SQF Food Safety Audit Edition 9

Finite Fiber - 101589

Summary

Audit Decision
Certified

Decision Date
January 26, 2025

Recertification Date
December 18, 2025

Expiration Date
March 3, 2026

Issue Date
January 27, 2025

Certificate Number
101589

Audit Type
Initial Certification

On-Site Audit Dates
December 17, 2024 - December 18, 2024

ICT Dates
-

Audit Rating

Good

Facility and Scope

Finite Fiber - 101589

3171 Albrecht Ave
Suite A
Akron, OH 44312-3532 United States

Products
19: Food Ingredient Manufacturing - Puricel (Cellulose powder)

Food Sector Categories
19. Food Ingredient Manufacturing

Scope of Certification
Cutting cellulose pulp rolls into powder packed in bags and totes

Certification Body and Audit Team

ASI Food Safety LLC

500 NW Plz Dr
Suite 700
St Ann, MO 63074 United States

CB#: 42254
Accreditation Body: ANAB
Accreditation Number: 1222

Lead Auditor: Mark Hertzel (C-369487)
Technical Reviewer: ALEJANDRA NAVARRO (C-377054)

Hours Spent on Site: 16

Hours of ICT Activities:
Hours Spent Writing Report: 8

Section Responses

Audit Statement - Audit

SQF Practitioner Name - Name the designated SQF Practitioner

Response: Robert Mastran

SQF Practitioner Email - Email of the designated SQF Practitioner

Response: bmastran@finitefiber.com

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

Response: Robert Mastran: Plant Manager (SQF Practitioner), Mike Gmerck: President, David Maroli: Development Engineer (SQF Practitioner), Denice Becard: FS Software Consultant (Food Ready) and Mark Hertzel: Lead SQF Auditor

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

Response: The 15,000 sq ft. site is in Akron, OH in an industrial area. No other structures are included in the scope of the SQF certification. The site manufactures powdered cellulose that is intended to be used as an ingredient for human grade food. The plant has 9, full time employees with operating hours 24/7 from Mon – Thursday (2, 12-hour shifts). The site has two HACCP plans (cellulose and blending). The site has identified one critical control point for both processing lines (magnets). The site's finished products are packaged onsite in bags and totes. No exemptions from the SQF code have been issued to the site.

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

Response: Robert Mastran: Plant Manager (SQF Practitioner), Mike Gmerck: President, David Maroli: Development Engineer (SQF Practitioner), Denice Becard: FS Software Consultant (Food Ready) and Mark Hertzel: Lead SQF Auditor

Auditor Recommendation - Auditor Recommendation

Response: Please issue certification pending corrective action approval.

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: Auditor reviewed the site's "2.1.1 Management Policy" (dated 12/17/24) that describes the site's commitment to produce safe quality food ingredients. The methods and resources are described in the policy. The site's signed management policy is displayed in English in the breakroom. The policy was signed by the Plant Manager, President and Development Engineer (SQF Practitioner). On a monthly basis, the food safety team meets to discuss the implementation and maintenance of the SOP defined in the food safety plan along with food safety culture performance and food safety objectives and performance measures. The site's food

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safety objectives are defined as reducing customer complaints, recalls and issues to ensure customer satisfaction. The site has a goal of reaching an 85% or better on SQF certification audits. Reviewed the site's job descriptions form that was observed to include information regarding the employee name, job description and backup. The site's SQF Practitioner is the Plant Manager and the site's Development Engineer is the SQF Practitioner backup. Both employees are full time employees at the site. Auditor reviewed the site's current org chart (dated 11/12/24) that describes the reporting structure at the site. Individuals with food safety roles are highlighted in yellow. The site's Plant Manager and Development Engineer report to the president. Auditor reviewed the site's Development Engineer's HACCP certificate (dated 12/1/24) and internal auditing cert (issued through ASI- cert issued 11/7/24). Auditor also reviewed the site's Plant Manager's "Seafood HACCP Alliance" cert (dated 7/13/17) and "Better Process Control School" certificate of completion (issued may 2016). The SQF audit is the site's initial certification and no blackout dates were communicated to the CB (ASI).

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: Compliant

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

Response: Compliant

Summary -

Response: Reviewed the site's "2.1.2- Quality Objectives and Continuous Improvement" policy (dated 12/17/24) that describes the site's management review process. Auditor reviewed the site's November 2024 management review meeting record that was observed to include information regarding the topics reviewed that included changes to the food safety management system, food safety culture, food safety objectives, internal/external findings, CAPA status, customer complaints, hazard and risk management, follow up items from previous meetings, meeting minutes, new business products, internal quality, open CAR's and comments. The site's Plant Manager, President, and Development Engineer participated in the meeting. Management review meetings are conducted monthly.

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: Auditor reviewed the site's "2.1.3 Customer Complaint Management" (dated 12/07/24) that describes the site's customer complaint handling process. The site's Sales and Quality Department are responsible for the handling and documentation of customer complaints. The site uses a software system known as "FoodReady" and "Sage" to enter customer complaint information. No food safety or quality related complaints were logged by the site in the last 12 months, however auditor requested the site to retrieve the form that would be used in a real life customer complaint event. The site's customer complaint form that is housed in the Food Safety software system was observed to include information regarding the complaint number, date complaint received, product name, lot number, complaint type, customer information, source of complaint, complaint description, how the product was used, etc. CAPA information is also stored in the food ready software system.

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: A summary of the site's quality management system was reviewed. The food safety policy, org chart and all other related policies and procedures to meet the SQF requirements are housed in the site's "FoodReady" software system. The site manufactures one product (cellulose) that is manufactured with one ingredient with the addition of water. The site is exploring opportunities to sell their product into the human/pet food market and at the time of the audit, no product has been shipped from the site into the pet food or human grade market as an ingredient. The site is registered with the FDA. The site's food safety plan was reviewed in December 2024. Process controls that impact food safety were described in the food safety

plan (hazard analysis and flow diagrams). Raw material specification, ingredients specifications, packaging specifications and finished product specifications are housed in the FoodReady software system.

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: The site's "2.2.2 Document Control" procedure (dated 12/8/24) describes the site's document control methods. SOP's are issued to management team through "Food Ready" with updates in the form of electronic files on the Food Review website. Review and approval for adequacy prior to issue of each controlled document is accomplished by the SQF Practitioner. Each document used at the site requires an acknowledgement by the Plant Manager or Working Supervisor. Only the SQF Practitioner's have the authority to approve and edit SOP's.

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: The site has a formal records procedure that was reviewed. The procedure outlines the methods the site uses for completing records and the record retention time for each type of record. Records are retained for one year past the shelf life of the product the record is completed for. Auditor noted records to be accessible and retrieved in a timely manner during the onsite audit.

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: Auditor reviewed the site's "2.3.1 Procedures for Product Development and Realization" procedure (dated 12/17/24) that describes the site's procedure for product development. A step by step procedure for product development is described in the policy. Records of product formulation, process development and trials conducted on the product must be maintained for at least the shelf life of the product plus one year. Auditor reviewed recent product development records that were observed to include information regarding the date, temp of water, viscosity of water, cake thickness, time, volume of water, permeability darcies, and average. Auditor also reviewed PC production data test records (dated 11/5/24) that were observed to include information regarding the lot number, mesh size, tapped bulk density, moisture and grade.

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: Auditor reviewed a specification sheet for packaging material (50# bags) that was observed to include information regarding the product description, expiration date, instructions for packing, supplier name/location, and ISO 22000 certificate. The site's "Roll Pulp Certificate of Analysis" was reviewed and observed to include information regarding the bill of lading, destination, ship date, sales order, grade spec, diameter, width, material number, and quality characteristics (dirt, moisture, air dry, brightness ISO, basis weight dry and ADMT). Changes to product composition would require approved suppliers to alert the site prior to shipment. Reviewed the site's "2.6 Label Verification" procedure that describes the site's label

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verification procedure. All approved labels are housed in a password protected drive. Auditor reviewed a finished product label that was observed to include information regarding the product name, grade, site address, ISO certification, lot number and expiration date. Reviewed the site's current contract service provider register that was observed to include information regarding the service provided, approved service provider name, frequency of services and certifications.

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: • N/A- The site does not use contract manufacturers.

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

Response: N/A

Evidence: • N/A- The site does not use contract manufacturers.

2.3.3.3 - Contractual agreements with third party storage and distribution businesses shall include requirements relating to customer product requirements and compliance with clause 2.3.3.2 of the SQF Food Safety Code: Food Manufacturing. Contractual agreements shall be approved by both parties and communicated to 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: • N/A- The site does not use contract manufacturers.

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

Response: N/A

Evidence: • N/A- The site does not use contract manufacturers.

Summary -

Response: N/A- The site does not use contract manufacturers.

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: Auditor reviewed the site's "SQF Manufacturing 2.3.2- 2.3.4 Specification Approved Supplier Program" (dated 12/17/24) that describes the site's approved supplier program that is managed by the SQF Practitioner. The SQF Practitioner evaluates raw material and packaging material based on an established criteria. Documentation includes supplier third party audits, spec sheets, nutritional facts, allergen checklist, letter of guarantee, and food contact packaging verification. Auditor reviewed the site's "hazard assessment matrix" the site used when boarding the cellulose product used at the site. Also reviewed the site's COA for "roll pulp" that was observed to include information regarding the quality characteristics, grade spec, diameter, width and material number. A "GRAS" (generally recognized as safe) statement was retrieved by the site for their cellulose product. Auditor reviewed monthly third party lab analysis reports (dated 6/19/24) for cellulose samples that were observed to be satisfactory for heavy metals (lead, mercury, arsenic and cadmium) and microbiological analysis (listeria, salmonella, coliforms). Customers may require micro analysis for each lot number of pulp roll that is received at the site. Auditor reviewed an ISO 9001:2015 certificate (expires 03/06/27) for the tote sacks (primary packaging) used by the site. The site is not receiving ingredients/packaging material from a site under the same corporate ownership. The site's approved material and approved supplier register is reviewed annually.

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: Auditor reviewed the site's "2.4.1- Food Legislation" (dated 12/17/24) that describes the site's methods for staying in compliance with regulatory requirements. The site is responsible for complying with all food legislation requirements about the Safe Food for Canadian Regulations (SFCR) and FSMA (allowable wet variance, allergen requirements, maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, and labeling etc.). The site's SQF Practitioner coordinates the regulatory affairs provides resources for training where applicable and engages the practitioner on site. The SQF Practitioner must be knowledgeable on the current food legislation about the country of manufacture and country and sale. Requirements include maximum chemical residue, food safety requirements for ingredients and packaging, food descriptions, net weight and nutritional declaration. The site would notify SQFI and their certification body (ASI) within 24 hours upon identification of a food safety or issue of a regulatory warning letter. The site's FDA, USDA recall notification, food safety magazine/publication FDA and regular food safety training are used as resources to stay in compliance with regulatory/statutory requirements.

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: The property, buildings and equipment are located, constructed and designed to ensure food is manufactured in a safe, hygienic environment. The site has written and implemented those Good Manufacturing Practices applicable to the scope of this certification (SQF edition 9, module 2 & 11- FSC 19- Food Ingredient Manufacturing).

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: Minor

Evidence: • Minor NC- The site's hazard analysis for their two raw materials used in processing activities was not available for review when requested. The site's description for their critical control point monitoring activities for

CCP # 1 (magnets) was also not available for review when requested. The documents were provided before the end of the first day of the audit.

Root Cause: After revising the HACCP plan in our HACCP software, we did not check a box designating the critical control point by mistake. Our plan did not properly print, and we did not test this after our most recent HACCP revision. The raw material risk assessment was not uploaded into our HACCP software.

Corrective Action: Correction - immediate: We reviewed the HACCP plan and corrected the mistake. This allowed us to print the HACCP plan and risk assessment properly. Corrective Action - long term: After making any changes to the HACCP plan, the SQF practitioner(s) will review, sign, and date to ensure information is presented correctly. Preventive action: The HACCP plan will be reviewed in detail before presenting.

Verification Of Closeout: Reviewed evidence the site had a completed HACCP plan at the close of the first day of the audit. The plan will be reviewed annually or as needed when changes to plant require HACCP revisions. Approved: MH

Completion Date: January 15, 2025 **Closeout Date:** January 7, 2025

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: The site has two HACCP plans that are identified as cellulose manufacturing and blending. Auditor reviewed the site’s HACCP for cellulose that was observed to include the following information: - Plant Information- plan name, food products, overview, intended use, packaging type, distribution controls, storage/package fill data (ambient), processing description, and product properties and characteristic (water activity, pH, viscosity, shelf life, density, etc.) - Processing Flow Diagram- magnets are located after each cutting step defined in process flow diagram - Procedures- receiving, storage, loading, packaging/labeling, roll feed, pulp pre-grind, rare earth magnet, final grinding, secondary magnet, cyclone separator, hydrating screw, bulk bag packer, warehousing and shipping - Hazard Analysis- step, potential hazards, likely to occur? justification, control measures to reduce/eliminate hazard, and critical control points (1 CCP= magnet) - HACCP Plan Summary - Ingredients & Equipment - HACCP Team- Development Manager, Plant Manager, President, and Inside Sales The site's HACCP plan was reviewed on 12/10/24 by the HACCP team. Auditor reviewed CCP monitoring activities (dated 12/13/24) that were logged in the FoodReady weekly preventative maintenance checklist. The CCP record was noted to include information regarding the pre-requisite line, magnet line, screen/blade check, employee and verification. Minor NC- The site’s hazard analysis for their two raw materials used in processing activities was not available for review when requested. The site’s description for their critical control point monitoring activities for CCP # 1 (magnets) was also not available for review when requested. The documents were provided before the end of the first day of the audit.

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: Auditor reviewed the site's "2.4.4 Finished Product Sampling" procedure (dated 12/17/24) that describes the site's methods for finished product sampling. Samples are collected based on an established sampling frequency that was available for review. A one pound sample is collected for every batch of finished product that requires a chemical and physical analysis. In addition, a minimum of one- two lb. sample is collected for samples that require particulate iron analysis. The site has an onsite lab that is used to conduct internal lab analysis for density, moisture, and sieve analysis. All food safety analysis is conducted by an external laboratory. Auditor reviewed monthly third party lab analysis reports (dated 6/19/24) for cellulose samples that were observed to be satisfactory for heavy metals (lead, mercury, arsenic and cadmium) and microbiological analysis (listeria, salmonella, coliforms). The third party labs (Alliant Food Safety and Roesink Laboratories) are certified ISO /IEC Standard 17025:2017 accredited labs. Reviewed ISO 17025:2017 biological testing cert (cert number AGS US011717-2/5 for Roesink Laboratories). Customers may require micro analysis for each lot number of pulp roll that is received at the site. Auditor reviewed internal lab records (dated 12/17/24) that were observed to include information regarding the date, production date, bulk density check, moisture analysis and sieve analysis.

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: The site's non-conforming materials and product procedure is defined in "2.4.5 Non Conforming Materials and Product" (dated 12/17/24). All employees involved in placing materials and finished products on hold at the facility are trained on the procedure. Non-conforming product is tagged with a hold sign and moved to a designated hold area. The site's non-conforming product reports are housed in the "Food Ready" software system. The site has not logged any non-conforming product records in the last 12 months. Non-conforming record templates were reviewed and noted to include information regarding the date, issue, product name, lot number, root cause analysis, corrective action, preventative action, and additional notes/comments.

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: N/A

Evidence: • N/A- All reworked product is used for industrial purposes only.

Summary -

Response: N/A- All reworked product is used for industrial purposes only.

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: Auditor reviewed the site's "SQF Food Manufacturing 2.4.7- Product Release" procedure (dated 12/17/24) that describes the site's product release program. The site's packaging operator are trained to confirm the product labels meet the approved product labels by comparing against the approved product label register. The approved product label register is regularly updated by the R & D department whenever a product label is updated. Auditor requested the site to retrieve final release records for November, 2024 that were retrieved by the site and noted to include information regarding the "Inspection Checklist" (customer PO, lot number, customer name, ship date, COA, Packing List, Labels, Verify Data, trailer inspection, verification, and inspected by name), Shipment Inspection Form (reviewed QC Final Inspection stamp on record), food ready checklist (reviewed outbound carrier inspection- dated 11/12/24), BOL and COA. The site does not use contracted or off-site warehouses.

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: The site has implemented a procedure "2.4.8 Environmental Sampling" (dated 12/17/24) that was reviewed. The site's SQF Practitioner/Plant Manager is responsible for the EMP (environmental monitoring program) program. The zone description, frequency, specific pathogens tested and corrective action for unsatisfactory results are described in the program. The site is testing for listeria (hygiena) on a monthly basis and also tests for protein residue (pro clean) on food contact surfaces in processing areas on a weekly basis. The site's EMP results are logged into a spreadsheet titled "Environmental Program" that was noted to include information regarding the microbiological test frequency, microbial limit, lab analysis log and key (area, equipment sampling location and zone number). Reviewed recent EMP data (dated 11/30/24 - present) that was observed to include information regarding the date, area, equipment/location, zone, testing for, sample number, sample taken by, retest (no retests were noted), positive/negative (all noted positive) and corrective action. The site has not logged any unsatisfactory results since they began their EMP program in November 2024. If pathogens were detected in zone 1, all affected products manufactured in the same line would be

placed on hold and tested for the pathogen before release. All products contaminated by pathogens above the allowable limit would be recalled from the marketplace and destroyed.

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: The site's "2.5.1 & 2 Verification and Validation" procedure (dated 12/18/24) was reviewed. The site has one CCP which is the magnet in line 1 that is used as a control for foreign material (ferrous metal). Auditor reviewed the calibration certificate for the magnets used (CCP 1) that was issued by the manufacturer of the magnet (reviewed certificate for the DC Gaussmeter- dated 10/01/24). The certificate is valid for one year.

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: Auditor reviewed the site's "2.5.1 & 2 Verification and Validation" (dated 12/18/24) that describes the site's verification and validation methods. The site has verification schedule that was developed by the SQF Practitioner that is risk-based. The site conducts internal audits annually to ensure the site's quality management system is verified for effectiveness. The site's following programs are verified on a scheduled frequency: - Premises and Building Exterior Inspection - Pest Control - Cleaning and Sanitation - Personnel Hygiene and Practices - Compressed Air Quality - Water Quality - Shipping/Receiving and Storage - Physical Hazard Control and Procedures - Equipment Maintenance and Calibration - Environmental Monitoring Program Auditor reviewed the site's verification schedule that was observed to include information regarding the frequency, verification/validation, type of verification, and type of validation.

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: The site's "2.5.3 Corrective and Preventative Actions" (dated 12/18/24) describes the site's corrective and preventative action procedure. The site's SQF Practitioner and Department Manager are responsible for the CAPA (corrective/preventative action) program that has been implemented by the site. Deviations to the site's quality management system can be defined as customer complaints, findings during internal/external audits, daily food safety checks, and product withdrawal/recall. Any designate is trained on the 5 why's method to determine the root cause analysis and complete a non-conformance report. All issued CAPA's are stored in "FoodReady." Auditor reviewed recent CAPA records (dated 11/01/24) that were observed to include information regarding the incident details, description of non-conformance (employee didn't wash hands), root cause (not following GMP's), description of corrective action (written warning/retraining), preventative action (monitoring and logging employee use of the handwashing station).

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: Minor

Evidence: • Minor NC- Several sections of the SQF code in module 11 have not been audited by the site in the last 12 months.

Root Cause: We did not begin internal audits until after completing each SQF module. The written portion of module 11 was completed close to our audit leaving little time to document audits.

Corrective Action: Correction - immediate: We completed the internal audits for SQF module 11. Internal audit forms were added to our HACCP software with our new and old audit results for better recordkeeping. Corrective Action - long term: Defined schedule of annual audit to ensure all elements of FSQMS are audited at least annually. Monthly management meeting includes a section for Internal audit. Internal audit assignments in our HACCP software sends notifications to the SQF practitioners and Plant Manager when the next internal audit is due. Preventive action: We are conducting and documenting internal audits for 1-2 SQF System Elements during each of our monthly meetings.

Verification Of Closeout: Reviewed evidence the site conducted an internal audit on all elements in the SQF module 11 (version 9) checklist. Also reviewed evidence the site has an internal audit schedule that will ensure all

elements will be audited annually. Approved: MH

Completion Date: January 8, 2025 **Closeout Date:** January 6, 2025

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 the site's "2.5.4 Internal Audit Procedures" (dated 12/18/24). The site's Plant Manager, Development Engineer and SQF Practitioner is responsible for the internal auditing program that has been implemented by the site. The site uses an internal audit checklist that is downloaded from the SQFI website. Auditor reviewed the site's recent internal audit (dated November and December 2024) that was observed to include information regarding the person conducting the audit (DM), element name, complies (yes or no), and evidence. Reviewed corrective action related to a finding issued during the 12/6/24 internal audit (no food safety objective defined). Reviewed the site's Development Engineer's internal auditing training course certificate (issued by Root Works- dated 11/7/24). Minor NC- Several sections of the SQF code in module 11 have not been audited by the site in the last 12 months.

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: The site's "2.6.3- Mock Recall" and "2.6 Internal Lot Identification" (dated 12/18/24) describes the

site's product identification procedure. Examples of the code system(either printed on a sticker of stamped onto bags) is described in 2.6. The site takes into account the name of product, bulk density, intended for food or industrial, plant location (site has 2 locations in Akron, OH), month, year and pallet number order when assigning lot numbers. A sticker or stamp are added to the center of the bag side and on the opposite to the spout. Stamps are used when customer will not accept tickets. The site does not have product changeover or label reconciliation records (only cellulose is produced). Auditor reviewed batching records (dated 12/4/24) that was observed to include information regarding the date, lot number, ticket number, net weight, operator, stock number, ticket number, weight, manufacturing code, order number, bag lot number, supersack lot number, and pallet number.

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 the site's "2.6.3 Mock Recall" (dated 12/18/24) that describes the site's product traceability system. The site's Director of Quality is responsible for the traceability/mock recall program used at the site. The site challenges their traceability system/mock recall program annually by conducting a mock recall exercise. The purpose of the site's mock recall is to test the ability to trace all relevant raw material, production and shipping data within a given time frame (2 hours). 100% of finished product or 98% of raw material must be accounted for within 2 hours. Auditor reviewed recent mock recall records (dated 12/12/24) that was conducted by RM and DM in 1 hour. The site was able to successfully recover 100% of the finished product chosen for the exercise (40 pallets and 2 partials of lot number P0112042401-40, PC650B73574 and PC 650B73575). The date, start time, end time, time taken, reason for recall (mill reported possible ammonia contamination rolls), mock recall class, initiated by, type of recall, ingredient details, product name, ingredient receiving date, production date, product lot number, quantity to recall and all supporting documents were available for review.

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 the site's "2.6.3 Mock Recall" (dated 12/18/24) that describes the site's product traceability system. The site's Director of Quality is responsible for the traceability/mock recall program used at the site. The site challenges their traceability system/mock recall program annually by conducting a mock recall exercise. The purpose of the site's mock recall is to test the ability to trace all relevant raw material, production and shipping data within a given time frame (2 hours). 100% of finished product or 98% of raw material must be accounted for within 2 hours. Auditor reviewed recent mock recall records (dated 12/12/24) that was conducted by RM and DM in 1 hour. The site was able to successfully recover 100% of the finished product chosen for the exercise (40 pallets and 2 partials of lot number P0112042401-40, PC650B73574 and PC 650B73575). The date, start time, end time, time taken, reason for recall (mill reported possible ammonia contamination rolls), mock recall class, initiated by, type of recall, ingredient details, product name, ingredient receiving date, production date, product lot number, quantity to recall and all supporting documents were available for review. The site's defined recall team leader (RM) would notify their regulatory sources, legal team, SQFI, and certification body within 24 hours of a recall event.

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 the site's "2.6.4 Crisis Management" that describes the site's crisis management plan for events outside of the site's control. The site's President, Plant Manager, and SQF Practitioner are responsible for the site's crisis management plan. The site's training records, register of customer contact, potential crisis and contingency programs are outlined in the plan. The plan is challenged annually by the QA Manager, VP of Operations and CEO. The site's emergency coordinator is the Plant Manager (RB). Reviewed the site's recent annual mock crisis exercise (dated 11/5/24) records. The site simulated an electrical outage scenario and documented the date, scenario type, performed by, contact list, preliminary action, raw material assessment, packaging material assessment, product inventory, and conclusion (site was able to meet customer needs- no issues noted).

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: The site's "2.7.1- Food Defense Plan" (dated 12/18/24) was available for review. The plan describes the site's methods for their food defense program. The site used the FDA's food defense plan builder when establishing their food defense program. The builder plan details information regarding the facility

information, process/product description, vulnerability assessments, mitigation strategies, food defense monitoring procedures, corrective action processes, food defense verification procedures, supporting documents, food defense plan and signature. On 12/4/24, the site challenged the food defense plan by having a vendor machine vendor come to restock the machine and not sign in at the front office. He entered the front door and entered the breakroom but was stopped by an associate, who verified hid identity and reason for the visit. Also reviewed the site's "00-Visitor Sign-In Form" procedure that describes the site's visitor sign in procedure. Auditor challenged exterior doors during the site inspection that were noted to be functioning as intended. The site keeps all access doors locked when not in use. The site also has installed interior and exterior cameras and conducts employee background checks on potential hires. Auditor reviewed the site's "Camera Location" form that was noted to display information on the location of each interior/exterior camera employed by the site.

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: The site's "2.7.2- Food Fraud Plan" (dated 12/18/24) was reviewed. The purpose, definitions, types of fraud activity, pulp roll stock description, product mislabeling threat, dilution threat, counterfeiting threat and controls to mitigate the risks have been defined by the site. The site conducted a risk-assessment style evaluation to food fraud using the FDA plan. The plan was designed to address the risk factors identified in the food fraud vulnerability assessment. The site determined that each identified risk was considered low as all raw materials are received/inspected upon receipt, COA's are received and verified with every shipment, and no historical data found to support cellulose pulp fraud. The assessment was conducted on 12/6/24 by the SQF Practitioner. The resources used when conducting the assessment are defined as the Canadian Food Inspection Agency, Industry's role in combatting food fraud, FSMA final rule for mitigation to protect against intentional adulteration, and small entity compliance guide.

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: Auditor reviewed the site's "2.8.1 Allergen Management" program (dated 12/18/24) that describes the site's allergen management program. The policy does not apply to the site as they do not handle allergens. To prevent the accidental introduction of allergen through the supplier, contract manufacturer and contractor, site personnel, and visitor activities, the site has implemented the following: - training on allergens - GMP and personnel hygiene policies to prevent cross-contamination from employees lunches and visitors - site personnel must remove PPE before lunch and practice hand washing before handling food - All visitors and contractors must wear clean clothing and practice hand washing before entering the production facility Reviewed allergen training records (issued 11/25/24) to all employees. Reviewed SQF and HACCP Training records (dated 11/24/24) issue to all employees. The training was issued to all employees via a power point slideshow. Reviewed the site's SQF/HACCP Training signage record that was observed to include information regarding the printed name, signature, and date.

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: Appropriate training is provided for all plant personnel for all tasks to ensure the effective implementation of the SQF system. Training programs are the assigned responsibility of the SQF Practitioner. The effectiveness of the facility ‘s training program was evidenced by interviews with plant employees: RM (Plant Manager- interviewed on all SQF related programs), MG (President- interviewed on food safety culture), and KB (Maintenance Lead- interviewed on CCP monitoring- magnet checks).

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: Minor

Evidence: • Minor NC- Auditor requested the site to retrieve training records on the receiving/shipping procedure for employee “DC” and the site was unable to retrieve the records.

Root Cause: We did not have a designated location to organize and store training records.

Corrective Action: Correction - immediate: Employee was retrained and signed a new training form. Corrective Action - long term: An audit of all training records has been completed, and all employee training records are accounted for. Preventive action: We purchased a designated binder for storing signed sqf employee training records.

Verification Of Closeout: Reviewed evidence the employee received documented training on the receiving SOP along with evidence the site will audit their training program on a scheduled frequency to ensure all employees are trained on required programs (job specific and PRP refresher training topics). Approved: MH

Completion Date: January 2, 2025 **Closeout Date:** January 13, 2025

Summary -

Response: Auditor reviewed the site's training matrix that is maintained on an excel spreadsheet with information regarding the employee name, job title, training topic and score (1= trained documents, 2= capable of performing job under supervision, 3= capable of performing job without supervision and 4= capable of training others). The site's "2.9 Training and Education" procedure (dated 12/18/24) was available for review. All employees are trained on HACCP/SQF procedures upon hire and every 6 months in GMP's, principles and blood borne pathogens as well as the area of their employment (shipping, bagging, etc.) in the first month of employment. "Minor NC- Auditor requested the site to retrieve training records on the receiving/shipping procedure for employee “DC” and the site was unable to retrieve the records.

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: Minor

Evidence: • Minor NC- The site has not conducted an assessment of their local activities and the site environment.

Root Cause: Lack of clarity on the requirement.

Corrective Action: Correction - immediate: The site environment and surrounding areas were assessed and documented. Corrective Action - long term: Site assessment completed & documented. Preventive action: Annual site assessment has been added to our Internal Audit Program as well as the Verification & Validation Schedule.

Verification Of Closeout: Reviewed evidence the site assessed their local environment. The internal audit and verification and validation schedule was reviewed and noted to include information regarding local assessments. Approved: MH

Completion Date: January 2, 2025 **Closeout Date:** January 14, 2025

Summary -

Response: Reviewed the site's USA- State of OH Office of the Secretary of State license number (issued 03/28/24 by OH Secretary of State). Also reviewed the site's FDA registration (expires 12/31/24). Minor NC- The site has not conducted an assessment of their local activities and the site environment.

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: N/A

Evidence: • N/A- Waste traps are not used at the facility.

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: N/A

Evidence: • N/A- Pipes carrying sanitary waste or wastewater are not used at the facility.

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: Auditor observed the site's flooring to be well-maintained and constructed of material that would not contribute to a food safety risk. The site's flooring was observed to be sloped in a manner that would allow proper water drainage in wet processing and cleaning rooms. The site's walls and ceilings were observed to be constructed of material that would not contribute to a food safety/quality risk. Auditor noted wall to floor junctions to be sealed and free of dirt/debris. Door hatches and windows and their frames in storage areas were noted to be constructed in a manner that would not contribute to a food safety risk. Doors and hatches were noted to be made of solid construction and windows were observed to be made of shatterproof glass or similar material. N/A- Waste traps are not used at the facility. N/A- Pipes carrying sanitary waste or wastewater are not used at the facility.

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: Auditor observed the site's lighting to be of appropriate intensity and covered with shatter-proof light fixtures.

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: Compliant

Summary -

Response: The site has an onsite lab located separately from processing activities. The QC lab was noted to have handwashing, waste handling/removal and was noted to be clean.

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: Minor

Evidence: • Minor NC- Observed an unsealed man door on the northeast wall in the site’s blending area during the walk-through.

Root Cause: We had an obstruction outside the door that would rub against the door seal when opened too far.

Corrective Action: Correction - immediate: We replace the seal 2 hours after the finding. Corrective Action - long term: On our Weekly inspection checklist performed by the working supervisor (or plant manager), we will check the door seal integrity and report any issues. Preventive action: Ongoing Monitoring of door seals via Weekly Inspection Checklist.

Verification Of Closeout: Reviewed evidence the door seal was addressed during the second day of the audit. Also reviewed revised weekly inspection forms that will ensure the plant's door seals are inspected and addressed as needed. Approved: MH

Completion Date: January 2, 2025 **Closeout Date:** January 7, 2025

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: Auditor observed overhead doors to be sealed in a manner that would protect the site from dust, vermin or pest entry. Auditor noted doors to be self-closing and closed when not in use. Auditor noted electric insect devices to be in a manner that would not contribute to a food safety or quality risk. Minor NC-Observed an unsealed man door on the northeast wall in the site's blending area during the walk-through.

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: No issues with ventilation was noted during the site inspection. An exterior baghouse was observed during the exterior inspection and was noted to be functioning as intended. Fans and exhaust vents were noted to be well-maintained, clean and located in a manner that would not contribute to a contamination risk.

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: Compliant

Summary -

Response: Specifications for equipment and utensils were reviewed. No issues with the design, construction, storage and use of equipment and utensils were note during the site inspection. Bins used for non-conforming material and industrial use were clearly identified. Raw material storage, packaging material storage and finished product storage was noted to be separate to avoid cross-contamination. Equipment surfaces were noted to be smooth, impervious and designed for appropriate cleaning. Equipment and utensils must be purchased from an approved source. Records of non-conforming equipment are maintained in the PM (preventative maintenance) folders. No issues with forklifts or pallet jacks were noted during the interior inspection.

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: Minor

Evidence: • Minor NC- Auditor observed a large pile of metal floor scale platforms stored against the exterior of the north side of the plant during the exterior walk-through.

Root Cause: The scales were discarded and placed along the back of the building before our company decided to pursue SQF. Inspection personnel overlooked the scales.

Corrective Action: Correction - immediate: The scales were moved away from the building and placed alongside the dumpster for disposal. Scales were disposed of afterwards. Corrective Action - long term: Appropriate Staff alerted to the issue -monthly inspections of the exterior of the building updated to include old equipment parts. Preventive action: Ongoing monthly inspection of the building exterior.

Verification Of Closeout: Reviewed evidence the site removed the scales away from the building along with plans to check the exterior and surrounding areas of the plant during monthly inspections. Approved MH

Completion Date: December 20, 2024 **Closeout Date:** January 6, 2025

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: The site's exterior grounds and parking lot were observed to be well-maintained and free of waste, debris and, vegetation. Auditor did not observe rainfall during the onsite audit but noted the parking lot to be designed in a manner that would allow sufficient water drainage. The perimeter of the building was observed to be free of waste, clutter or misc. equipment. Auditor noted pathways leading from restrooms/breakrooms to processing areas to be effectively sealed. Minor NC- Auditor observed a large pile of metal floor scale platforms stored against the exterior of the north side of the plant during the exterior walk-through.

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: Minor

Evidence: • Minor NC- During the blending area inspection, auditor observed peeling tape on the top of the puck conveyor that is used to convey material into the blender.

Root Cause: The tape we originally used was not appropriate for this repair.

Corrective Action: Correction - immediate: Removed peeling tape. Corrective Action - long term: We replaced the existing tape with durable metal tape, which will not peel. Preventive action: Regular equipment inspections are being performed during daily maintenance.

Verification Of Closeout: Reviewed evidence the peeling tape noted during the inspection was removed and replaced with non-peeling material. Also reviewed evidence the site will begin to perform daily equipment inspections to prevent the issue from reoccurring. Approved: MH

Completion Date: January 6, 2025 **Closeout Date:** January 13, 2025

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 the site's "11.2.1 & 2 Post Maintenance Critical Inspection Program" (dated 12/18/24) that describes the site's maintenance program that is managed by the Plant Manager. Prior to any work on food contact equipment or surfaces, the site must start a "Post Maintenance Critical Inspection Form." Each piece of equipment that comes into direct contact with the product and/or contact surface that requires maintenance is recorded on the inspection form. When maintenance work has been completed, the maintenance person initials, signs and dates a form that is submitted in the FoodReady sofware program. Auditor reviewed recent weekly magnet preventative maintenance records (dated 12/13/24) that were observed to include information regarding the line number, work instruction, strength check, findings located on magnet, condition of magnet, employee name, date and verification. Minor NC- During the blending area

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inspection, auditor observed peeling tape on the top of the puck conveyor that is used to convey cellulose material into the blender.

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: Maintenance staff and contractors are required to sign into the "FoodReady" tablet prior to work. The tablet briefs all visitors and contractors on PPE/GMP requirements . Auditor did not observe tools, debris from maintenance activities during the site inspection. Maintenance records were reviewed and indicated the site has a formal maintenance post-clean verification activity after the completion of maintenance activities.

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 the site's "11.2.3 Calibration and Taring of Packaging Scales" that describes the site's calibration methods. The site's Plant Management is responsible for the site's calibration activities. The site's monitoring activities, name of equipment, frequency of calibration, etc. is described in the procedure. Auditor reviewed third party scale calibration records (dated 11/14/24- issued by Brechbuhler Scales Inc.). The site's "2.5.1 & 2 Verification and Validation" procedure (dated 12/18/24) was reviewed. The site has one CCP which is the magnet in line 1 that is used as a control for foreign material (ferrous metal). Auditor reviewed the calibration certificate for the magnets used (CCP 1) that was issued by the manufacturer of the magnet (reviewed certificate for the DC Gaussmeter- dated 10/01/24). The certificate is valid for one year.

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: Minor

Evidence: • Minor NC- Interior trap #7 was observed to be inaccessible due to being blocked by ice melt during the blending area inspection.

Root Cause: We need a designated location for the ice melt.

Corrective Action: Correction - immediate: We moved the ice melt and trap#7 is now accessible. Corrective Action - long term: On our monthly checklist performed by the SQF practitioner and plant manager, we will check the trap locations and ensure they are not obstructed. Preventive action: Employees need additional training to know the location of traps and know not to obstruct them.

Verification Of Closeout: Reviewed evidence the site addressed the inability to access the device along with training and monthly inspection records ensuring that all pest control devices are accessible during PCO visits.

Completion Date: January 6, 2025 **Closeout Date:** January 13, 2025

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: The site's "11.2.4 Pest Control Program" (dated 12/18/24) describes the site's pest control program that is managed by Plant Management and a third party provider (EcoLabs). Ecolabs visits the site monthly and updates a physical binder after each visit. Auditor reviewed the Eco Lab binder that is maintained at the site and was observed to include information regarding: - Agreement Scope - Service Data- reviewed recent 12/2/24 pest control record signed by site and PCO (exterior mouse activity noted) - Diagram- (dated 7/10/24) reviewed for accuracy during interior/exterior inspection - Regulatory Documents and Proof of Insurance - Certifications/Licenses- reviewed PCO/Business license (issued by OH Dept. of Ag for Eco labs- expires 9/30/25) - SDS/Labels - General Information Minor NC- Interior trap #7 was observed to be inaccessible due to being blocked by ice melt during the blending area inspection.

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: N/A

Evidence: • N/A- CIP systems are not used.

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

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

Response: Compliant

Summary -

Response: "11.2.5 Sanitation" procedure (dated 12/18/24) has been implemented and was reviewed. The site's Plant Manager and SQF Practitioner are responsible for the site's sanitation program. Cleaning records include weekly cleaning list (located in FoodReady), FoodReady checklist-post maintenance critical inspection and exhibit 1 sanitation guidelines. Reviewed recent cleaning records (dated 11/01/24 - 11/29/24) that were

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observed to include information regarding the task name, date, initials and verification. Also reviewed weekly inspection checklist records (maintained in the FoodReady software tablet system). The weekly inspection records were observed to include information regarding the approval date, current status, cleaning task, and yes/no.

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: Auditor observed personnel during the site inspection to be following the requirements outlined in element 2.4.2. Auditor did not observe staff to display symptoms or signs of infectious diseases. Auditor did not observe food items or beverages in processing, packaging or storage areas. Auditor did not observe evidence of tobacco use (smokeless or cigarettes) by employees during the site inspection. Auditor observed first aid kits in the site's breakroom. The site's visitor sign in process has signage regarding individuals who are sick or displaying signs of an illness/disease to not enter the site. The site has discontinued COVID-19 screening protocols (temperature checks, employee/visitor whereabouts questions, etc.) but still requires employees, visitors and contractors to leave the premises if they are feeling ill or displaying signs or symptoms of a disease or illness.

11.3.2 - Hand Washing

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: N/A

Evidence: • N/A- Gloves are not used at the site.

Summary -

Response: Auditor observed the site to have hand washing sinks in bathrooms, breakrooms and entry ways of cellulose processing and warehouse storage areas. All hand washing sinks were observed to have soap, hot water and hands-free paper towel dispensers. The office bathroom was observed to be clean, well-maintained and of an appropriate size for the number of employees working at the facility. Auditor observed hand washing signage in all areas of the site where hand washing is required. Per the site's GMP policy, personnel are required to wash their hands after restroom use, eating, drinking, smoking, and entering/re-entering processing areas. N/A- Gloves are not used at the site.

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 the site's "11.3- Food Safety Guidelines- Personnel Practices" that describes the site's personal cleanliness/clothing policy. Uniforms and gloves are not required by the site. Personnel must report to work in clean clothing and shoes. A hooded respirator must be worn during blending activities. Auditor reviewed recent "Break and Handwashing Log" records that were observed to include information regarding the date, time and initials. Also reviewed GMP training records (dated 10/28/24).

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: Auditor was required to read and review the site's "CGMP/PPE" policy prior to the commencement of the site inspection. Visitors are required to follow the same site procedures as full-time personnel. Auditor reviewed the site's visitors log that was observed to be completed per the site visitor's policy. Auditor was escorted by full-time personnel throughout the duration of the onsite audit.

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: N/A

Evidence: • N/A- There are no high-risk foods or processing operations at the site.

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: N/A

Evidence: • N/A- Outside eating areas are not used at the site.

Summary -

Response: Auditor observed the site's breakroom to be clean and well-maintained. The breakroom, restrooms, etc. were observed to be clean, well- maintained, climate controlled, spacious enough for employees and the lighting was noted to be of appropriate intensity. Adequate drainage was noted. Breakrooms and restrooms were observed to be equipped with hand washing sinks (soap, paper towels and signage noted). Uniforms are not required at the site. N/A- There are no high-risk foods or processing operations at the site. N/A- Outside eating areas are not used at the site.

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: All staff engaged in product storage areas were observed to be following the requirements per the site's GMP policy. Doors were noted to be closed when not in use. Waste containers and bins were observed to be properly labeled as such and were observed to be in areas that would not contribute to a food safety risk. Sensory conduction activities are conducted by authorized personnel. The site's continual process flow is designed in a manner that would not contribute to food safety or quality risk.

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: Compliant

Summary -

Response: Reviewed the site's "4.30.FFP.01- Environmental Water Monitoring Procedure" (dated 9/14/23) that describes the sites water sampling procedure. The site's water used in processing, cleaning activities is derived from a local well that is tested on a scheduled frequency. Reviewed recent in-house water analysis records (dated 11/18/24) that were observed to be satisfactory for E. Coli and total coliforms. Also reviewed a potable

water analysis (dated 09/09/24) for the well water used at the site. If water is found to be contaminated, water would no longer be added until the issue is resolved.

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 weekly PM records that were noted to include information the site is checking water for nozzles, replacing filters and adding salt to the water softener (if needed).

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 the site's "4.30.FFP.01- Environmental Water Monitoring Procedure" (dated 9/14/23) that describes the sites water sampling procedure. The site's water used in processing, cleaning activities is derived from a local well that is tested on a scheduled frequency. Reviewed recent in-house water analysis records (dated 11/18/24) that were observed to be satisfactory for E. Coli and total coliforms. Also reviewed a potable water analysis (dated 09/09/24) for the well water used at the site

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: • N/A- Ice is not used at the 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: • N/A- Ice is not used at the 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: • N/A- Ice is not used at the facility.

Summary -

Response: N/A- Ice is not used at the 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 compressed air test analysis reports and PM records (issued by Akron Air Products- dated 11/17/24- no leaks noted) and Roesink Microbiology Laboratories LLC (issued 10/11/24). The site's air testing procedure is described in 11.5.5 Compressed Air Supply (dated 12/17/24) that was reviewed.

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: N/A

Evidence: • N/A-The site does not have temporary or overflow storage.

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: Reviewed the site's "Food Safety Guidelines Training Shipping" procedure that describes the site's receiving, storage and shipping activities. Reviewed recent "00/02 Outbound Carrier Inspection" records (dated November and December 2024) that are maintained in the FoodReady software system. The records were noted to include information regarding the picture of the load, picture of seal, trailer inspection checklist, outbound/inbound, product name, lot number, employee and date (11/22/24).

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: • N/A- There is no cold storage, freezing, or chilling of foods at the facility.

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: • N/A- There is no cold storage, freezing, or chilling of foods at the facility.

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: • N/A- There is no cold storage, freezing, or chilling of foods at the facility.

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

Response: N/A

Evidence: • N/A- There is no cold storage, freezing, or chilling of foods at the facility.

Summary -

Response: N/A- There is no cold storage, freezing, or chilling of foods at the facility.

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: Auditor observed the inbound raw material and packaging material to be in the site's main warehouse away from processing activities. The site’s inbound/outbound product storage in the site's warehouse was observed to be arranged in a manner that would not contribute to a cross-contamination or other food safety risk.

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: Reviewed the site's "00/01/02- Chemical Inventory" (dated 12/16/24) that was observed to include information regarding the approved by date (12/16/24), last inspected by, current status, food grade/non food grade, chemical name, EPA number, storage location, use and date approved. Chemicals are contained in a locked yellow cabinet in the shipping area.

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: N/A

Evidence: • No refrigerated units

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: N/A

Evidence: • No refrigerated units

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: Reviewed the site's "Food Safety Guidelines Training Shipping" procedure that describes the site's receiving, storage and shipping activities. Reviewed recent "00/02 Outbound Carrier Inspection" records (dated November and December 2024) that are maintained in the FoodReady software system. The records were noted to include information regarding the picture of the load, picture of seal, trailer inspection checklist, outbound/inbound, product name, lot number, employee and date (11/22/24).

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: • N/A- There are no high-risk food processing activities conducted at the facility.

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: • N/A- There are no high-risk food processing activities conducted at the facility.

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: • N/A- There are no high-risk food processing activities conducted at the facility.

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: • N/A- There are no high-risk food processing activities conducted at the facility.

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: • N/A- There are no high-risk food processing activities conducted at the facility.

Summary -

Response: N/A- There are no high-risk food processing activities conducted at the facility.

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: • N/A- There is no thawing of food at the facility.

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: • N/A- There is no thawing of food at the facility.

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: • N/A- There is no thawing of food at the facility.

Summary -

Response: N/A- There is no thawing of food at the facility.

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 the site's "11.7.3 & 11.7.4- Control of Foreign Material Contamination of Foreign Materials" (dated 12/18/24) that describes the site's methods for controlling foreign material contaminations. The site's SQF Practitioner is responsible for reviewing and updating the Glass and Brittle Plastic Register.

Auditor reviewed/requested the site to retrieve their most recent glass/brittle plastic inspection record that was reviewed (dated 12/13/24) in the site's FoodSafety software system with information regarding the item, condition, quantity, date inspected and corrective action (none noted).

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 the site's "11.7.3 & 11.7.4- Control of Foreign Material Contamination of Foreign Materials" (dated 12/18/24) that describes the site's methods for controlling foreign material contaminations. The site's SQF Practitioner is responsible for reviewing and updating the Glass and Brittle Plastic Register. Auditor reviewed/requested the site to retrieve their most recent glass/brittle plastic inspection record that was reviewed (dated 12/13/24) in the site's FoodSafety software system with information regarding the item, condition, quantity, date inspected and corrective action (none noted).The site has one CCP which is the magnet in line 1 that is used as a control for foreign material (ferrous metal). Auditor reviewed the calibration certificate for the magnets used (CCP 1) that was issued by the manufacturer of the magnet (reviewed certificate for the DC Gaussmeter- dated 10/01/24). The certificate is valid for one year. Auditor requested the site to demonstrate the magnet check procedure during the site inspection and the individual who described/demonstrated the activity demonstrated a sufficient understanding of the activity,

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: N/A

Evidence: • N/A- The site does not have a trademarked procedure for the disposal of trademarked material waste.

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: N/A

Evidence: • N/A- The site does not accumulate inedible animal feed.

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: N/A

Evidence: • N/A- The site does not accumulate liquid waste.

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: Auditor reviewed the site's "11.8 Waste Disposal" procedure (dated 12/12/24) that describes the site's waste disposal program. Waste removal effectiveness if verified during weekly inspection checklist activities (reviewed weekly checklist- dated 12/16/24). N/A- The site does not have a trademarked procedure

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for the disposal of trademarked material waste. N/A- The site does not accumulate inedible animal feed. N/A- The site does not accumulate inedible animal feed.