SQF Food Safety Audit Edition 9
Ideation - Ideation

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
66158 | 146881

AUDIT RATING
95
Good

DECISION DATE
10/29/2021

AUDIT TYPE
INITIAL CERTIFICATION

RECERTIFICATION DATE
09/30/2022

AUDIT DATES
09/29/2021 - 09/30/2021

EXPIRATION DATE
12/14/2022

ISSUE DATE
11/10/2021

Facility & Scope

Ideation (65335)
Ideation
1500 Marietta Blvd.
Atlanta , GA 30318
United States

Food Sector Categories:
13. Bakery and Snack Food Processing

Products:
Brownies, Cookies, Doughnuts, Fresh and Frozen Bread, and Sheet Cakes

Scope of Certification:
Manufacturing of Baked Goods.

Certification Body & Audit Team

DNV GL
1400 Ravello Drive
Katy, TX 77449
United States

CB#: CB-1-DNV
Accreditation Body: ANSI
Accreditation Number: 0848

Lead Auditor: Beyer , Quentin (9732)
Technical Reviewer: Wagner, Shawna (128935)

Hours Spent on Site: 17
Hours of ICT Activities: 0
Hours Spent Writing Report: 8

Non-Conforming

11.1.2 Building Materials

Doors and windows meet the requirements of the standard. Wall to wall and wall to floor junctions are constructed properly. Drop ceilings in Employee areas are constructed to allow monitoring. Stairs and platforms in food processing and handling areas are made up of sound construction.

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: MINOR

EVIDENCE: 1. Close to the ceiling, on the side of the dividing wall where the product cooling belt transfers into the cooling room, above the product cooling bed, there is a 90 degree electrical box and conduit wrapped in black plastic. The plastic appears aged. The plastic is loose and moves with the air flow in the room. Potential to contaminate the product on the belt. 2. In the wet sanitation room, as you exit to the oven area, wall on the right is damaged, not even and regular and impervious. **Please note # 2 has been corrected. The sanitaiton room wall has been repaired.

ROOT CAUSE: 1. Food Safety Team failed to identify black plastic during monthly GMP audits 2. Food Safety Team overlooked damaged wall during monthly GMP audits

CORRECTIVE ACTION: 1. Black plastic tape removed to ensure foreign materials are not posing a risk to finished product 2. Embossed FRP panels installed to ensure compliance with 11.1.2.4

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/04/2021 **CLOSEOUT DATE:** 10/22/2021

11.2.1 Repairs and Maintenance

The preventative maintenance program is documented and implemented. There is a planned maintenance schedule for the equipment and facility. There is a daily, monthly, quarterly and annually maintenance program for the equipment and facility. Maintenance practices do not pose risk of the product safety and integrity. Below listed P.M. records were reviewed and it conforms to the procedure. Compressor air filters change records for 2021 documented. Before purchasing equipment, or pieces of equipment, the site conducts an assessment to ensure that it meets the needs of the applicant, meets the safety requirements of the operators, the safety and quality of the expected products, is suitable for departmental operations, and that maintenance and cleaning requirements are available or easy to implement. The procedure includes the following elements: • Evaluation checklist completed by the Safety manager, Quality dep. , Maintenance dep., Operations dep. • Pre-start -up checklist followed by trial on site • Verification review • Action list • Change log • Approval and change history

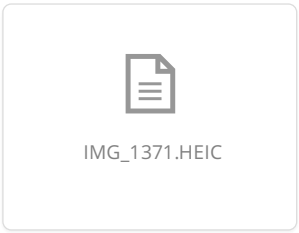
11.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: MINOR

EVIDENCE: Temporary repair- aged, clear- colored tape wrapped around an electrical switch box, box mounted behind the LVO tray washing machine. No plan in place (work order) to address the completion of the repair so the tape can be removed.

ROOT CAUSE: Food Safety Team failed to identify clear tape wrapped around the electrical switch box in washroom area during monthly GMP audits

CORRECTIVE ACTION: 1. Tape removed from electrical switch box behind the LVO



VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/04/2021 **CLOSEOUT DATE:** 10/22/2021

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

Lighting and ventilation in the amenity areas was observed to be adequate. Staff amenitities were available in sufficient numbers for all staffing. Change rooms were observed to be clean and tidy. Personnel are supplied with uniforms or coveralls and provided a locker for personel items. Dirty frocks and uniforms are stored away from clean items. Showers are not required. No high risk. Provision is made for the laundering and storage of clothing worn by staff engaged in processing operations in which clothing can be heavily soiled. Restrooms were observed to be Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and kept clean and tidy. Sanitary drainage did appear appropriate. Restrooms did have hot water, paper towels, soap, and hand washing signs. Sanitary drainage is connected to the city sewer system.

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.

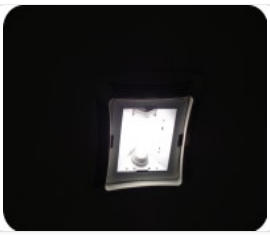
RESPONSE: MINOR

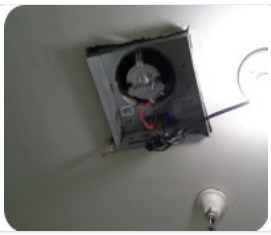
EVIDENCE: This site has employee restrooms that open to a production area. They lack an adjoining room (airlock, 2 doors). The restrooms do have negative ventilation that exhausts to the exterior. Both men's and women's ventilation units appeared dusty and soiled.

ROOT CAUSE: 1. Food Safety Team failed to recognize restroom must be in vestibule to ensure compliance with 11.3.5.6.i. 2. Food Safety Team failed to identify soiled ventilation units during monthly GMP audits. 3.Sanitation team overlooked ventilation units during daily cleaning

Purchase Request Todd L P... 10.06.21.xlsn

CORRECTIVE ACTION: 1. Ensure airlock installed to separate restrooms from processing and food handling areas 2. Clean both units to ensure they are free of dust and soil 3.Work order created to generate a Purchase Order to contract a construction company to perform the work.





Purchase Request Todd L P... 10.06.21.xlsn

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/04/2021 **CLOSEOUT DATE:** 10/22/2021

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

All cleaning and sanitation hazardous chemicals were observed to be stored in cages with restricted access. Chemicals were observed to be in their refillable tanks, 55 or 5-gallon drums and dispensed using programmable titrators provided by the facility's chemical company. The storage of all chemicals was legally compliant. Storage areas had first-aid kits and spill-management kits within easy reach. SDS sheets for all chemicals were available to employees. No utensils or ingredients were stored in chemical storage areas. Chemicals were stored in such a manner as to inhibit cross-contamination between chemicals. All chemicals had instructions for use. Cleaning/Sanitation maintained an inventory of chemicals which was provided to this Auditor.

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: MINOR

EVIDENCE: Hazardous cleaning and sanitizing chemicals are stored in a locked cage in the wet sanitation room. There is first aid (eyewash) immediately outside the door to the oven area and to the left of the room. The eyewash was mounted on a hand sink with hot and cold water knee pedals close together. Potential if a person got chemical in their eye(s) it would be very easy to push the hot water instead of the cold water. **Please note this was immediately corrected at the time of the audit. An eye wash/shower was installed, easily accessible in the room close to the chemical storage area, with ambient water supply.

ROOT CAUSE: 1.Maintenance team failed to understand the importance of installing the eye wash stations

CORRECTIVE ACTION: Installed eye wash stations.

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/04/2021 **CLOSEOUT DATE:** 10/22/2021

11.7.3 Control of Foreign Matter Contamination

Each area/room has its own register of brittle surfaces. All areas of the plant were audited in Sept. of 2021.

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: MINOR

EVIDENCE: This site does not have documented inspection of brittle/breakable surfaces for the forklifts and electric pallet jacks used to move pallets of ingredients or products into and out of food handling/contact zones.

ROOT CAUSE: Food Safety Team overlooked the exclusion of all glass and brittle plastic in the facility

CORRECTIVE ACTION: 1.Update current glass and brittle plastic inspection report to include the glass and plastic identified on forklifts and electric pallet jacks

QF047 Glass and Brittle Plastic- October 1.pdf

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/22/2021 **CLOSEOUT DATE:** 10/22/2021

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Mirna Ramirez
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** mirna.rimeriz@ideation.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Tim Ray: VP Special Projects, Shawanna Earl: Director Quality Assurance, Ryan Byrd: VP Operations, Mirna Ramirez: QA Supervisor, Albert DoFonzo: VP R&D, Ryan D. Hodge: President, Quentin Beyer: 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:** Ideation (dba H & F bread) is a gluten free baking company. It has been at its present address since 2016. On July 01, 2021, it became a gluten -free baking company. It produces Ready -to -eat gluten free breads, brownies, cakes, donuts, and cookies. Intended customers are the general public. Allergens in products include milk, eggs, treenuts, peanuts. Typical shelf-life of products is 6-18 months. 133 employees, 50,000 sq. ft. All finished goods are shipped to a distribution center, Castellini Company, located in Conley, GA. The distribution center received a SQF audit, certificate # 10228 / 120684, issued 06/22/2021. Their score was 99%.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Shawanna Earl: Director Quality Assurance, Ryan Byrd: VP Operations, Mirna Ramirez: QA Supervisor, Albert DoFonzo: VP R&D, Ryan D. Hodge: President, Quentin Beyer: SQF Auditor.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** I recommend certification.

Section Responses

2.1.1 Management Responsibility (Mandatory)

There is a documented food safety and quality policy, FS # 001, revised 06/07/2021, signed 08/07/2021, by all senior executives of the company, and is documented under the “Food Safety and Quality” policy. The policy is written in an English and Spanish language. The food safety and quality policy is posted at the employee entrance, and lunch room. The food safety and quality policy covers the aspects of Personal safety commitment, Environmental commitment, and Safety and Quality commitment. The policy addresses several management commitments, which are monitored by quality/safety indicators on a monthly basis. Ex. Commitment to achieve a right first time quality culture & engagement through people development and on-going training program, commitment to adhere to standardized global policies, system and standards, optimize and standardize testing capability through automation, validation and trend analysis, and leverage cross-functional ways of working to ensure quality is designed a new product development stage. There is a documented organizational chart, updated 09/28/2021. The SQF team is composed of: Plant Manager, Sanitation Supervisor, Operations Quality Manager, Quality Supervisor, etc. The position of SQF practitioner is assumed by the Operations Quality Manager. The SQF practitioner is full time employee of the company and she has completed HACCP, PCQI, and SQF training. HACCP Manager training 07/07/2016, PCQI training- FSPCA Preventive controls for Human Food- with Food preventive Control Alliance 04/14/2017. The Quality Supervisorvisor is also the back-up SQF practioner. She is also HACCP certified, 09/08/2021. Job descriptions exist for all key positions that impact product safety and quality. Several descriptions were verified during the audit: • Director of Quality Manager, June 17, 2021, is the SQF Practitioner. The identified QA substitute is the Operations Quality Supervisor. • Operations Quality supervisor- is responsible, among other things, for calibration files; maintain training matrix, maintain and revise SOP, SSOP and forms; review COA, shipped with documentation; update CAPA, etc. During the audit, employees and managers were interviewed who are responsible to pre-operational inspections and operators responsible for CCP's (metal detectors and baking in bakeries) and PCs . All were very familiar with their work, properly completed their documents, properly referred to their work instruction, and reported to their immediate supervisor or AQ in the event of deviations or non-conformities. The Human Resource, SQF Practitioner, Supervisors and Health & Safety manager are responsible for establishing and implementing the training needs of the company related to food safety and quality programs. Senior management has established processes to improve the effectiveness of the SQF system to demonstrate continuous improvement.

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 **EVIDENCE:** This site may shut donw for all USA Hoidays, including Juneteeth.

2.1.2 Management Review (Mandatory)

The senior management is involved in the SQF system review. Practioners meet with senior management daily and monthly. The management review procedure is documented, reviewed 06/17/2021) and it includes review of the SQF system, policy manual, customer complaints, audit findings, corrective actions and their resolution and investigation. Completed to describe items reviewed and for which data are analyzed, compiled, trended and action required are identified. Meetings include: External audit results, Internal audit results, Customer complaints, Key performance indicators (for operations), Key performance indicators (for Quality), Continuous improvement- QIP (Quality improvement projects) + Site specific goals, Status of preventive actions systems: preventive maintenance (PM program) and BCP- Business continuity program in place, HACCP review, Quality food plan review, Status of corrective action, Change management, Product development and design, Management commitment to food safety/quality, Training, CAR to be implemented (Identification and their follow up). SQF Practioner meetings with senior site management include attendance, SQF system subjects, mangement responses. Reviewed notes of these meetings from July 19 and Aug. 26, 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3 Complaint Management (Mandatory)

The methods and responsibility for handling, investigation and resolution of customer complaints, FS008, June 04, 2021, are documented and implemented. Initially, customer complaints are received at the corporate office and then forwarded to the designated personnel, Plant Mgr. and SQF Practioner for follow up and corrective action. Trend of customer complaint data are investigated and analyzed by the SQF practitioner. For complaints, foreign material and out of specifications- Taste, odor, appearance and texture. Based on trend of complaints analysis, the foreign matter decreasing is related to FSS new program, PPI program and staging in progress. The trend analysis is reviewed during weekly staff meeting with senior management and QA personnel. Customer complaint corrective actions are implemented and records are maintained. Customer complaints and their investigation records are maintained. Ex. Complaint received and investigated on 03./23/2021, missing cookie, only 7 in a package of 8 of product. Corrective actiosn include re-training hankd-packing personnel. Trend reports are maintained, foreign material complaint trends to date 2021 were reviewed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

There is a documented food safety and quality manual , reviewed and validated on 09/27/2021, maintained and made available to staff. The food safety and quality manual is on company server and is accessible by the supervisors, and they provide documents to the plant employees. The food safety and quality policy is written in an English language. The food safety and quality manual includes policy statement, organizational chart, reference the written procedures and the pre-requisite programs. Pre-requisistes include environmental monitoring, contractor program, rework, Quality Hold, Self-inspection, Sanitation program (MSS, SSOP's, and Pre-Op Inspection), Receiving program, maintenance, allergen program, traceability and recall program, chemical control program, foreign material control, calibration, pest control, GMP's, and Training. GMP's were reviewed several times in the last 18 months and updated to include COVID-19 procedures. Changes are documented.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

FS # 010 is the SOP for the document control procedure, It is managed by a QA Supervisor/Documentation Specialist who is responsible to publish all approved document. The Quality Assurance Manager, Plant Manager; Maintenance Manager, Quality Supervisor, Sanitation Supervisor and Warehouse Supervisor are all involved in the development of a procedure, modification or revision of procedures, forms or work instructions. Final authorization is given by the SQF Practitioner before it is approved at the corporate level and published. During the audit, revision of the version of several documents (cited in this report) with revision date and approval and history of changes are readily accessible and safely stored.

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

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

The methods and responsibility for monitoring, verifying, maintaining and retaining records is documented and implemented. All records are legible and signed by the personnel responsible for monitoring and verifying. Records are readily accessible, retrievable and securely stored. Electronic and hard copy records are stored for 2 to 7 years as per the company record policy. HACCP Plans are stored permanently. (Product shelf life is 180 days to 365 days). This Auditor reviewed verified records of monitoring CCP's, PC's. and records demonstrating lot traceability, shipping and receiving inspections, sanitation, etc. from from July 07,09,16, and Sept. 13,14,15, 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.1 Specification, Formulation and Realization

FS # 012, issued June 07, 2021, explains that Product research and development is done on-site. The internal R&D team on site, development takes place when the product is at the product commercialization stage. Once product is developed, the product formulation is validated by facility trials, shelf life trials and product testing by internal R&D team, Quality and production Managers. The facility trials, product testing and pre-run checklist records are maintained at the site. During the audit, reviewed documentation of new product test run. Pre-run Call checklist is in completing by QA Managers, R&D Manager. Sensory testing was completed on-site. R & D determines shelf-life using excelerated methods.

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

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

FS # 013, origin 06/17/2021,. All raw, packaging and processing aid materials specifications are documented, are kept current and comply with the relevant legislation. Based on regulations requirements (FDA), customer's requirements, process capabilities, supplier's approval program, etc., products specifications are established and agreed with the suppliers, which confirmed its agreement by providing (COA) certificate of analysis for each lot of raw material, ingredient, processing aid and packaging material received. Ingredients, packaging and processing aid materials product specification sheets were reviewed and compared at their COA, ERX. additive Xantham Gum. Finished product specifications are documented, current, approved by the site and its customer, accessible to relevant staff, and include microbiological, chemical, and physical limits; composition to meet label claims; labeling and packaging requirements; and storage conditions. Also includes Physical (moisture, pits, odor/flavor, color), Organoleptic specifications, List of allergen(s)-gluten <10 ppm, Storage and shelf-life. Contract service provider specifications checked during audit included Cleaning and Sanitizing chemical supplier. A register of all contract service specifications observed current and maintained. Validated June 17, 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.3 Contract Manufacturers

No contract manufacturers.

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

2.3.4 Approved Supplier Program (Mandatory)

FS # 016, reviewed 06/17/2021, states the Director of Quality is responsible to approve any supplier. Procurement is also involved in this process: selection, approval, monitoring and evaluation of suppliers (products, services and co-manufacturing services). Yearly, QA evaluates the supplier performance and decides to reject or retain as an approved supplier. QA maintains the approved supplier list and all information on agreed specifications of raw materials, ingredients, packaging materials, and services (verified by COA at receiving); QA monitors suppliers for risk of food fraud through regulatory publicaitons monitoring. Monitoring includes emergency plan, the prior performance of the supplier; the risk level of the raw materials ingredients, packaging materials, and services supplied; A summary of the food safety controls implemented by the approved supplier (as GFSI supplier and its certificate). Site food defense program to develop and implement related to incoming materials and ingredients from that supplier; Site's food fraud vulnerability assessment and mitigation plan to develop and implement related to incoming materials and ingredients from that supplier; Supplier satisfaction and claims; Third party audit, as required; Raw materials, ingredients, and packaging materials received from other facilities under the same corporate ownership are considered as all other suppliers. Reviewed proof of third party audit, FSSC 22000, valid unitl March 31, 2022, and vulnerability assessment for A___, supplier of oat flour. During the audit, tracking of batches of raw materials received, their specifications, certificates of analysis, their suppliers' systems and certificates, as well as their performance, and the risks of fraud (related to their origin, the complexity of the supply chain, the history of the supplier and the product, etc. All required information is available on the raw material tracking spread sheet.

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

2.4.1 Food Legislation (Mandatory)

The Directer of QA is responsible for ensuring food supplied complies with the food safety legislation that applies to the food and its production in the country of origin and its production in the country of destination. The Kerry corporate regulatory department is responsible for keep informing QA and management personnel and also, enforcing changes related to the legislation, scientific and technical development or changes. The Kerry sales and corporate regulatory department sends emails to QA and management personnel about the changes. The company recall program states that SQFI and the certification body -DNV-will be notified in email writing within 24 hours upon identification of a food safety that requires public notification. The SQFI and certification body contact information is documented in the recall plan emergency contact list. Types of legislation at which the site and products have to comply include: US Food defense regulatory requirements for Prior Notices of Imports and administrative detention of food, FDA regulations, FSPCA for Preventive Controls for Human Food, FDA for trucker- Guidance for industrial sanitary transportation of food. SOP 2.4.1 also states SQFI will be notified in the event of a regulatory warning or event.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

This site maintains a GMP policy, doc # 295, reviewed and updated June 21, 2021, that meets all the expectations of FDA CFR and SQFI. Facility and equipment are designed to manufacture safe food. The food safety fundamentals are followed (Module 11). No exemptions. Employees training in GMP's June 07 and 30, 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

The Food Safety plan appears to meet regulatory-FSMA exepctations. Within the HFood Safety plan, a HACCP plan, reviewed and validated on 09/27/2021. The HACCP plan flow diagram demonstrates preventive Controls (PC's) at step # 12, internal temperature after bake, minumum 195 F, and step # 15, metal detection. These PC's are also Critical Control Points (CCP's). CCP # 1 is baking time and temperature, critical limits vary with product, 260 F to 370 F. CCP # 2 is product is free from metal, monitored at the metal detector. The metal detectors and X-ray are challenged with 2.0 mm Fe, 2.0 mm NFe, and 3.0 mm SS. every hour. Additional PC's are at receiving, cooling, hand pack, and shipping (truck inspection) steps. Pre-requisites include: 1. Sanitation program, Water quality, cGMP's, and building facility control, pets management, chemical control, customer complaints, recall and traceability, and Allergen control. Reviewed verified documents monitoring the Food Safety plan, PC's, and CCP's, from July 07,09,16, and Sept. 13,14,15, 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.4	Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions. **RESPONSE:** COMPLIANT
2.4.3.5	The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative uses of the product. **RESPONSE:** COMPLIANT
2.4.3.6	The food safety team shall develop and document a flow diagram covering the scope of each food safety plan The flow diagram shall include every step in the process, all raw materials, packaging, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation. **RESPONSE:** COMPLIANT
2.4.3.7	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs. **RESPONSE:** COMPLIANT
2.4.3.8	The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT
2.4.3.9	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure. **RESPONSE:** COMPLIANT
2.4.3.10	Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure. **RESPONSE:** COMPLIANT
2.4.3.11	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard(s) and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1). **RESPONSE:** COMPLIANT
2.4.3.12	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT
2.4.3.13	The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure. **RESPONSE:** COMPLIANT
2.4.3.14	The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur. **RESPONSE:** COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4 Product Sampling, Inspection and Analysis

All samples are sent to S___ labs for analysis. Certificate for Crete, IL, Lab, A2L2 Microbiological and Chemical certification number 1105.15, valid until March 31, 2022. Responsibility for development of new and revised products lies at the corporate level. The facility only participates in terms of conducting trial runs on facility equipment. Product testing and shelf life testing are conducted through corporate channels. All records of product development are maintained at corporate level. When the decision is made as to whether a new product will be commercialized, food safety and quality plans are assessed to determine if the new product falls under an existing program. The facility has a Commercialization Procedure, that documents the facility's responsibility for new product development. Location tests are performed and recorded. Reviewed verified documents monitoring, inspections, and analyses, from July 07,09,16, and Sept. 13,14,15, 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Materials and Product

The method and responsibility for handling non-conforming materials is documented in FS # 022, reviewed 06/07/2021, and implemented. QC Hold report is completed. Non-conforming product records are maintained. Hold records checked and conform to the procedure. Hold records and destruction of product that did not meet standards are documented. This Auditor reviewed QA Hold product produced on)7/09/2021, discarded as waste on 07/10/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.6 Product Rework

This site does not do rework. Product that does not meet food safety or quality standards is discarded as waste.

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

RESPONSE: NOT APPLICABLE

2.4.7 Product Release (Mandatory)

FS # 024, , reviewed June 15, 2021. Label verification document includes all of the checks reviewed before product is released for shipment. Product under test for Gluten are held in the Contracted finished goods warehouse until negative test results are received. The responsibility and methods for releasing product is documented and implemented. Positive release specialists are responsible to release finished products. When finished product testing: sensory, physical and microbiological characteristics- results) is completed and is compliant to regulatory, customer requirements and corporate requirements, finished product testing results are reviewed by the positive release specialists, whom enter data of finished products. Finished products are released for shipping. Product release records are maintained.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

FS #025, , verison 2, issued April 03, 2021. Samples are taken (typically 9 per month) from pre-designated risk areas, and sent to a Third party lab for analysis for E. Coli, Listeria, and Salmonella. Results from July 04 and Sept. 05 were negative. This site also samples finished product and sends it to the same lab minumum monthly, and also per customer request, and analyzed for E. coli, L. monocytogenes, and Salmonella. Results from Sept. 05 and 23, 2021, were negative.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

FS # 026, issued 06/18/2021, Validation and verification activities are performed. The frequency and methods used to validate and verify food safety fundamentals, critical limits, and other food safety and quality controls identified in food safety and quality plans are documented. Pre-reqiusites validated over multiple days. Re-validation of baking time and temperature from the Journal of Food Protection, Vol 77, No. 4, 2014, pages 635-639. Discussed in Senior Mgmt meeting,

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

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

Verification activities are performed as described in FS # 026, issued 06/08/2021.. The frequency and methods used to verify food safety fundamentals, critical limits, and other food safety and quality controls identified in food safety and quality plans are documented in FSMA training procedures. Documents must be verified before shipment. Verification activities records are maintained. Below listed verification records were reviewed and it conforms to the procedure. Examples include: Pre-operation inspections, ATP and protein swabs records; This Auditor reviewed verified records of monitoring CCP's, PC's. records demonstrating lot traceability, shipping and receiving inspections, sanitation, etc. See also 2.4.3. summary for dates reviewed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

FS # 027, issued 06/18/2021. The responsibility and methods for handling corrections and corrective actions are documented, implemented and reviewed during meetings involving: Plant Manager, Production Manager, Director of Quality Manager, Maintenance Manager. Corrective actions records are maintained. Corrective action records were reviewed and found to conform to the procedure. Reviewed corrective actions. Root cause was conducted and determined. Corrective actions for this incident were discussed in Senior Managment meetings.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4 Internal Audits and Inspections (Mandatory)

Internal audits, FD # 028, issued 09/07/2021, is developed to cover all of the SQF system. The internal audit program covers all procedures and records, involved in different sections: Management, Food safety plan and training, Quality Plan and its training, Inbound services and receiving, Outbound (R&D, contract manufacturing and reworks), Facility, Security (Crisis management, recall and Food fraud), Maintenance, Storage, Hygiene: cleaning/sanitation and clothing, Allergen, high risk area, Identity preserved, High risk food, Process, Foreign objects, Personnel during process, Detection of foreign matter, Process flow. Internal audit fo SQF systems completed in Sept. 2021. The procedure is intended to verify that activities relating to the quality and food safety management systems comply with established procedure and also to determine the effectiveness of those. The internal audit of the SQF sytem was reviewed. Monthly, GMP inspections are perform by the internal audit team. Pre-Ops inspections/internal audits include GMP compliance. No essential material present; No evidence of excessive lubricant; No overhead leaks; No evidence of condensation; No evidence of pooled water on equipment; No evidence of pooled water on floor; No evidence of peeling paint; No evidence of damaged equipment; Description of Visual inspection- failures sites. Glass and Brittle Plastic audits are divided up by room/area, and conducted quarterly over several day, Reviewed Sept. 2021. Site inspections (interior and exterior) of premises are also performed (Work order issues by PM program), on monthly basis by maintenance team.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.1 Product Identification (Mandatory)

FS # 029, issued Sept. 29, 2021, provides expalnation of how all products are identified. Raw material identification is maintained. Finished product is identified by either Julian or best by calendar date, depending on customer requirements. Training for all employees in product identification procedures in Sept. 2021. This Auditor reviewed verified records of monitoring CCP's, PC's. Records demonstrating lot traceability.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

FS # 030, issued 08/18/2021, provides the responsibility and methods used to trace product is documented. The SOP is implemented. Product trace system is traceable for one up and one back. Traceability system effectiveness is checked semi-annually. Traceability is maintained for rework product. Incoming materials receiving and finished products shipping records are maintained. Employees use reports to pull ingredients from warehouse areas and deliver to rooms where the Operators use the same report to document the lot numbers and quantities (lbs) they used.

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

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

The responsibility and methods used to withdraw and recall product is documented and implemented, and reviewed. Investigation and corrective actions records are documented. The product withdrawal and recall system is reviewed, tested and verified semi-annually. The President has the responsiblity to determine if a recall will be conducted. Product withdrawals, recalls and mock exercises records are maintained. Below mock recall and traceability exercise records were reviewed and it conforms to the procedure. Procedure to contact by email SQFI and DNV within 24 hours of an event is clearly stated on page 2 of the recall program. Mock exercise performed during the year. Packaging trace exercise completed 09/16/2021. 100% in 2 hours. Lot number of ingredient 100% trace in 2 hours on 09/16/2021. Finished product trace 08/26/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.4 Crisis Management Planning

FS # 031, origin date 06/17/2021. The plan tested and verified on 06/17/2021. There is a crisis management -pan documented and implemented. Food safety threats are identified as follows: short of incoming material supplies, service and employees; loss of utilities (gas, power, electricity, water, air); IT failure, disaster (bomb threat, fire, flood, tornado, malicious tampering) and recall. Crisis management plan reviews and verification records are maintained.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

FS # 033, issued Sept. 18, 2021, describes the food defense plan. The site security team, The policy statement: assure the health, welfare and success of the business, Food security& Defense- self assessment checklist, Risk assessment and critical asset and the identification of countermeasures, Plan management and site exercise. Site security and defense self-assessment checklist, includes: Plan management and exercises in all facilities, Food defense planning consideration for warehouse, plant and site where handle food. The responsibility and methods used to withdraw and recall product is documented and implemented. Investigation and corrective actions records are documented. Personal security procedure, Food production& plant/sites that handle food (as mixing and batch areas, access log for raw material storage, Reporting protocols, Employee security procedures including initial training and annual refresher, Non-employees security procedures, Operations restrictions: utilities, third party and restricted areas as: Shipping/receiving and warehouse inspection (lack of tampering or damages), Production shutdowns, Finished products (Hold process), Mail security, Door/hatches closed and sealed, Physical security: alarm system. FSIS food defense assessment completed in 2021. Food defense challenge completed 08/26/2021, mock scenario of loss of electrical power. The Team determined the building needed more emergency lighting.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.2 Food Fraud (Mandatory)

Food Fraud vulnerability assessment completed 07/04/2021. The methods, responsibility and criteria for identifying the site's vulnerability to food fraud is documented, implemented and maintained. The Quality Director/ QA Manager is responsible on-site. The food fraud vulnerability assessment include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety. The food fraud program (site’s vulnerability and mitigation plan) is managed. Decision tree involved checked during the audit. The supplier approval program is included in the food fraud program.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.8.1 Allergen Management (Mandatory)

Allergen mangement FS # 035, issued 08/28/2021. Allergens on-site are milk/dairy, egg, tree nut, and peanut. allergen identification, rework, re-blend done, storage, labeling, production (correct handling process and dedicated tools), storage procedures; finished products handling, in production plant; Allergen training including temporary worker, specific standards (hairnet/clothing control), utensils (color code); Cross-contamination control procedures. The site at the time of the audit, does not have any of the three Canadian allergens that are not on the FDA big 8 list. - Allergen identification is managed by QA. - Allergen matrix included in each food safety plan Vs production schedule. - Allergen cross contamination controls procedures are developed and implemented which includes production scheduling, sanitation, cleaning verification and allergen swab test. Sanitation prevention addresses cleanliness of food contact surface and prevention of cross contamination (re-contamination). - Monitoring steps include: Visual inspection, ATP (Charm test), Protein swab (Hygiena- Residual sensitive protein < 0,3 ug), Sanitizer strength, Records- Pre-op- inspection Form and sanitizer chemicals concentration- Sanitizer, Verification by PCQI.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.1 Training Requirements

FS # 036, origin 06/17/2021. Yearly, all employees are trained on the different elements of SQF (Quality and Food safety codes). The program is developed in collaboration with the Plant Manager, Director of Quality Manager and all senior managers involved in SQF team. The program is managed by the Quality Manager and its team. The employee training program is documented and implemented. Specific training is provided to maintain and improve training for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory 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

2.9.2 Training Program (Mandatory)

Lead Operator B. C. trained in HACCP and CCP's, verified by written quiz, 09/11/2021. 30 employees trained in Good Documentaiton practices on 08/23/2021. Training program is provided in English. All employees are required to speak and read English. Training program includes: Welcome and history, Benefits overview, Kerry policies/code of conduct, Time keeping, GMPs, Confined space, LOTO, Machine guarding, Safety program review, Emergency prepared news, PPE, Allergen, Food facility defense, HACCP, Foreign material control, Document control, Maintenance program review, General offices services, Quality program review, Hold/Release program

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

Business license form the State of Georgia Dept. of Agiculture, expiry June 30, 2022. Local activity and environment has been assessed.

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

RESPONSE: COMPLIANT

11.1.2 Building Materials

Doors and windows meet the requirements of the standard. Wall to wall and wall to floor junctions are constructed properly. Drop ceilings in Employee areas are constructed to allow monitoring. Stairs and platforms in food processing and handling areas are made up of sound construction.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: 1. Close to the ceiling, on the side of the dividing wall where the product cooling belt transfers into the cooling room, above the product cooling bed, there is a 90 degree electrical box and conduit wrapped in black plastic. The plastic appears aged. The plastic is loose and moves with the air flow in the room. Potential to contaminate the product on the belt. 2. In the wet sanitation room, as you exit to the oven area, wall on the right is damaged, not even and regular and impervious. **Please note # 2 has been corrected. The sanitaiton room wall has been repaired.

ROOT CAUSE: 1. Food Safety Team failed to identify black plastic during monthly GMP audits 2. Food Safety Team overlooked damaged wall during monthly GMP audits

CORRECTIVE ACTION: 1. Black plastic tape removed to ensure foreign materials are not posing a risk to finished product 2. Embossed FRP panels installed to ensure compliance with 11.1.2.4

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/04/2021 **CLOSEOUT DATE:** 10/22/2021

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.3 Lightings and Light Fittings

Lighting intensity is sufficient in food processing areas and at inspection stations. All lights are protected in the processing and storage areas. Light fittings in warehouses and other product storage areas pose no food safety risk.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.4 Inspection/ Quality Control Area

The site has several product inspection stations. These are used to prepare samples for laboratory analysis or sensory testing (flavor, size/shape, texture, appearance and color and other analysis, depending on customers requirements, to inspect operators' gloves or to complete production reports. All stations have appropriate lighting and hand washing stations are nearby, as well as garbage bins.

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

RESPONSE: COMPLIANT

11.1.5 Dust, Insect, and Pest Proofing

All external windows and doors are protected and sealed. Personnel access doors are effectively fly-proofed and self-closing. External doors and overhead dock doors are adequately sealed and fly-proofed. Bait stations are not located inside food storage areas or processing areas. Insect devices are located appropriately and do not pose contamination to product or equipment.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.6 Ventilation

The food processing and handling areas have adequate ventilation. There are baking areas and baking areas adequately exhausted.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.7 Equipment and Utensils

Before purchasing equipment, or pieces of equipment, the site conducts an assessment to ensure that it meets the needs of the applicant, meets the safety requirements of the operators, the safety and quality of the expected products, is suitable for departmental operations, and that maintenance and cleaning requirements are available or easy to implement. The procedure includes following elements: • Change modification form • Evaluation checklist completed by the Safety manager, Quality dep. , Maintenance dep., Operations dep. • Pre-start -up checklist followed by trial on site • Verification review • Approval and change history Edible and inedible material bins are properly designed and maintained. Inedible materials bins are properly identified. Waste water is properly discharged on the floor. Protective clothing is easily cleanable.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.8 Grounds and Roadways

Exterior grounds are maintained to minimize dust and provide pest harborage areas except water pooling observed outside the engine room during site tour. Paths, roadways, loading and unloading areas are maintained to prevent hazard to the food safety operation of the premises. Surrounding is kept neat and tidy to provide hygienic and sanitary operation of the premises. External paths from amenities to the facility are sealed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.1 Repairs and Maintenance

The preventative maintenance program is documented and implemented. There is a planned maintenance schedule for the equipment and facility. There is a daily, monthly, quarterly and annually maintenance program for the equipment and facility. Maintenance practices do not pose risk of the product safety and integrity. Below listed P.M. records were reviewed and it conforms to the procedure. Compressor air filters change records for 2021 documented. Before purchasing equipment, or pieces of equipment, the site conducts an assessment to ensure that it meets the needs of the applicant, meets the safety requirements of the operators, the safety and quality of the expected products, is suitable for departmental operations, and that maintenance and cleaning requirements are available or easy to implement. The procedure includes the following elements: • Evaluation checklist completed by the Safety manager, Quality dep. , Maintenance dep., Operations dep. • Pre-start -up checklist followed by trial on site • Verification review • Action list • Change log • Approval and change history

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

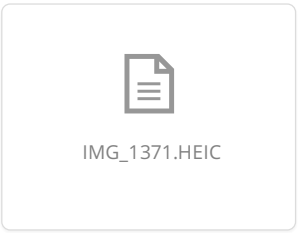
11.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: MINOR

EVIDENCE: Temporary repair- aged, clear- colored tape wrapped around an electrical switch box, box mounted behind the LVO tray washing machine. No plan in place (work order) to address the completion of the repair so the tape can be removed.

ROOT CAUSE: Food Safety Team failed to identify clear tape wrapped around the electrical switch box in washroom area during monthly GMP audits

CORRECTIVE ACTION: 1. Tape removed from electrical switch box behind the LVO



IMG_1371.HEIC

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/04/2021 **CLOSEOUT DATE:** 10/22/2021

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.2 Maintenance Staff and Contractors

Maintenance staff and contractors document the removal of all tools and debris. This site uses work order- inspection form" to document tool and debris removal after work is completed. Reviewed examples of these completed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.3 Calibration

Fs # 038, 09/22/2021, Calibration policies and procedures, and records there of are documented. Metal detectors and X-ray calibrated and validated by factory trained technician on 05/26/2021. Thermometer used ot calibrate product temperature check thermometers, serial # 817221, calibrated 03/04/2021. Thermometers used to check product internal temperatures (PC) calibrated daily by QA Technicians. Reviewed these logs from Sept. 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.4 Pest Prevention

Preventive measures in place to facilitate the effectiveness of the pest control program include closing doors at all times, regular indoor and outdoor waste removal, daily facility cleanliness inspections and monthly outdoor environmental tours. The method and responsibility are documented and implemented for the pest management program. The QA manager is responsible for overseeing the pest management program. The company has hired external contractor A__ to monitor and control the pest activity Statement of Work/Service Agreements is current and signed by the QA Manager on 09/21/2021. The pest and vermin management program is developed which includes target pests, frequency of inspections and methods to prevent and eliminate pest. Pesticide usage log, entries complete. There is a pest control map (last updated 09/08/2021) describing location of interior and exterior pest traps. Weekly interior and biweekly exterior pest control traps are monitored by the external service contractor. Reviewed these weekly service reports from Jan. and Aug. 2021. Pest control service contractor inspections, pest control trend analysis and pesticide usage log records are maintained. Pest sighting log has multiple hand-written sightings by employees. Pest control technician licenses were verified during the audit, expiry 06/30/2023. Pesticides are applied by licensed pest control technician (PCO) only. The PCO removes all containers he empties from the site. The facility does not store pesticide on site. No animals permitted on-site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.5 Cleaning and Sanitation

FS # 040, 09/22/2021, documents cleaning and sanitizing procedures. Validation of cleaning procedures includes allergen swabbing in room dedicated to allergen products. Allergen swabs from . 2021 before cleaning/removal of allergens from formulas that use daily as an ingredient were "absent" before cleaning. A Master Sanitaiton Schedule of surfaces and equipment that is cleaned on a schedule is maintained. Chemical tritration logs are maintained by employees who use the chemicals. Reviewed records of these tritrations from July 05, 12, 21, 26, 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.1 Personnel Welfare

GMP policy was reviewed. Infectious diseases are covered in this policy and with training. The site is using metal detectable band aids and ear plugs. These are verified annually. Personnel that are suffering from infectious diseases may not engage in product handling or processing operations. Employees must report to the manager on site. There were not any observations of smoking, chewing, eating, drinking or spitting on the site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.2 Handwashing

Hand wash stations were observed to be located in appropriate places. They did offer hot water, knee controls, liquid soap, hands free paper towels, and a garbage receptacle. There are also automatic handwashing machines. Personnel were observed to be handwashing when needed. Gloves are used and were observed to be used per the GMP policy.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3 Clothing and Personal Effects

Personnel can wear either uniforms or a frock. Personnel observed did have clean clothing. Soiled clothing can be changed at any time during the shift. Wet cleaning clothing was observed to be clean and in good condition. Employees are required to wear hairnets, beard snoods, glasses, earplugs, and disposable gloves where needed. Shoes were observed to be clean. Employees and visitors are not permitted to wear jewerly or other loose objects. Employees may wear a plain wedding band. There were not any observations of employees wearing jewelry.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.4 Visitors

Visitors to the site were required to sign in and understand the site GMPs, including COVID_19 control measures. Visitors who display illness are not permitted in the production areas. Visitors are escorted and were observed to be complying with hand washing requirements. Visitors must show proper identification.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

Lighting and ventilation in the amenity areas was observed to be adequate. Staff amenitities were available in sufficient numbers for all staffing. Change rooms were observed to be clean and tidy. Personnel are supplied with uniforms or coveralls and provided a locker for personel items. Dirty frocks and uniforms are stored away from clean items. Showers are not required. No high risk. Provision is made for the laundering and storage of clothing worn by staff engaged in processing operations in which clothing can be heavily soiled. Restrooms were observed to be Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and kept clean and tidy. Sanitary drainage did appear appropriate. Restrooms did have hot water, paper towels, soap, and hand washing signs. Sanitary drainage is connected to the city sewer system.

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: NOT APPLICABLE

EVIDENCE: No high risk areas.

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: NOT APPLICABLE

EVIDENCE: Showers are not required.

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.

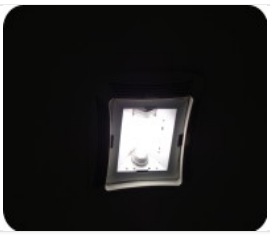
RESPONSE: MINOR

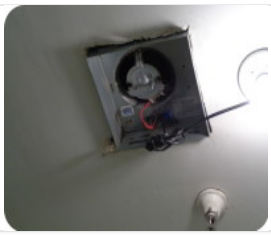
EVIDENCE: This site has employee restrooms that open to a production area. They lack an adjoining room (airlock, 2 doors). The restrooms do have negative ventilation that exhausts to the exterior. Both men's and women's ventilation units appeared dusty and soiled.

ROOT CAUSE: 1. Food Safety Team failed to recognize restroom must be in vestibule to ensure compliance with 11.3.5.6.i. 2. Food Safety Team failed to identify soiled ventilation units during monthly GMP audits. 3.Sanitation team overlooked ventilation units during daily cleaning

Purchase Request Todd L P... 10.06.21.xlsn

CORRECTIVE ACTION: 1. Ensure airlock installed to separate restrooms from processing and food handling areas 2. Clean both units to ensure they are free of dust and soil 3.Work order created to generate a Purchase Order to contract a construction company to perform the work.





Purchase Request Todd L P... 10.06.21.xlsn

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/04/2021 **CLOSEOUT DATE:** 10/22/2021

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

Staff observed and interviewed were aware of the site GMP policies. Policy was being followed by employees during the audit. No wearing of false fingernails or eyelashes, long nails or polish is allowed. There were not any observations of smoking, chewing, eating, unauthorized drinking or spitting on the site. Clear water in company approved containers in approved areas only. The flow of personnel is managed. Sensory testing is conducted in the lab area only. Wash down hoses were stored off the floor.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.1 Water Supply

The site is supplied by the City of Atlanta. The site has adequate supplies of hot and cold water. The backflow preventation is conducted 1x per year by an approved supplier. There was not any observations of cross-contamination. Water is sent to an approved 17025 lab and all results were found to be acceptable. Reference methods were documented on the COA. Backflow preventors are tested by a licensed plumber annually.

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: NOT APPLICABLE

EVIDENCE: No water is stored on-site.

11.5.2 Water Treatment

No water is treated.

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.5.3 Water Quality

This site receives potable water from the City of Atlanta. This site samples the water at points-of -use and sends the samples to Silliker, Stone Mountain, GA. Results from 09/27/2021 were <1.1 for coliform and E. coli and <1 Heterotrophic. The ab states it uses SMEWW 22nd ed 9221 B for coiforms and SMEWW 19th ed. 9221 F for E. coli. and SMEWW 22nd ed. for Heterotrophic Count.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.4 Ice Supply

Thi site does not utilize or purchase ice.

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: NOT APPLICABLE

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: NOT APPLICABLE

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: NOT APPLICABLE

11.5.5 Air and Other Gasses

Compressed air does not come in contact with the food.

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: NOT APPLICABLE

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: NOT APPLICABLE

11.6.1 Receipt, Storage and Handling of Goods

The site is properly storing raw materials and finished product. Stock rotation did appear to be effective. Equipment was observed to be properly placed and was able to be properly cleaned. Records are in process to handle product out of shelf-life.

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: NOT APPLICABLE

EVIDENCE: No temporary 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: NOT APPLICABLE

EVIDENCE: No temporary storage.

11.6.2 Cold Storage, Freezing and Chilling of Foods

The facility's cold storage were in full operation, with temperatures being monitored electronically and automatically, with an alarm system set to register in case temperatures fall out of a certain range. Probes were mounted in the warmest past of the coolers. Sufficient capacity was available for the raw materials requiring refrigeration. Drainage from defrost and condensate lines was controlled and discharged into the drainage system. Reviewed freezer and cooler temperature records (all within limits) from August. 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

Rooms used for packaging and raw materials were cleaned, maintained, and kept in a dry state. Racks used did allow for pest inspection and were maintained. Forklifts did not appear to present any food safety risks.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

All cleaning and sanitation hazardous chemicals were observed to be stored in cages with restricted access. Chemicals were observed to be in their refillable tanks, 55 or 5-gallon drums and dispensed using programmable titrators provided by the facility's chemical company. The storage of all chemicals was legally compliant. Storage areas had first-aid kits and spill-management kits within easy reach. SDS sheets for all chemicals were available to employees. No utensils or ingredients were stored in chemical storage areas. Chemicals were stored in such a manner as to inhibit cross-contamination between chemicals. All chemicals had instructions for use. Cleaning/Sanitation maintained an inventory of chemicals which was provided to this Auditor.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: Hazardous cleaning and sanitizing chemicals are stored in a locked cage in the wet sanitation room. There is first aid (eyewash) immediately outside the door to the oven area and to the left of the room. The eyewash was mounted on a hand sink with hot and cold water knee pedals close together. Potential if a person got chemical in their eye(s) it would be very easy to push the hot water instead of the cold water. **Please note this was immediately corrected at the time of the audit. An eye wash/shower was installed, easily accessible in the room close to the chemical storage area, with ambient water supply.

ROOT CAUSE: 1.Maintenance team failed to understand the importance of installing the eye wash stations

CORRECTIVE ACTION: Installed eye wash stations.

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/04/2021 **CLOSEOUT DATE:** 10/22/2021

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

Thi site receives both frozen and refrigerated temperature products. REeiewed documented temperature checks from Aug 15 and 30, Sept. 09, 2021. The site's Food Inspection requires that all tankers and trailers be inspected for cleanliness, infestation, odors, damage, etc. before loading and that vehicles be secured from tampering by use of seal or other agreed method. It was observed during the audit tours that loading practices do not expose products to detrimental conditions. Trailers and vehicles used for transport were observed to be properly secured from tampering by a seal or padlock. Seal numbers are recorded on the inspection records. Practices were observed during facility walkthroughs and found to be compliant with the facility's policy and best 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: NOT APPLICABLE

EVIDENCE: All finished goods are shipped at ambient temperatures.

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: NOT APPLICABLE

EVIDENCE: All finished goods are shipped at ambient temperatures.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.1 High-Risk Processes

No high risk foods. Products are packaged in dedicated rooms that are segregated from ingredients and other processes. These rooms are operated by dedicated staff. Product transfer points after the mixing step are designed to not compromise the products and minimize the risk of cross-contamination.

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

RESPONSE: NOT APPLICABLE

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: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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: NOT APPLICABLE

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: NOT APPLICABLE

11.7.2 Thawing of Food

Frozen products are kneaded until they are flowable. Packaging is disposed of properly.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: No air thawing.

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: COMPLIANT

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: COMPLIANT

11.7.3 Control of Foreign Matter Contamination

Each area/room has its own register of brittle surfaces. All areas of the plant were audited in Sept. of 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: This site does not have documented inspection of brittle/breakable surfaces for the forklifts and electric pallet jacks used to move pallets of ingredients or products into and out of food handling/contact zones.

ROOT CAUSE: Food Safety Team overlooked the exclusion of all glass and brittle plastic in the facility

CORRECTIVE ACTION: 1.Update current glass and brittle plastic inspection report to include the glass and plastic identified on forklifts and electric pallet jacks

QF047 Glass and Brittle Plastic- October 1.pdf

VERIFICATION OF CLOSEOUT: I have reviewed and I approve Corrective actions, root cause, and evidence of corrective actions. Quentin Beyer. Oct. 22, 2021.

COMPLETION DATE: 10/22/2021 **CLOSEOUT DATE:** 10/22/2021

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: NOT APPLICABLE

EVIDENCE: No glass instrument dial covers or MIG thermometers.

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: NOT APPLICABLE

EVIDENCE: No pumps with rubber impellers. No gaskets (no sanitary piping).

11.7.4 Detection of Foreign Objects

Metal detectors calibrated and validated by Factory Technicians 05/26/2021. The foreign material control monitoring equipment (metal detectors and X-ray) responsibility and methods are documented and implemented. Procedures reviewed included Metal detector and X-ray monitoring procedure. Metal detectors and the X-ray are monitored, validated and verified as per the company procedure. The metal detectors are equipped with rejection arm and box to isolate defective product when it is rejected. Below listed validation records were reviewed and it conforms to the procedure. Metal detector calibration records, Magnets pull strength check records, Metal detectors, magnets, and in-line filters monitoring and verification records are maintained. Listed records, including Sifters inspection records, Metal detector check records, In-line filter inspection records, and Magnets inspection records were reviewed. They conformed to the written procedure. See 2.4.3. summary for dates of records of metal detector monitoring reviewed by this Auditor.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.8.1 Waste Disposal

The waste handling responsibility and methods are documented and implemented. Waste collection areas observed cleaned and maintained during site audit. Waste observed removed on a regular basis from food handling and processing areas during site audit. Waste containers, bins, vehicles and storage areas observed cleaned and maintained during site audit. Solid waste is properly held in a separate area and adequately disposed. There is animal feed, general and recycling waste. These wastes are picked up by the waste handling company on regular basis. The liquid waste is treated outside the plant (waste water treatment) to remove solid and then liquid waste water is treated to balance pH prior to release. This waste water pH is monitored daily. Waste handling is monitored and documented. On-site laboratory is separated from processing and storage areas.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: No trademarked items.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT