SQF Food Safety Audit Edition 9

Pure Functional Foods - 16640

Summary

Audit Decision
Certified

Decision Date
May 20, 2025

Recertification Date
April 26, 2026

Expiration Date
July 10, 2026

Issue Date
May 20, 2025

Certificate Number
16640

Audit Type
Unannounced

On-Site Audit Dates
April 2, 2025 - April 3, 2025

ICT Dates
-

Audit Rating

Excellent

Facility and Scope

Pure Functional Foods - 16640

267 State Route 89
SAVANNAH, NY 13146 United States

Products
Hot cocoa mixes, Ingredient premixes, sunflower press cakes, protein flour.; seed oils

Food Sector Categories
19. Food Ingredient Manufacturing
21. Oils, Fats, and the Manufacturing of Oil or Fat-based Spreads

Scope of Certification
Food Ingredient Manufacture; Oils, Fats, and the Manufacturing of Oil or Fat-based Spreads

Certification Body and Audit Team

EAGLE Food Registrations, Inc.

220 E Monument Ave
Suite 510
Dayton, OH 45402-1287 United States

CB#: 40756
Accreditation Body: ANAB
Accreditation Number: 894

Lead Auditor: Greg Bikofsky (C-366202)
Technical Reviewer: Jeffrey Pry (C-366244)

Hours Spent on Site: 18
Hours of ICT Activities:
Hours Spent Writing Report: 8

Section Responses

Audit Statement - Audit

SQF Practitioner Name - Name the designated SQF Practitioner

Response: Viorela Buzica

SQF Practitioner Email - Email of the designated SQF Practitioner

Response: ViorelaB@purefunctionalfoods.com

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

Response: Greg Bikofsky (EAGLE); Lead Auditor, Viorela Buzica; SQF Practitioner, Dale Weed; President, Dana Weed; General Manager.

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

Response: The company is a family owned producer and co-packer of ingredient systems. The site is Gluten Free and packs milled flour from seeds, vegetables and roots. They also blend and co-pack various powder mixes, i.e.. Cake and cookie mixes. The site co-packs bulk and retail products. The site is in the process of bringing in seed oil (into building #2), where they will produce seed oil and also protein powder, which is the bi-product when oil is removed from the seed. The site has three building. The main building #1, in addition to storage, contains milling, powder blending and designated allergen room storage and processing room. Building #2 has a milling and hopes to process seed oils. Building #3, which is about a mile up the road and it is strictly for warehousing. The site generally operates 5 days per week, although they offer an optional four day work week for many of their employees. The hours are staggered, and they are generally open from 6am until 6pm and there are approximately 35 employees between the three buildings.

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

Response: Greg Bikofsky (EAGLE); Lead Auditor, Viorela Buzica; SQF Practitioner, Dale Weed; President, Dana Weed; General Manager, Kate Duvall; Executive Assistant.

Auditor Recommendation - Auditor Recommendation

Response: Recertification is recommended once the nonconformances are remediated.

2.1.1 - Management Responsibility (Mandatory)

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

Response: Compliant

2.1.1.2 - Senior site management shall lead and support a food safety culture within the site that ensures at a

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed the QM 2.1 Management Commitment, reviewed 2.17.2025 (Management Responsibility). The requirements for the food safety policy is described. There is a requirement that it is prominently displayed. The sites policy statement was prominently displayed in a front entrance display case. It was signed by the President on 2.17.2025. The statement affirms the sites commitment to food safety culture, continuous

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improvement, customer requirements, and regulatory requirements. The sites organizational arrangement and specific food safety responsibilities for all levels of management are described. There is a general guide (chart for responsibilities). The Practitioners are defined. Reviewed the HACCP training certifications for the substitute practitioner (3.17.2012), and the HACCP certification for the Practitioner (3.8.2021). Reviewed the job descriptions for the Practitioner and back-up Practitioner. The Practitioner is the sites Compliance Manager an the back-up is a vice-president level officer at the company. The training program was judged to be comprehensive and well documented. Employees received PowerPoint training lessons. The practitioner provided them with quizzes to test their comprehension.

2.1.2 - Management Review (Mandatory)

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: Minor

Evidence: • None of the Management Review records showed that the site reviewed food safety objectives or performance measures.

Root Cause: Food safety objectives and performance measures were not included to the Management Review Form topics to be fully covered.

Corrective Action: The requirement Food Safety Objectives and Performance Measures were defined and added to the QMR 039 (A) to be covered for the next management review.

Verification Of Closeout: The updated Management review template, with performance objectives defined and the requirement to review them were judged to be acceptable.

Completion Date: April 16, 2025 **Closeout Date:** April 21, 2025

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

Summary -

Response: Reviewed QM 2.1 Management Commitment, rev. 2.17.2025 (Management Review). The requirements for conducting Annual management reviews are detailed. The site conducted an annual management review 2.25.2025. The site divided their annual management review into multiple March 2025 meetings. The review includes: food safety culture (covered 3.18.25), non-conformances and corrective actions (3.4.2025), Internal and external audits were reviewed (3.18.2025). Hazard Analysis (3.4.2025). The site also conducts weekly reviews. The site additionally conducts weekly Compliance Review Meetings. Reviewed Compliance Meeting minutes from 1/7, 1/14, 1/21, and 2/4/2025. Topics covered included internal audit findings, GFCO inspections, mock recall, organic review, FDA registration, SQF Assessment registration and payment, semi-annual cleaning and customer complaints. MINOR: 2.1.2.1 - None of the Management Review records showed that the site reviewed food safety objectives or performance measures.

2.1.3 - Complaint Management (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.1 Management Commitment, rev 2.17.2025 (QM 2.1.3 Complaint Management. All complaints are directed to Sales. They used the QMR003 form to document complaints. Reviewed complaint (Oct-Dec 2024), where multiple customers complained about too fine of a mesh size on their Xanthan Gum. Complaint details are documented into the customer Complaint Review report. There were 6 complaints in 2024. The complaints were documented for Quality Issues, Food Safety Issues, and Service issues, using the Customer Complaint Review Report - 2024.

2.2.1 - Food Safety Management (Mandatory)

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed the QM 2.2.1 Food Safety Management System, rev 1/25/2024. It describes the manual in 5 parts, policy statement, org chart, scope of certification, food safety plan and the inclusions of references.

Reviewed the sites organizational chart, last updated 4.1.2025. The practitioner and backup practitioner are identified on the organizational chart. Reviewed the posted policy statement, 2.17.2025 and signed by the owner of the company. The Food safety plan and good manufacturing plans were reviewed and updated.

2.2.2 Document Control (Mandatory)

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

Summary -

Response: Reviewed QM 2.2 Document Control and Records, rev 3.26.2025. The responsibilities are described in a Document Control Responsibilities table. The procedure describes the methods that the site uses for storage (electronic and paper documents). The site keeps a record of document changes on their Records Docs Changes spreadsheet.

2.2.3 - Records (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.2 Document Control and Records, rev 3.26.2025. The responsibilities for senior management, The Compliance Manager, shipping receiving warehouse, purchasing and material handling are described. There are general record keeping practices. The site maintains a master signature sheet to be used to cross reference signatures/initials. All records reviewed were judged to be well designed and used. During numerous times during the site inspections, employees conducting monitoring were asked to describe the methodology used. Documents were observed being brought to the location of the monitoring and completed contemporaneously, including the Receiving/Shipping Supervisor who demonstrated the Bizowie system, PO Receiver doc (incoming), and the Sales Order Form (outgoing). The maintenance Supervisor demonstrated the Maintenance Request and Hand Over Form, and the Preventative Maintenance Checklist. The R&D Supervisor demonstrated the R&D Bill of Materials Recipe and R&D Batch Sheet. The non-allergen Production area Operator demonstrated the Pre-Operational Inspection Record.

2.3.1 - Specification, Formulation, and Realization

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 2.3 specification, Formulations, Realization and Supplier Approval, rev. 3.27.2025. (QM 2.3.1 Product Formulation and Realization). Product Development is separated into five phases. Each one has responsibilities and requirements which must be met. There is a list of four "MUST NOTs". There is a requirement for conducting shelf-life trials. There is a chart for standard shelf life for different types of product. The procedure includes a water activity chart which is used as a reference. There is a small R&D laboratory in building #3, which the President attested will be a new concept development laboratory and managed by him. The primary R&D Laboratory is in Building #1. The R&D Laboratory Supervisor described the R&D process. Reviewed the "scale-up", documented on the R&D Bill of Materials (recipe). and for documenting laboratory scale development, they use the R&D Batch Sheet. Reviewed a new product development packet for Banana Bread, including specification Feb 2024, incl. customer, Formula, packaging and customer shelf life. The requirements for Finished Product specifications (order of priority) are described. There is a register of finished product specifications for AP Flour. Reviewed AP Flour specification, which included particle size, metal detection, gluten, allergens, GMO, and certifiable as kosher.

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

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed the 2.3 specification, Formulations, Realization and Supplier Approval, rev. 3.27.2025. There is a requirement for approving specification for all raw materials (ING and PKG). Raw Materials: reviewed BC Foods coffee specifications. There is a requirement for verifying specifications with COAs with each shipment. Reviewed the COA from 3.5.25 for BC Foods Coffee ING7003. The requirements for Finished Product specifications (order of priority) are described. There is a register of finished product specifications for AP Flour. Reviewed AP Flour specification, which included particle size, metal detection, gluten, allergens, GMO, and certifiable as kosher and non-go. Reviewed Contract Service Provider register. All of the contract service providers were re-approved 3.12.2025.

2.3.3 - Contract Manufacturers

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

Response: N/A

Evidence: • Not Applicable: Contract Manufacturers are not used by this site.

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

Response: N/A

Evidence: • Not Applicable: Contract Manufacturers are not used by this site.

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

Response: N/A

Evidence: • Not Applicable: Contract Manufacturers are not used by this site.

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

Response: N/A

Evidence: • Not Applicable: Contract Manufacturers are not used by this site.

Summary -

Response: Not Applicable: Contract Manufacturers are not used by this site.

2.3.4 - Approved Supplier Program (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 2.3 Specification, Formulation as, realization and Supplier Approval (GM 2.3.4 Approved Suppler Program. The methods and responsibilities for approving suppliers are described. Reviewed the Supplier Register, which includes the suppliers name , risk level , Approval status and date of review. The site uses Compliance Network to manage supplier approval. The Compliance Manager and Purchasing coordinates to review and approve suppliers. All approval documents are kept in Compliance Network. Suppliers are required to complete a questionnaire Required documents include: specification, (shelf life, storage), nutritional, Certificate of insurance, continuing guarantee and food fraud prevention program. All suppliers were reviewed 4.1.2025. Reviewed approval records for: American Instants, incl. specifications. Expired (4.24.25) SQF certification, Ardent Mills (packaging) BRC audit 9.17.2025, Fiber Smart FSSC, exp. 11.17.2026.

2.4.1 - Food Legislation (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.4 Food Safety Systems, rev 3.27/2025. The methods for complying with regulatory requirements are described. The practitioner and the backup practitioner are responsible for keeping up to date with regulatory requirements through FDA notifications. The procedure includes the requirements for contacting SQFI and the CB in writing.

2.4.2 - Good Production Practices (Mandatory)

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.4 Food Safety Systems, rev 3.27/2025. The site list exemptions for: 11.4.1.4 Sensory evaluation, 11.5 water is not used as and ingredients (but it is used for sanitation). Ice is not used, 11.6.2 No cold or frozen storage, 11.7.1 No kill step, 11.7.2 No thawing is required. The procedure requires a risk assessment and exemption request. Reviewed the risk assessment for the wood ceiling and exposed wooden walls in building #3, 3.25.25. The QMR 011 Department annual Cleaning Record includes the cleaning and cleaning inspection of the walls and ceiling. Reviewed inspection records from 2.6.2025.

2.4.3 - Food Safety Plan (Mandatory)

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

required to cover all products included in the scope of certification.

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

2.4.3.10 - Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the

process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.4 Food Safety Systems, rev 3.27/2025. The site has a chart with their Food safety plan requirements listed and numbered. Reviewed QM 2.4.3.2 Food Safety Plan (packing) rev 03.18.2025. PFF Milling Line Food Safety. The metal detection is the only CCP in each plan. There are also 12 PCs identified. Reviewed QM 2.4.3.2 Food Safety Plan Risk Assessment rev 3.26.2025, which includes biological, chemical and physical hazards for each processing step. The HACCP spreadsheet includes a "master plan" which describes the hazards, the critical limits, the monitoring methods, responsibilities and the records. The QM 2.4.3.2 Food

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Safety Team Members assigns the HACCP team members. Reviewed the QM 2.4.3.2 HACCP Plan Part 3: Product Profile and Descriptions Rev 3.26.2025, which describes the product, the microbiological profile, the shelf life and the storage conditions. Reviewed the flow diagram Savannah QM 2.4.3.2, Bending. The site has a food safety plan from their Binghamton location. Reviewed the metal detector (CCP 1) monitoring records (initialed and verified) from 12.24.24 - 3.12.25 (line B). Reviewed the metal detector record (initialed and verified) from 1.7.25 - 3.4.25 (line Z). Reviewed the metal detector records (initialed and verified) from 1.7.25 - 3.13.25 (line A). Reviewed environmental allergen monitoring 3.5.25 - 3.13.2025. Reviewed the PC 4 allergen test records were spot checked in the WO QC entries form, in their R&D laboratory computer from August 2024 - March 2025.

2.4.4 - Product Sampling, Inspection, and Analysis

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.4 Food Safety Systems, rev 3.27/2025. Sampling, inspection and analysis is under

the responsibilities of QC and the Compliance Manager. The site uses COAs and specifications to ensure that raw materials meet with specifications. The site uses a 3rd party laboratory for all microbiological analysis. Reviewed the Biotrax Testing Laboratory's (environmental and compressed air) ISO certification, exp 1.31.2026. Reviewed New York State Department of Health (water testing), expires 4.1.2026. Reviewed JLM (microbiological) ISO certification exp. 10.31.2025. Reviewed COAs E.coli, Listeria monocytogenes, and Salmonella analysis. Reviewed COAs from 6.25.2024 - 9.4.2024. Reviewed Eurofins (gluten testing kits), exp. 8.31.2026. Reviewed compressed air testing results from 7.25.24 (Milling Line, Allergen, Mixing and Packing lines. The laboratory conducts gluten allergen analysis using an Hygiena allergen test kit, on swabs, as required by one of their customers that makes an allergen-free claim. The on-site laboratory is primarily used for R&D, but they also conduct gluten and allergen analysis. Reviewed GFCO Proficiency Testing 3.18.25 for the Practitioner and the R&D Supervisor. The products produced have a shelf life from 12 to 24 months. Two retention samples are taken from each batch and held in the retain area for the duration of the shelf-life.

2.4.5 - Non-conforming Materials and 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

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

Summary -

Response: Reviewed QM 2.4 Food Safety Systems, rev 3.27/2025. The procedure describes the use of their Bizowie Receiver system to document the inspection or product and equipment. The procedure includes a numbered nonconformance process flow. The Practitioner maintains an Unusual Log/NC Product to keep records of breaches, non-conforming product, CAPAs and process deviations. Reviewed records from 5/31/2024 - 3/12/2025. Reviewed the out of service bag sewer from 3.10.2025, recorded on the QMR 038 (a) Non-conformance Report Form EQP Failure form. Reviewed the Compliance Manager dashboard 2025, which is used for tracking test & hold and hold investigation products. Reviewed records from 5.28.2024 - 3.26.2025.

2.4.6 - Product Rework

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

Summary -

Response: Reviewed QM 2.4 Food Safety Systems, rev 3.27/2025. The QM 2.4.6 Rework subsection includes a definition of rework, recoup, re-process, and Re-Bagging (poor seal or partial bags/boxes). It was attested by the Operations Manager, they no longer top off partially filled bags with the next runs production under any circumstances. All of their clients no take partially full bags from the end of each production run. Reviewed the process steps for product rework. The responsibilities and Methods are described. The site uses QMR 030 Rework-Repack Record rev 11.23.2013.

2.4.7 - Product Release (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.4 Food Safety Systems, rev 3.27.2025. The procedure describes the "types" or product release. The procedure describes Product Release gatekeepers steps, were "required criteria must be met before moving to the next step, including: Bake and Gluten Tests for release from Mixing to Packing, signing of Travelers Paperwork, signing of mixing batch sheet "final inspection", shelf stable products, and release of hold. the Compliance Manager dashboard 2025, which is used for tracking test & hold and hold investigation products. Reviewed records from 5.28.2024 - 3.26.2025. Reviewed a work order from 3/28/25, for 6-12 oz MBB Double Chocolate Cake Mix, which included the required release initials.

2.4.8 - Environmental Monitoring

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

Response: Compliant

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

locations as needed; and iv. Describe the methods to handle elevated or undesirable results.

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.4 Food Safety Systems, rev 3.27.2025. The QM 2.4.8 Environmental Monitoring subsection includes a breakdown of the environmental monitoring requirements, including the use of ATP swabs, pathogen swabs COA from 7.21.2024. Pathogen swabs are taken annually by the SQF Practitioner. Reviewed SOP QA005 Environmental Swabbing Testing procedure, which details the work instructions for taking environmental monitoring swabs and preparing samples for laboratory analysis. Reviewed the Practitioners Microbiological Laboratory Technician training certificate from 3.16.2016. Risk factors are imbedded into the procedure. Salmonella is identified as the "primary pathogen" of concern. The risk level is assessed as "low". Pathogen swabbing zones are described. Corrective actions for "positive" results are described, including the requirements for re-swabbing.

2.5.1 - Validation and Effectiveness (Mandatory)

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

Summary -

Response: Reviewed QM 2.5 System Verification, rev 3.27.2025. The QM 2.5.1 Validation & Effectiveness subsection describes the requirements for validating the HACCP plan and critical limits. Meeting the "Required Criteria" includes the PRPs, critical limits and management of changes. Reviewed the Milling Line QM 2.4.3.2 HACCP plan Part 9 - HACCP Validation, Rev 04.01.2025. Reviewed the calibration certificates for the test wands for the three test balls for the metal detector from 1/1/2022. Reviewed the Select Field Service, Inc calibration of the metal detector from 10.3.2024. Fe2.0, nfe2.0, 2.5ss. The site uses the CFR limits 7.0mm as a justification and validation for their current metal detection limits.

2.5.2 - Verification Activities (Mandatory)

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

Response: Compliant

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

maintained.

Response: Compliant

Summary -

Response: Reviewed QM 2.5 System Verification, rev 3.27.2025. The QM 2.5.2 verification subsection includes responsibilities, frequency and Methods for verifying different elements of the program. The 2024 Program Verification and Validation records from 3.31.2025 details the actual verification and validation activities that were conducted including the verification and validation of: Personal Practices, Training, Management of Pests, Maintenance, Cleaning and Sanitation, Supplier Approval, Transportation and delivery, Waste Management, Allergen Control and HACCP, Customer Complaints.

2.5.3 - Corrective and Preventative Action (Mandatory)

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.5 System Verification, rev 3.27.2025, QM 2.5.3 Corrective ad Preventative Action subsection describes the methods and responsibilities for documenting corrective actions. The Practitioner maintains an Unusual Log/NC Product to keep records of breaches, non-conforming product, CAPAs and process deviations. Reviewed Unusual Log records from 5/31/2024 - 3/12/2025. Reviewed the out-of-service bag sewing machine from 3.10.2025, recorded on the QMR 038 (a) Non-conformance Report Form EQP Failure form.

2.5.4 - Internal Audits and Inspections (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.5 System Verification, rev 3.27.2025, QM 2.5.4 Internal Audit. The methods and responsibilities are described. Reviewed the SQF Practitioners Internal Audit certification from 3/18/2024 from SCS Global. The practitioner conducts an annual internal audit of the following processes and practices: GMPs - employee hygiene, breakroom/bathroom, clothing, illness reporting and first aid (6/26/24); Training (7/30/24); Calibration (8/29/24), Pest Prevention (9/30/24), Maintenance (11/4/24), cleaning and sanitation (11/25/24), water/air supply(12/23/24), Physical contaminants (1/28/25), Supplier Approval (2/27/24), Transport and Delivery (3/12/2025). The Practitioner additionally uses the SQF Manufacturing checklist (2/13/25-3/14/25) as part of the internal audit. The Practitioner conducts bi-weekly GMP inspections, which includes hygiene, doors closed, exterior loading dock litter, restrooms (5/2024 - 2/2025).

2.6.1 - Product Identification (Mandatory)

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 2.6 Product Traceability and Crisis Management, rev. 2.1.2024. The 2.6.1 product Identification describes the identification process for Part identification, batch material gathering, mixing, and packing, milling, pressing, and warehousing. There are charts for FIN, ING, PKG, WIP and labeling. The structure of the code numbering is described.

2.6.2 - Product Trace (Mandatory)

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

Summary -

Response: Reviewed 2.6 Product Traceability and Crisis Management, rev. 2.1.2024. The subsection for 2.6.2 Product Trace includes the responsibilities & methods. It details the primary records including the PO Receiver and Shipping Records, Bizowie Inventory adjustment records, , electronic Breach register, red material usage register, mixing batch sheet, packing batch sheet, electronic label printing and verification worksheet, electronic or-tap record, pressing batch paperwork. The method for defining lots are described.

2.6.3 - Product Withdrawal and Recall (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 2.6 Product Traceability and Crisis Management, rev. 2.1.2024. Reviewed the subsection

2.6.3 Product withdrawal and recall. The responsibilities and methods are described. There are steps for investigation described in a chart. There is a recall flow diagram described. Reviewed the mock recall 12.7.5 oz Good Dee's GF Low Carb Brownie Mix, lot # FIN1827 21NOV2025B1. (Produced May 21, 2024). Produced 1009 lbs. Reviewed the batching records, the WIP packing records. Reviewed the Sales Order#3035, 5.23.24. Reviewed the loss. The Practitioner showed the Mock Recall summery 1/8/2025. It includes the summery of the investigation internal notification, external notification, documentation, and follow up.

2.6.4 - Crisis Management Planning

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 2.6 Product Traceability and Crisis Management, rev. 2.1.2024. Reviewed the 2.6.4 Crisis Management Planning subsection. The procedure lists the known risks from natural disasters like "wild fires" and from Local/Structural, including "fire" and "drain back-up". The responsibilities or Senior Management and responsibilities and contact information for the Crisis Management Team are described. The requirements for creating a risk assessment and yearly test are described. There is a list of emergency contacts, including regulatory, legal and the sites SQF certification body. Reviewed the sites crisis test, which was conducted on 3/13/2025. The mock crisis was for a power outage that lasted 5 days. The exercise includes immediate and short term actions, as well as long term actions. The exercise included a summery, root cause and disposition or affected product.

2.7.1 - Food Defense Plan (Mandatory)

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

Response: Compliant

2.7.1.2 - A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum: i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of

sabotage or terrorist-like incident; ii. The name of the senior site management person responsible for food defense; iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points; iv. The methods implemented to protect sensitive processing points from intentional adulteration; v. The measures taken to ensure the secure receipt and storage of raw materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents; vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, and finished products are held under secure storage and transportation conditions; and vii. The methods implemented to record and control access to the premises by site personnel, contractors, and visitors.

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 2.7 Food Defense and Food Fraud, rev 2/1/2024, subsection 2.7.1 Food Defense Plan. The procedure includes scope, and the designation of a "Threat Team". Potential threat sources are identified. Methods to verify and record the program are described. The requirements for visitors and contractors are described. Visitors are required to be escorted at all times, with the exception of the pest control operator and contractors that have undergone food safety training. Reviewed Food Defense test completed 3/18/2025. The test included an attempt by a non-employee to access each building #1, #2, #3. The test included a check that the person was not permitted to enter the building without an escort and it included a check of the security cameras. Reviewed the food defense PowerPoint presentation. The sites provides employees with a food defense quiz. The training records are maintained in the SQF Training Matrix. The training dates for all employees were conducted between 3.12.2025 - 3.20.2025, according to the matrix.

2.7.2 - Food Fraud (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 2.7 Food Defense and Food Fraud, rev 2/1/2024, subsection 2.7. Food Fraud. The procedure included an assessment of food fraud likelihood, conditions for food fraud, food fraud risks and identified raw materials. The procedure included Pre-Emptive Controls, and Post-Event Controls. The procedure includes the management of Food Faud Allegations from outside parties. Reviewed the sites Compliance Manager Dashboard 2025, which includes a food fraud assessment of each raw material that the site uses. The site requires a Food Fraud statement from suppliers that provide high food fraud risk items. The site also requires continuing guarantees from each supplier. Reviewed the Food Fraud statement from Parker Flavors, 4.4.2023. Reviewed letter of guarantee from Parker Flavors 1.7.2025. The Food Defense/Food Fraud plan was last reviewed 3.27.2025.

2.8.1 - Allergen Management (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.8 Allergen Management, subsection 2.8.1 Allergen Management, which describes the site as a gluten free facility. The responsibilities are described for the Compliance Manager (SQF Practitioner), R&D Production (Scheduler) HACCP Team, supervisors and the sites personnel. The procedure includes a risk analysis, methods for verification of allergens. The site identifies allergens in their register, which is identified in the procedure. The site uses line segregation to separate allergens from non-allergens and they use a change-over procedure for cleaning in between unlike allergens. The procedure includes management of rework. Review the allergen PowerPoint training, and reviewed allergen training that was conducted on various days during March 2025. Reviewed the allergen SOP for allergen testing, which was signed by the technician 3.25.2025. Reviewed the SOPs for the AlerTox-Sticks (peanut, fish, egg, multi-tree nut, milk, coconut, soy. It was stated that the site is aware that coconut was removed by the FDA as a Big 9 allergen, but the site still segregates coconut as a non-Big 9 allergen. Allergens are identified with a label. All allergens are stored in the "allergen room". Reviewed the QM 2.8a Gluten Management procedure, rev 3.27.2025 and includes responsibilities and a gluten risk analysis. The procedure includes requirements for verification, training, identification, segregation and line cleaning. Reviewed the QM 2.8b Allergen Testing Plan, 3.27.2025. Reviewed the January/February 2025, in-house allergen testing from 1.3.2025 - 2.18.2025. Reviewed the Eurofins allergen test results from 11.21.2024.

2.9.1 - Training Requirements

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.9 Training, rev. 3.27.2025, and subsection 2.9.2 Training Program. The procedure includes the requirements for the sites training program, HACCP training. The procedure includes the requirements for First (orientation training) and retraining. The procedure includes the requirements for maintaining a training skills register.

2.9.2 - Training Program (Mandatory)

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 2.9 Training, rev. 3.27.2025, and subsection 2.9.2 Training Program. Reviewed training records for the site, which includes names, dates and quiz scores for training provided. Reviewed records form GMP training, Allergen, Equipment Cleaning, Food Defense, Gluten, GMP, HACCP, Pest Control, Receipt Storage and Transportation, record verification, waste Management, Organic training and Chemical Training. Reviewed the PowerPoint training presentations for food defense, allergen and chemical use

training. The training includes safe handling, storage and dilution of bleach. The procedure includes spill clean-up instructions.

11.1.1 - Premises Location and Approval

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

Summary -

Response: Reviewed the building #1 site map which depicts the GMP areas and process flow. The map identifies the Allergen Room, the different production rooms, the lab, breakrooms, employee entrance and bathrooms. Reviewed the Ag Markets site certificate dated, 5.23, 2024, #xxxxxxx5951. Maintenance conducts a monthly inspection, which includes the exterior of the facility. The Practitioner conducts a bi-weekly inspection which includes the exterior of the loading and unloading area.

11.1.2 - Building Materials

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: All of the rooms have smooth concrete floors. The walls in the non-production rooms were constructed of painted block. Production rooms walls were constructed of metal-type panels. The production area ceilings are metal panel-type with flush mounted lighting. The storage area ceilings were constructed of wooden planks and beams. The interior non-production ceilings were observed to be clean, sturdy and free of damage. Overhead lights were mounted/suspended from the rafters. The site inspects the ceiling on a regular basis and describes the risks and risk mitigation in a documented risk assessment. The floors were sloped toward floor drains. The practitioner attested that there is no waste trap in the facility. Ducting, sprinkler pipes and other overhead structures were judged to be clean and well maintained. All man-doors and overhead doors were judged to be solidly constructed and were free of gaps when closed.

11.1.3 - Lightings and Light Fittings

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: The overhead lights in each of the three buildings were either covered LED or covered florescent. All of the lights were judged to be working and the production and storage areas were well illuminated. The production area lights were flush mounted. The storage lights were suspended, but low profile and were judged to not likely be impacted by the movement of inventory or other routine product handling practices. Some of the light fixtures in the warehouse had pull chains. The pull chains were considered in a risk assessment.

11.1.4 - Inspection/ Quality Control Area

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: N/A

Evidence: • Not Applicable: There are no inspection areas near the production lines.

Summary -

Response: Not Applicable: There are no inspection areas near the production lines.

11.1.5 - Dust, Insect, and Pest Proofing

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: All exterior man-doors and dock-doors were observed to be completely sealed when closed. Exterior man-doors are sturdy, heavy and self-closing. Loading bays had dock seals and or "extender" covers to prevent contaminants during loading and unloading. The insect light traps in each of the buildings were situated away from open product, packaging and equipment.

11.1.6 - Ventilation

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: None of the buildings utilize exhaust fans. The site uses circulating fans to move air within the facility. The air systems are services on the sites preventative maintenance plan. The plan and the service conducted in provided internally and was explained during the maintenance supervisor interview.

11.1.7 - Equipment and Utensils

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

11.1.7.9 - Non-conforming equipment shall be identified, tagged, and/or segregated for repair or disposed of 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: Minor

Evidence: • The facility has numerous held pieces of equipment in a designated storage area in building #3. The equipment came from their Binghamton location over a year ago. It was attested that some of the equipment can be used at this site, but some of the equipment is designated for auction and some cannot be used at the site, according to site management. The equipment includes conveyors, printers, forklifts and cabinets. Much of the equipment was judged to be dusty. The site has a three page inventory list, with "Equipment Number" and "Equipment Description" but it is undated and equipment is not designated for "return to service", repair or disposal on any record.

Root Cause: The equipment was brought up when the Milling Line from the Binghamton location was closed. Most of the items are stored there for back up equipment or parts.

Corrective Action: The Inventory list was updated and the equipment was designated for its intention. Some items are designated as return to service, some for disposal, some for repairs and some were listed for sale. The room is periodically inspected by maintenance and pest control is verifying the pest traps every two weeks.

Verification Of Closeout: Root cause and corrective action were judged to be acceptable.

Completion Date: April 22, 2025 **Closeout Date:** April 23, 2025

Summary -

Response: Reviewed QM 11.1 Site Location and Premises (Equipment Purchase Procedure). The methods for purchasing and modifying equipment are described. Equipment was judged to be well maintained and constructed of stainless-steel type material. Belts and hoses were constructed of material that was judged to be commonly used in food production operations. There is an SSOP for the cleaning of all of the equipment and utensils in the production areas for each building. The forklifts and pallet jacks are checked prior to use. The pallet jack inspection sheets are kept on a clipboard. The forklift checklists are attached to the machine. Reviewed the completed checklist on one of the Raymond standup forklifts in building #2. MINOR: 11.1.7.9 - The facility has numerous held pieces of equipment in a designated storage area in building #3. The equipment came from their Binghamton location over a year ago. It was attested that some of the equipment can be used at this site, but some of the equipment is designated for auction and some cannot be used at the site, according to site management. The equipment includes conveyors, printers, forklifts and cabinets. Much

of the equipment was judged to be dusty. The site has a three page inventory list, with "Equipment Number" and "Equipment Description" but it is undated and equipment is not designated for "return to service", repair or disposal on any record.

11.1.8 - Grounds and Roadways

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.1 Site Location and Premises (Grounds and Roadways). Each building had a minimum of 15' exterior perimeter that was observed to be free of over-grown vegetation or clutter. Stored building material was neatly stacks. The Practitioner conducts bi-weekly GMP inspections, which includes checking for exterior loading dock litter (5/2024 - 2/2025). Maintenance conducts a monthly exterior inspection monthly. Reviewed inspections from building #1 and #2 from 2.10.25 and 3.20.25. Reviewed inspection of Building #3 from 6.12.24 and 10.14.24.

11.2.1 - Repairs and Maintenance

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.2 Site Operation., rev 3/25/2025 (Repairs and Maintenance). The methods and responsibilities (Compliance Dept, IT, Production, and Maintenance Supervisory) for conducting maintenance are described. The requirements for maintenance staff and contractors are described. There are documented instructions for managing Maintenance Requests/Breakdowns, and there is a chart that shows the step-by-step for the Maintenance Process Flow. The requirements for GMPs, communication and product safety is described. The requirements for temporary repairs are described. The procedure includes a risk assessment for "core items", which are divided into three categories.. The requirements for the sites preventative maintenance plan is described. The requirements for using and storing food grade lubricants are described. Interviewed the Maintenance Supervisor in the Maintenance Office. Reviewed the maintenance chemical storage and use. He demonstrated his computer Access-type program for scheduling maintenance. Past due maintenance automatically turns "red" and completed maintenance turns "green". Reviewed completed QMR 002 Maintenance Request and Area Equipment Handover Form, which is used for "requested" maintenance. Reviewed records from 2.18.25 - 3.17.25. The records were completed, signed by the operator and verified. Reviewed the Preventative Maintenance Checklist Form, which is used to document preventative maintenance. Reviewed records from 7.18.2024 - 4.22.2025.

11.2.2 - Maintenance Staff and Contractors

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.2 Site Operation., rev 3/25/2025 (Repairs and Maintenance). The requirements for maintenance contractors are described. There is a requirement to escort contractor maintenance employees. The Maintenance Supervisor stated that maintenance forms are completed for outside contractors conducting maintenance on-site. The maintenance records include a requirement to remove tools and debris from the site post maintenance and prior to verification.

11.2.3 - Calibration

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.2 Site Operation., rev 3/25/2025 (11.2.3 Calibration). The methods and responsibilities for calibration are described. The policy for managing equipment failures, damage and unauthorized instructions are described. The requirements for creating a calibration schedule is described. Scales are calibrated annually by Wayne County, Dept of Weights and Measures - consumer affairs. One platform scale was calibrated 8.2.2024 and fifteen scales were calibrated on 10.2.2024. The metal detectors

were last checked by a third party contractor on 10.3.2024. Scales are checked by the site on a daily bases using a calibration weights. The checking of scales was demonstrated by the Operations Manager during the Pre-Operations inspection.

11.2.4 - Pest Prevention

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.2 Site Operation., rev 3/25/2025 (Pest Control). The methods and responsibilities

are described. Target pests and method of preventions are identified. The requirement for verifying a site map and list of approved chemicals are described. The requirements for the pest control contractor practices are described. The site uses Platinum Pest Control as their 3rd party pest control contractor. They manage interior rodent stations, exterior bait stations, insect light traps and pheromone traps. Reviewed the PCOs certificate of liability, exp. 3.8.2026. There is an IPM Service Agreement, 1.1.2025. Reviewed the NY State business license, exp. 8.31.2026. Reviewed the license of the technician, exp. 1/21/2026, the supervisor, exp2/21/2028, the owner, exp. 4.21.2026. Reviewed the GMP training certifications for the technician and supervisor, dated 10.14.2024. Reviewed the pest control map, which includes the (mechanical, bait, ILT and pheromone traps, dated 10.2.2024. Reviewed the pest control map against sites randomly noted during the audit of each building. Reviewed service reports from 1/21/2025 - 3.19.2025. Reviewed signed Approved pesticide list, November, 2024.

11.2.5 - Cleaning and Sanitation

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Minor

Evidence: • In the Building #2 Milling Room, there were numerous stored sanitation tools, hanging on wall hooks in the Milling Room, where the handles were wrapped with duct tape or clear packing tape. Including a black broom that had clear packing tape and a long handled tool that was wrapped with duct tape. There was also a long wooden handled brush stored with the cleaning tools.

Root Cause: Milling Line sanitation tools are mostly made up with used tools left from the other milling facility that got moved from Binghamton to Savannah. An employee tried to use the long handle for reaching out the corners/ceiling to clean the dust by connecting two handlers with duct tape.

Corrective Action: The employees were instructed not to use tape on any tools/equipment, and all the cleaning tools were inspected, cleaned and the worn out cleaning tools or wooden handles were disposed of.

Verification Of Closeout: The root cause and corrective actions and photo evidence were judged to be acceptable.

Completion Date: April 22, 2025 **Closeout Date:** April 23, 2025

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.2 Site Operation., rev 3/25/2025 (Cleaning and Sanitation) The Methods and responsibilities are described. The Compliance Manager is responsible for monitoring and validating the sites cleaning records. The methods for dry cleaning methods and wet cleaning methods are described. Thee methods for using and storing of cleaning chemicals are generally described. Reviewed SSOP 101 Mixing Area Equipment Cleaning, rev 3.18.2025, which reviewed mixing area cleaning types, Quality Clean, Certification Clean and Food Safety Clean. The procedure including interior and exterior of equipment, including tools Reviewed the SSOP 103 Cleaning and Sanitation of Departments,, 3.18.2024 which describes general cleaning of the floors, garbage pails, and racks. There is a general inspection/cleaning/restocking procedure for the bathrooms. The chemical training includes dilution instructions for bleach as a sanitizer. It was attested that the site typically uses Purell sanitizer, which is purchased pre-blended. The site typically uses a dry cleaning method, except when change over from allergens. The production areas have adjoining wash rooms for cleaning, and drying equipment. The QMR 011 (a) Cleaning and Sanitation Master Schedule, rev 2/17/25,

includes the frequency and methods for cleaning the floors, stairs, break rooms, and bath rooms. Reviewed OS-0003 Cleaning and disinfecting Bodily Fluid Spills. During the pre-op, and operator demonstrated how it was completed and recorded Non-Allergen Production area, using the QMR 011 Pre Operational Inspection Record. The Operations Manager demonstrated the QMR 011 Pre-Operational Inspection Record - Warehouse. Both checklists require a cleanliness inspection. MINOR: 11.2.5.5 - In the Building #2 Milling Room, there were numerous stored sanitation tools, hanging on wall hooks in the Milling Room, where the handles were wrapped with duct tape or clear packing tape. Including a black broom that had clear packing tape and a long handled tool that was wrapped with duct tape. There was also a long wooden handled brush stored with the cleaning tools.

11.3.1 - Personnel Welfare

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. Medical Amendment added: Code Amendment #1A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.3 Personnel Hygiene and Welfare. (11.3.1 Personnel Welfare). The program includes the sites policies for minimizing the risks of contamination of food and food contact surfaces from personal hygiene and wounds and other sources of bodily fluids. Employees with symptoms of communicable diseases are required to notify their supervisors. The policy includes the requirement for employees with hand cuts to wear blue metal detectable bandages.

11.3.2 - Handwashing

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

Response: Compliant

11.3.2.2 - Handwashing stations shall be provided adjacent to all personnel access points and in accessible

locations throughout food handling and processing areas as required.

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.3 Personnel Hygiene and Welfare. (11.3.2 Hand washing). The policy requires that employees wash their hands prior to entering the processing areas and throughout the day. Each processing room has a small, stainless steel handwashing stations inside the entrance of the room. The handwash sinks are hands free, have blendable hot and cold water. There is wall mounted soap and paper towel dispensers, and trash pails at each hand wash station. There are also hand wash stations at each breakroom and toilet room. Signage, reminding employees to wash their hands are located at each station. The procedure includes the requirement for gloves, hair and beard nets.

11.3.3 - Clothing and Personal Effects

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.3 Personnel Hygiene and Welfare. (11.3.3 Clothing and Personal Effects.). The policy includes a description of permitted and prohibited clothing. Clothing was judged to comply with the sites documented clothing policy. Color coded hair nets are required in allergen production areas. The employees were observed complying with the sites hygiene and jewelry policy. Lockers are provided to all employees for the storage of jackets and personal items.

11.3.4 - Visitors

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.3 Personnel Hygiene and Welfare. (11.3.4 Visitors). It requires that visitors are escorted while in the facility. Visitors are required to sign in and out. They are required to wear hair nets, beard nets and remove all jewelry. Visitors are required to remove hairnets when they go outside and wear a new one upon re-entry.

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

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

beverages if required; and v. Kept clean and free from waste materials and pests.

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.3 Personnel Hygiene and Welfare. (11.3.5 Staff Amenities (changing rooms, toilets, break rooms). The site requires hair nets, beard nets. Lockers are used for personal belongings. Locker rooms are available to employees for storing personal items. The site has determined that none of their processes are high risk. There were numerous toilet rooms available Each toilet room had a sink, wall mounted soap and paper towel dispensers. Each one was maintained in a clean and fully stocked condition. Reviewed QMR 011(b) Cleaning and Sanitation Master Schedule, which describes the daily cleaning of the employee break and bathrooms. The breakrooms had tables, refrigerators, microwave ovens and ware-wash sinks. They were maintained in a tidy condition.

11.4.1 - Staff Engaged in Food Handling and Processing Operations

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; v. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor.

Response: Compliant

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

Response: Compliant

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

Response: Compliant

11.4.1.4 - In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone,

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

Response: Compliant

Summary -

Response: Reviewed 11.4 Personnel Processing Practices, rev 3.25.2025, 11.4.1 Staff Engaged in food Handling and Processing Operations. The procedure includes a chart with requirements for employees to enter through the proper doors, handling product and packaging, and handling waste and hoses. Building #1/#2 and Building #3 has a trash and carboard dumpster. All washdown hoses and compressed air lines were hung off of the floor on a hook. The policy describes the requirements for personal processing practices, including drinking water, hair and beard restraints. Employees were consistently observed complying with the required practices. Reviewed the building #1 site map which depicts the GMP areas and process flow. The map identifies the Allergen Room, the different production rooms, and the employee entrance. The site doesn't require in-process sensory evaluation. Sensory evaluation is only conducted on finished and prepared product. The R&D laboratory prepares product for sensory evaluation, which is conducted in the large meeting room next to the laboratory.

11.5.1 - Water Supply

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Minor

Evidence: • Potable water is brought from building #1/#2 in a tank, where it is used in building #3. There is no method for cleaning the water tank and there are no records that the tank was ever cleaned or that the water is tested in building #3 to determine if the storage tank or water lines are contaminating the water before it is used in building #3.

Root Cause: Before refilling, the water tank was visualy inspected and cleaned when necessary but the activity was not never recorded. The water test was ommited for building #3 since the source was tested quarterly.

Corrective Action: On 04/14/25 a water sample was collected from building #3 - sink and sent to the lab to be tested for total coliform (the COA was mailed but not received yet - the result is negative) . An SSOP 106-Cleaning Water Tank was created and people were instructed on how to clean the water tank along with filling out the water tank cleaning record.

Verification Of Closeout: The Environmental Laboratories COA was judged to be acceptable.

Completion Date: April 22, 2025 **Closeout Date:** April 25, 2025

Summary -

Response: Reviewed QM 11.5 Water, Ice, and Air Supply rev. 3.25.2025 (11.5.1 Water Supply). The procedure affirms that the site only used potable water. The site has a well. The site heats water so that it is effective for cleaning and washing hands. The site tests the back flow valve (check-valve device) quarterly. Reviewed Preventative Maintenance Checklist Backflow Preventer check from 12.10.2024 and from 2.10.2025. MINOR: 11.5.1.6 - Potable water is brought from building #1/#2 in a tank, where it is used in building #3. There is no method for cleaning the water tank and there are no records that the tank was ever cleaned or that the water is tested in building #3 to determine if the storage tank or water lines are contaminating the water before it is used in building #3.

11.5.2 - Water Treatment

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.5 Water, Ice, and Air Supply rev. 3.25.2025 (11.5.2 Water Treatment). The site uses a carbon/20 micron sediment cartridge filtration system canister. Reviewed the PM for the monthly filter replace and housing clean. Reviewed the maintenance record from 1.8.25, 2.10.25, 3.12.25.

11.5.3 - Water Quality

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; orvii. The manufacture of steam that will come into contact with food or be used to heat water that will come into contact with food.

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.5 Water, Ice, and Air Supply rev. 3.25.2025 (11.5.3 Water Quality). The water on site is used for washing hands and equipment. The site uses a ELAP Accredited Environmental Laboratory. Reviewed the JIL Environmental Laboratories. Reviewed potability testing COA for Building #1 (12.11.2024) and COA for Building #2 (3.10.2025) and it is stated that the water in building #3 is not tested because it is the same water is building #1 and #2.

11.5.4 - Ice Supply

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

Response: N/A

Evidence: • Not Applicable: Ice is not used at this facility.

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

Response: N/A

Evidence: • Not Applicable: Ice is not used at this facility.

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

Response: N/A

Evidence: • Not Applicable: Ice is not used at this facility.

Summary -

Response: Not Applicable: Ice is not used at this facility.

11.5.5 - Air and Other Gasses

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed QM 11.5 Water, Ice, and Air Supply rev. 3.25.2025 (11.5.5 Air and Other Gasses). Reviewed compressed air testing COA from the Milling Line, Allergen Room, Mixing, and Packing Room from Biotrax 7.23.2024.

11.6.1 - Receipt, Storage and Handling of Goods

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: QM 11.6 Storage and Transport, rev. 3/25/2025 (11.6.1 Receipt Storage and Handling of Goods). The procedure includes the responsibilities and methods for managing inventory (FIFO) . The site has dedicated warehouse sections for FIN (finished), Labels (PKG & Labels), ING (ingredients) and EQP (equipment). There is

a requirement for checking shelf-life during cycle count. Reviewed the receiving and inventory management process with the Receiving/Shipping Supervisor. He demonstrated the Bizowie system. Material are entered into Bizowie when they are received and it is then used to manage the inventory. We reviewed the paperwork used at receiving, PO Receiving Doc. Required records include the Work Order and COA. Required information includes an inspection of the seal/lock. The seal number is required. The inspection is conducted with a black light, which is kept in the Shipping/Receiving Desk. The black light is used to inspect the interior of the trailer. The inspection also requires the inspection for pest activity and odor. It was also described how the site generates a pallet tag, with allergen identification and that organic materials receives a green dot. Reviewed PO Receiver records from 12.30.2024 to 2.18.2025.

11.6.2 - Cold Storage, Freezing and Chilling of Foods

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: N/A

Evidence: • Not Applicable: The site doesn't freeze or chill food.

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

Response: N/A

Evidence: • Not Applicable: The site doesn't freeze or chill food.

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: N/A

Evidence: • Not Applicable: The site doesn't freeze or chill food.

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

Response: N/A

Evidence: • Not Applicable: The site doesn't freeze or chill food.

Summary -

Response: Not Applicable: The site doesn't freeze or chill food.

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

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

Response: Compliant

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

Response: Compliant

Summary -

Response: QM 11.6 Storage and Transport, rev. 3/25/2025 (11.6.3 Storage of Dry Ingredients). The requirements for the storage rooms, storage racks and vehicles are described. The dry storage areas were separate from wet areas. The dry storage areas were judged to be well maintained and tidy. Racks were observed to be in good repair. QMR 011(b) Cleaning and Sanitation Master Schedule includes warehouse cleaning. The QMR 011 Pre-Operational Inspection Record - Warehouse is used for inspecting the non-production areas, including Shipping/Receiving and Dry Storage.

11.6.4 - Storage of Hazardous Chemicals and Toxic Substances

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: QM 11.6 Storage and Transport, rev. 3/25/2025 (11.6.4 Storage of Hazardous Substances). There is a requirement for restricting access to chemical storage areas. There are requirements for segregation and managing daily supplies of chemicals. There are lockable chemical storage areas in each building. The site uses Simple Green and pre-diluted Purell sanitizer for equipment cleaning. The Maintenance area also keep food grade and non-food grade maintenance chemicals in separate storage cabinets. There is a chemical inventory sheet on the inside of each storage cabinet door. All chemicals and daily used spray bottles were labeled. The QM 2.9 Training Program. Requires orientation and annual retraining. Reviewed chemical training records for the site, which includes names, dates and quiz scores for chemical training. Reviewed the PowerPoint training presentations for food defense, allergen and chemical use training. The training includes safe handling, storage and dilution of bleach. The procedure includes spill clean-up instructions. Chemical usage is documented on the Chemical Usage Form. Reviewed the Building #3 Chemical Usage Form 3.4.2025 - 3.20.2025.

11.6.5 - Loading, Transport, and Unloading Practices

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: QM 11.6 Storage and Transport, rev. 3/25/2025 (11.6.5 Loading, Transport and Unloading Practices). Responsibilities are described. The Pre-operational inspection (warehouse) includes an inspection of the shipping/receiving areas. The Receiving/Shipping Supervisor described the outgoing processes using the Sales Order Form. The form requires a breach inspection (leaking bag), as well as the application of a seal for all overnight trips. Containers are inspected prior to loading. Reviewed shipping record Sales Order from 2.20.2025 - 3.27.2025.

11.7.1 - High-Risk Processes

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

Response: N/A

Evidence: • Not Applicable: The Site doesn't produce high risk products.

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

Response: N/A

Evidence: • Not Applicable: The Site doesn't produce high risk products.

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

Response: N/A

Evidence: • Not Applicable: The Site doesn't produce high risk products.

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

Response: N/A

Evidence: • Not Applicable: The Site doesn't produce high risk products.

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

Response: N/A

Evidence: • Not Applicable: The Site doesn't produce high risk products.

Summary -

Response: Not Applicable: The Site doesn't produce high risk products.

11.7.2 - Thawing of Food

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

Response: N/A

Evidence: • Not Applicable: The Site doesn't thaw material.

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

Response: N/A

Evidence: • Not Applicable: The Site doesn't thaw material.

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

Response: N/A

Evidence: • Not Applicable: The Site doesn't thaw material.

Summary -

Response: Not Applicable: The Site doesn't thaw material.

11.7.3 - Control of Foreign Matter Contamination

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 11.7 Separation of Functions. Rev. 3.25.2025. The procedure includes the requirements for Equipment and building Physical Contaminants Prevention, Straight to Pack items, and-ins during packaging process and customer supplied pre-mixed material. There is a requirement for preventing glass contamination. There is a glass register for each of the three buildings. Glass is checked with each of the Pre-Operational inspections. Reviewed the QMR 011 (g) Pre-Operations Inspection record Warehouse 1/13/2025. The operator conducting the warehouse pre-op uses a copy of the glass register as a guide. The Shipping/Receiving Supervisor from building #1 showed laminated copy of the glass register at the shipping desk. Each process has screens (different sizes) that are used. The screens are generally used for quality purposes. Pallets are checked during the Warehouse Pre-operational Inspection.

11.7.4 - Detection of Foreign Objects

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 11.7 Separation of Functions. Rev. 3.25.2025. (Detection of foreign Objects). The requirements for detecting physical contaminants during processing and rework. Observed the QMR 025 Metal Detection Test & Reject Record, during the initial floor inspection on 4.2.2025. It was started at 5.38am and it was used to check the Packing Room metal detector every hour after start-up. The operator demonstrated the metal detector on line B during the Pre-Operation Inspection. Reviewed the metal detector monitoring records (initialed and verified) from 12.24.24 - 3.12.25 (line B). Reviewed the metal detector record (initialed and verified) from 1.7.25 - 3.4.25 (line Z). Reviewed the metal detector records (initialed and verified) from 1.7.25 - 3.13.25 (line A).

11.8.1 - Waste Disposal

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: Reviewed 11.8 Waste Disposal, rev 3.26.2025 (QM 11.8 Waste Disposal). The requirements for removing dry waste is described. Liquid waste (from wet cleaning) is not collected and goes down the floor drain. There is a cardboard and regular trash dumpster for buildings 1/2 and there are the same for building #3. The site doesn't generate any waste that goes to animal feed. Waste Management is a prompted topic line in the sites annual management review.
