EVIDENCE:

10.5.2 Control of Foreign Matter Contamination Operations

Methods and responsibility for the prevention of foreign matter contamination are documented in 11.7.5 reviewed 3/8/2023. Preventative maintenance and internal audits are performed to ensure plant and equipment remains in good condition. Temporary fasteners are not allowed. The knives and scissors are checked out and collected at the beginning and end of each shift, cleaned and sanitized during sanitation shift and inspected as part of the pre-op. A full glass and brittle plastic register is maintained and checked monthly, reviewed from 3/15/2023, 2/16/2023 and 1/19/2023.

10.5.2.1 The methods and responsibility for the prevention of foreign matter and glass contamination shall be documented and implemented. Procedures and resulting records shall ensure:

i.Containers, equipment, and other utensils made of glass, porcelain, ceramics, brittle plastic, or similar materials are not permitted where exposed product is handled, unless clearly identified, required for effective operational controls, and regularly inspected;

ii.Regular inspections are conducted to ensure food handling/contact zones areas are free of glass and brittle plastic and any items made from the previously identified materials are in good repair;

iii. Wooden pallets and other wooden utensils or tools used in food handling/contact zones are dedicated for that purpose. Their condition is subject to regular inspection, and they are cleaned and maintained in good order;

iv. Product handling areas are routinely inspected to remove risks from foreign material, such as debris, wood, stones, metal, detached/deteriorated equipment, and other physical hazards; and

v. Personnel are to be made aware of their responsibility to adhere to the site's foreign matter and glass controls.

RESPONSE: COMPLIANT

EVIDENCE:

10.5.2.2 Knives and cutting instruments used in product handling 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

EVIDENCE:

10.5.2.3 Gaskets 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

EVIDENCE:

10.5.3 Detection of Foreign Objects Operations

Foreign material detection devices are not used for repack items. Products are visually inspected/graded/sorted and handpacked. Items are placed on hold if any foreign matter contamination is observed. Final disposition will be determined by upper management. The glass and brittle plastic procedure details the procedures to use in the event of glass breakage. The procedure required isolation of the area until cleaning and inspection to assure removal.

10.5.3.4 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

EVIDENCE:

10.5.3.5 In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, and thoroughly inspected (including cleaning equipment and footwear), and the completed actions approved by a suitably responsible person before restarting operations.

RESPONSE: COMPLIANT

10.5.4 Receiving and Shipping

The methods and responsibilities are outlined in the Loading, Transport and Unloading procedures (11.6.5 reviewed 3/8/2023). Loading docks are covered to protect product. Trucks are sealed upon shipping. Transport vehicles are inspected prior to loading and unloading. Shipping and Receiving log is used to inspect loading and unloading of trailers. Trailer inspection records for 2023 were reviewed complete and verified. Loading practices are designed to minimize any unnecessary exposure of product to conditions that could potentially affect product integrity. Trailer temperatures are checked and recorded on the receiving log prior to unloading raw materials. Loading docks are covered to protect product during unloading.

10.5.4.1 Personnel conducting receiving activities shall ensure agricultural inputs, packaging materials, and product are not contaminated during the unloading process. Work instructions and training shall include the following practices:

i. Vehicles are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the agricultural input, packaging, or product;

ii. Vehicles (e.g., trucks/vans/containers) are secured from tampering using a seal or other agreed-upon and acceptable device or system;

iii.Unloading docks are designed to protect the product and in good operating condition (refer to 10.1.2.7); and

iv. Where temperature control is required, the refrigeration unit's storage temperature settings and operating temperature are checked and recorded before opening the doors. Unloading is completed efficiently, and product temperatures are recorded at the start of unloading and at regular intervals during unloading.

Recording documents for vehicle inspection, identification of approved suppliers, and temperature checks shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

10.5.4.2 Personnel conducting loading and transporting of harvested and/or packaged product shall ensure that product integrity is maintained. Work instructions and training shall include the following practices:

i.Inspections for ensuring vehicles are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on products;

ii.Securing vehicles (e.g., trucks/vans/containers) from tampering using a seal or other agreed upon and acceptable device or system;

iii.Loading docks are designed to protect the product and in good operating condition (refer to 10.1.2.7); iv.Verification that appropriate storage conditions are maintained during transportation to final destinations; v.Prevention of cross-contamination with other hazards and potential spoilage;

vi. Use of appropriate stock rotation practices; and

vii.Recording and maintaining documents for vehicle inspection, transport conditions, and stock rotation.

RESPONSE: COMPLIANT

10.6.1 Water Supply

Adequate supply of water is available. The facility utilizes city water as their potable water supply. There were no cross connections or observed issues that could affect the quality of the water. The facility keeps the city water report on file and sends out samples for potability tests at monthly, last tested 3/30/2023. Back flow prevention devices are were installed and tested annually, last tested on 1/19/2023. The is no non-potable water.

10.6.1.1 A water supply plan shall be prepared that describes the water sources and the operational areas they serve and shall include the location of water sources, permanent fixtures, and the flow of the water system. The plan shall be kept current and revised when changes occur.

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

EVIDENCE:

10.6.1.2 Adequate supplies of potable water drawn from a known clean source shall be provided for use during operations, cleaning the premises and equipment, and handwashing.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.6.2 Water Treatment

Water is not treated.

10.6.3 Water Quality

Adequate supply of water is available. The facility utilizes city water as their potable water supply. There were no cross connections or observed issues that could affect the quality of the water. The facility keeps the city water report on file and sends out samples for potability tests at monthly, last tested 3/30/2023.

10.6.3.1 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 operational 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

EVIDENCE:

10.6.3.2 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, cleaning, or from within the site. The frequency of analysis shall be risk-based, and at a minimum annually.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.6.4 Ice Supply

No ice is used.

10.6.5 Air and Other Gasses

Compressed air does not contact repacked product.

10.7.1 Ambient/Dry Storage

Equipment storage area allows access for cleaning. Storage areas are properly designed and constructed for hygienic storage. Proper stock rotation (FIFO) is used. No alternative storage is used. There is no cold storage.

10.7.1.1 The responsibility and methods for ensuring proper storage of inputs, packaging, and finished product shall be documented and implemented. The methods shall ensure:

i.Effective stock rotation;

ii. Utilization of inputs, work-in-progress, and finished product within their shelf life;

iii.Risks to temporarily stored materials and/or products are analyzed, and controls are applied if necessary; iv.Rooms used for the storage of product ingredients, packaging, and other dry goods are located away from wet areas (refer to 10.1.2); and

v.Records are maintained to control storage and stock rotation.

RESPONSE: COMPLIANT

EVIDENCE:

10.7.1.2 Dry ingredients and packaging shall be received and stored separately from field product or chilled materials to ensure there is no cross-contamination. Unprocessed field products shall be received and segregated to ensure there is no cross-contamination.

RESPONSE: COMPLIANT

EVIDENCE:

10.7.1.3 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and areas behind the racks. Storage areas shall be cleaned at a predetermined frequency (refer to 10.2.5.1) and designed and constructed to prevent packaging from becoming a harborage for pests or vermin.

RESPONSE: COMPLIANT

EVIDENCE:

10.7.2 Cold Storage, Controlled Atmosphere Storage, and Chilling of Foods

Cooler temperatures are continuously monitored by a digital system and viewable on cell phones. The system notifies managers if any temperatures are exceeded. Adequate cold storage space is available. Condensate is properly drained. All packaging and dry ingredients are properly stored on racks in the warehouse. There are no wet areas. Equipment storage area allows access for cleaning. Storage areas are properly designed and constructed for hygienic storage. Proper stock rotation (FIFO) is used and expiration dates are checked on raw materials before use.

10.7.2.1 The site shall provide confirmation of the effective operational performance of coolers, controlled atmosphere facilities, and cool rooms. They shall be designed and constructed to allow for the hygienic and efficient refrigeration and storage of food and be easily accessible for inspection and cleaning.

RESPONSE: COMPLIANT

EVIDENCE:

10.7.2.2 Sufficient refrigeration and controlled atmosphere capacity shall be available to chill or store the maximum anticipated throughput of products with allowance for periodic cleaning of storage rooms.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.7.2.4 Cool and controlled atmosphere rooms shall be fitted with temperature and atmosphere monitoring equipment and located to monitor the warmest part of the room and fitted with measurement devices that are easily read and accessible.

RESPONSE: COMPLIANT

10.8.1 Storage of Hazardous Chemicals and Toxic Substances

Daily supplies of chemicals are properly stored in a caged area of the warehouse separated from the processing areas. The area is kept locked to only allow access to authorized personnel. The room is properly ventilated, equipped with first aid and eye wash and spill kit. No risk to food products was observed. Fumigants are stored in a separate building away from all products and other chemicals and is kept locked only accessible to the employee who is licensed to handle pesticides.

10.8.1.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to personnel, product, packaging, product handling equipment, or areas in which product is handled, stored, or transported. Specifically, they shall not be stored inside food handling areas and product and packaging storage rooms.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

10.8.1.3 Hazardous chemical and toxic substance storage facilities shall:

i.Be compliant with national and local legislation and designed so there is no cross-contamination between chemicals;

ii.Be adequately ventilated;

iii.Be provided with appropriate signage indicating the area is a hazardous storage area;

iv.Be secure and lockable to restrict access only to personnel with formal training in handling and use of hazardous chemicals and toxic substances;

v. Have instructions, including up-to-date Safety Data Sheets (SDS), on the safe handling of hazardous chemicals and toxic substances, readily accessible to personnel;

vi.Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility; vii.Have suitable first aid equipment and protective clothing available close to the storage area; viii.In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and

ix.Be equipped with spillage kits and cleaning equipment.

RESPONSE: COMPLIANT

EVIDENCE:

10.8.1.4 Hazardous chemical and toxic substances shall be handled and applied by properly trained personnel. These materials shall be used by, or under the direct supervision of, trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces.

RESPONSE: COMPLIANT

10.8.1.5 The site shall dispose of unused chemicals and empty containers in accordance with regulatory requirements and ensure that:

i.Empty chemical containers are not reused;

ii.Empty containers are labeled, isolated, and securely stored while awaiting collection; and iii.Unused and obsolete chemicals are stored under secure conditions while awaiting authorized disposal by an approved vendor.

RESPONSE: COMPLIANT

EVIDENCE:

10.9.1 Waste Management

The responsibility and methods are outlined in the Waste Management procedure (11.9 reviewed 3/8/2023). Waste is removed daily from the warehouse. No areas observed with waste accumulation. Containers for waste are properly maintained and vehicles and equipment used for waste are properly cleaned. Product waste is adequately contained, held in a separate area, and disposed daily. Daily monitoring of the control of waste materials is performed. Waste water is drained into a pond away from the facility.

10.9.1.1 The methods and responsibilities that describe the effective and efficient disposal of dry, wet, liquid, and solid waste, including inedible material, unusable packaging, and trademarked materials, from the premises shall be documented and implemented.

Reviews of the effectiveness of waste management will be part of the site's daily inspections, and the results of these inspections shall be included in the relevant reports.

RESPONSE: COMPLIANT

EVIDENCE:

10.9.1.2 Waste shall be regularly removed from food handling or processing areas so it does not create food safety risks for finished product and packing operations.

Designated waste accumulation areas shall be maintained in a clean, tidy conditions until external waste collection occurs.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

10.9.1.5 Inedible waste designated for animal feed shall be stored and handled so it does not cause a risk to the animals or to further processing.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.1 Premises Location and Approval

The facility is located in an industrial area of Hillsville, VA. The surrounding area is well maintained. The site is approved with proper licensing. Auditor reviewed Virginia Department of Agriculture and Consumer Services, Food Manufacturer Permit expires 6/30/2023, FDA registration expires 12/31/2024.

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

EVIDENCE:

11.1.2 Building Materials

Surfaces are properly constructed. Product (stainless steel) and non-product contact surfaces are constructed of materials that do not pose a product safety risk. Floors are properly constructed and graded. The waste traps are located outside of the production area near the chemical cage and also one outside of the building on the opposite side from the employee entrances. Walls, ceilings, partitions and doors are properly constructed and maintained. Stairs are properly constructed and maintained.

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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.

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.1.3 Lightings and Light Fittings

The lights throughout the facility were shatter proof. The lighting was sufficient throughout.

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.

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.1.4 Inspection/ Quality Control Area

Inspection areas are provided and suitable with proper lighting.

- 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

EVIDENCE:

11.1.5 Dust, Insect, and Pest Proofing

All doors and windows are adequately sealed to protect against dust and pest contamination. Rodent traps are located away from the processing areas and do not pose a risk to the products. Bait stations are located along the exterior perimeters only.

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.

EVIDENCE:

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

EVIDENCE:

11.1.6 Ventilation

There was adequate ventilation throughout the facility during the audit. The nitrogen freezing tunnel and heating/extraction areas are properly ventilated.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

Food processing equipment, utensils and clothing are properly designed and maintained. All containers for food contact and trash cans are labeled. A color code is in place for utensils: white for food contact, yellow for non-food contact, black for floors and drains. Racks are located at the exit to production for storing smocks when employees go on break.

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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.

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.1.8 Grounds and Roadways

The grounds surrounding the plant are maintained and free from waste and accumulated debris. Surroundings are kept neat and tidy and do not present a hazard to sanitary operations.

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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1 Repairs and Maintenance

Maintenance procedures and responsibilities are outlined in 11.2.9 reviewed 3/8/2023. Preventative maintenance checks from 2022 and 2023 were reviewed including daily, weekly, bi-weekly, monthly checks of equipment and the facility. Equipment failures are documented on Work Order forms. Maintenance staff and contractors follow company GMP policies. Temporary repairs are not allowed. Food grade lubricant is used on all food processing equipment.

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.2.1.7 Food contact equipment and equipment located over food contact equipment shall be lubricated with foodgrade 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

EVIDENCE:

11.2.2 Maintenance Staff and Contractors

Maintenance staff and contractors follow company GMP policies. Preventative maintenance schedules and work orders are prepared to cover equipment, the buildings and facility grounds. Maintenance work order logs include checks for removal of tools and parts and cleaning and sanitizing of the area after maintenance work is complete.

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

EVIDENCE:

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

EVIDENCE:

11.2.3 Calibration

The methods and responsibility for the Calibration Protocol (11.2.11 reviewed 3/8/2023) are defined. The methods and responsibility for addressing disposition of potentially affected product is detailed under procedure 11.2.11. Hold procedure is followed. All equipment is calibrated against reference standards as stated in 11.2.11. Auditor observed calibration records: cooler thermometers (verified with NIST certified thermometer weekly and documented on Thermometer Calibration Log), NIST certified thermometer (issued 1/10/2023), scales (calibrated by 3rd party 2/8/2023), metal detectors (checked hourly during production with standards and validated by the manufacturer at least annually, last on 2/14/2023).

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

11.2.4 Pest Prevention

The Integrated Pest Management (11.2.11 reviewed 3/8/2023) details the methods and responsibility for integrated pest management within the facility. Pest inspections are performed by Strikeforce Pest Prevention Elimination monthly and all records are kept in a binder in the SQF Practitioner's office. Pest control management plan is maintained and includes a labeled site map, approved chemical labels and SDS, inspection reports, and proper licensing. Inspections are conducted by technicians licensed by Virginia Department of Agriculture and Consumer Services, Office of Pesticide Services, Pesticide Applicator Certificate expires 6/30/2023 and Pesticide Business License expires 3/31/2024. Inspection reports are left with the site by the technician after each inspection. Auditor observed pest findings logs and PCO recommendations from 2023. Annual site assessment / IPM Review was last conducted on 2/14/2023 and included system review and recommendations; and trend analysis from 10/19/2022. Fumigants are stored in a separate building, locked and only accessible to the employee who is licensed for pesticide handling.

- **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.

EVIDENCE:

- **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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

11.2.5 Cleaning and Sanitation

Sanitation procedures have been developed and maintained for specific areas. The procedures detail what, how and who is responsible for cleaning each area. Processing equipment and protective clothing are properly cleaned. Verification of sanitation is performed through daily pre-operational inspections. Auditor reviewed cleaning records and pre-op inspection forms from 2022 and 2023. Approved chemicals are purchased from an approved supplier, SDS and inventory are maintained. The chemicals are stored in a locked room separated from production. All chemical containers are properly labeled and properly disposed of when empty.

- 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

EVIDENCE:

- **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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.3.1 Personnel Welfare

Employees are trained on infectious disease concerns in their GMP refresher training and during their new hire training. During the audit, there were no employees observed in production areas who showed signs of infectious diseases. Employees are trained on exposed cuts and lesions in their GMP refresher training and during their new hire training. During the audit, there were no employees observed in the production areas who showed signs of having open wounds or lesions. Use of tobacco, eating, drinking or smoking is not allowed in the production areas. A lunch room is available to employees for eating and drinking.

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

Code Amendment #1

A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.3.2 Handwashing

Employees are instructed to wash their hands before starting and/or returning to work. Observation of employees during the audit noted adherence to the facility hand wash policy. Hand wash sinks are located at the employee entrances, in the bath rooms and break rooms. All hand wash basins are constructed of stainless steel or non-corrodible materials. Hand wash basins are supplied with water, liquid soap, paper towels and a waste container. Signs are available at all wash stations which are legible and prominently displayed in English and Spanish. Gloves are used over clean hands.

- **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

EVIDENCE:

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

EVIDENCE:

- **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

EVIDENCE:

- **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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: MINOR

EVIDENCE: Clean gloves were in open bins directly under a new clock in computer.

ROOT CAUSE: The new time clock had been recently installed and the bins containing the clean gloves where inadvertently put back under the time clock.

CORRECTIVE ACTION: New bins with lids were ordered and the clean gloves put in them. They were also moved to the other side of the table so they are not under the time clock.

VERIFICATION OF CLOSEOUT: auditor reviewed and approved

COMPLETION DATE: 04/28/2023 **CLOSEOUT DATE**: 05/03/2023

11.3.3 Clothing and Personal Effects

Clothing worn by staff is properly maintained, clean and did not pose a risk to the product. Disposable gloves are used over clean hands. The facility does not allow the use of jewelry except medic alert jewelry and plain wedding bands. There was no observation of employees wearing jewelry.

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.3.4 Visitors

Visitors are required to sign-in at the visitor's entrance. Visitors are also required to read and sign the GMP requirements prior to entering the facility. Appropriate clothing and footwear are covered in the requirements. All visitors are required to follow the employee GMP and clothing requirements.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

Staff amenities have sufficient lighting and ventilation to accommodate the maximum number of plant personnel. Change rooms are not required, smocks are worn over personal clothing. Lockers are provided for storing personal items. Showers are not required but are available in the locker rooms. Toilets are adequate in number for the maximum number of staff. Toilets are constructed so that they can be easily maintained and are tidy and clean. They are located in the offices separate from the processing areas. Hand wash sinks are provided inside each rest room. The hand washing sinks are designed and constructed as per section 11.3.2.3. The lunch room is located in a separate building by the employee entrance, separated from the processing areas. It is equipped with refrigerators, microwaves and sink. It was observed to be well lit, maintained and clean. Hand wash signs are posted in English and Spanish.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.4.1 Staff Engaged in Food Handling and Processing Operations

Plant personnel were observed only entering or exiting the facility through the designated employee entrances. Employees have been instructed to keep exterior doors closed when not in use. During the audit, all exterior doors in the production areas were observed to be maintained closed by plant personnel. There were no employees observed wearing false fingernails or fingernail polish in the processing areas of the facility. Trash containers were observed to be properly identified and emptied at a regular frequency. There are no wash down hoses.

- **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

EVIDENCE:

- **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

EVIDENCE:

11.5.1 Water Supply

Adequate supply of water is available. The facility utilizes city water as their potable water supply. There were no cross connections or observed issues that could affect the quality of the water. The facility keeps the city water report on file and sends out samples for potability tests at monthly, last tested 3/30/2023. Back flow prevention devices are were installed and tested annually, last tested on 1/19/2023. The is no non-potable 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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

11.5.2 Water Treatment

Water is not treated.

11.5.3 Water Quality

Adequate supply of water is available. The facility utilizes city water as their potable water supply. There were no cross connections or observed issues that could affect the quality of the water. The facility keeps the city water report on file and sends out samples for potability tests at monthly, last tested 3/30/2023.

- **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

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

11.5.4 Ice Supply

Ice is currently not used.

11.5.5 Air and Other Gasses

Compressed air is used to help remove corn husks. The air is filtered and the filters are checked and changed by maintenance as part of the PM program, last serviced by 3rd party on 2/10/2023. The air is also tested by a 3rd party accredited lab annually, last on 3/20/2023.

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

EVIDENCE:

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

EVIDENCE:

11.6.1 Receipt, Storage and Handling of Goods

All packaging and dry ingredients are properly stored on racks in the warehouse, there are no wet areas. Equipment storage area allows access for cleaning. Storage areas are properly designed and constructed for hygienic storage. Proper stock rotation (FIFO) is used. No alternative storage is used. There is no cold storage.

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

EVIDENCE:

11.6.2 Cold Storage, Freezing and Chilling of Foods

Cooler temperatures are continuously monitored digitally with alarms if temperatures are exceeded. The facility has adequate cold storage areas for products with sufficient space. Discharge from condensate are properly drained.

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

EVIDENCE:

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.

EVIDENCE:

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

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

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

All packaging and dry ingredients are properly stored on racks in the warehouse. There are no wet areas. Equipment storage area allows access for cleaning. Storage areas are properly designed and constructed for hygienic storage. Proper stock rotation (FIFO) is used and expiration dates are checked on raw materials before use.

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

EVIDENCE:

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 predetermined frequency.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Daily supplies of chemicals are properly stored in a designated caged area separated from the processing areas. The cage is kept locked to only allow access to authorized personnel. The room is properly ventilated, equipped with first aid and eye wash, spill kit, and SDS. No risk to food products was observed. No pesticides are stored on site.

- **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.

EVIDENCE:

- **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

EVIDENCE:

- **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

EVIDENCE:

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

EVIDENCE:

- **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

EVIDENCE:

- **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

EVIDENCE:

11.6.5 Loading, Transport, and Unloading Practices

The methods and responsibilities are outlined in the Loading, Transport and Unloading procedures (11.6.5 reviewed 3/8/2023). Loading docks are covered to protect product. Trucks are sealed upon shipping. Transport vehicles are inspected prior to loading and unloading. Shipping and Receiving log is used to inspect loading and unloading of trailers. Trailer inspection records for 2022 and 2023 were reviewed complete and verified. Loading practices are designed to minimize any unnecessary exposure of product to conditions that could potentially affect product integrity, the loading docks are covered.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

11.7.1 High-Risk Processes

The facility is not high risk.

11.7.2 Thawing of Food

No thawing is conducted.

11.7.3 Control of Foreign Matter Contamination

Methods and responsibility for the prevention of foreign matter contamination are documented in 11.7.5 reviewed 3/8/2023. Preventative maintenance and internal audits are performed to ensure plant and equipment remains in good condition. Temporary fasteners are not allowed. The knives and scissors are checked out and collected at the beginning and end of each shift, cleaned and sanitized during sanitation shift and inspected as part of the pre-op. Corn cutting blades are also inspected as part of the pre-op and they are sharpened and replaced by maintenance as needed. A full glass and brittle plastic register is maintained and checked monthly, reviewed from 3/15/2023, 2/16/2023 and 1/19/2023.

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

EVIDENCE:

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

EVIDENCE:

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.

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

All corn is run through metal detectors after being sealed in primary packaging. Metal detectors are checked hourly with 2mm Fe, 2mm NFe, and 4mm SS. Items are placed on hold if any foreign matter contamination is observed. Final disposition will be determined by upper management. The glass and brittle plastic procedure details the procedures to use in the event of glass breakage. The procedure required isolation of the area until cleaning and inspection to assure removal.

Minor: One metal detector was not properly rejecting all products into the reject bin during the metal detector checks observed in the initial audit walkthrough. The timing was immediately adjusted to reject product more accurately into the bin. All tests were properly detecting the test balls and the light and alarm were properly functioning.

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

EVIDENCE:

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

EVIDENCE:

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: MINOR

EVIDENCE: One metal detector was not properly rejecting all products into the reject bin during the metal detector checks observed in the initial audit walkthrough. The timing was immediately adjusted to reject product more accurately into the bin. All tests were properly detecting the test balls and the light and alarm were properly functioning.

ROOT CAUSE: The employee testing the metal detector was turning off the air supply to the plunger before doing the tests. He did this to prevent the test balls from being damaged when they were ejected into to the locked bin.

CORRECTIVE ACTION: The employee (Nathan Edwards, Repack Manager) who performs the tests was retrained to keep the air on so the plunger is properly tested. The test balls will be placed inside the packed item so they are not loose and do not get damaged when the plunger ejects them into the locked bin. Two other repack employees were trained on the testing process as well to serve as back ups to the Repack Manager.

VERIFICATION OF CLOSEOUT: auditor reviewed and approved

COMPLETION DATE: 04/28/2023 **CLOSEOUT DATE**: 05/03/2023

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

EVIDENCE:

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

EVIDENCE:

11.8.1 Waste Disposal

The responsibility and methods are outlined in the Waste Management procedure (11.9 reviewed 3/8/2023). Waste is removed daily from the warehouse. No areas observed with waste accumulation. Containers for waste are properly maintained and vehicles and equipment used for waste are properly cleaned. Product waste is adequately contained, held in a separate area, and disposed daily. Daily monitoring of the control of waste materials is performed. Liquid waste is properly drained.

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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.

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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

EVIDENCE:

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