SQF Food Safety Audit Edition 9

Food & Beverage Inc., dba Chris's Cookies - Chris's Cookies

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
8724 | 170302

AUDIT RATING

Excellent

DECISION DATE
11/18/2022

AUDIT TYPE
INITIAL CERTIFICATION

RECERTIFICATION DATE
10/10/2023

AUDIT DATES
10/10/2022 - 10/11/2022

EXPIRATION DATE
12/24/2023

ISSUE DATE
11/25/2022

Facility & Scope

Food & Beverage Inc., dba Chris's Cookies (44770)
Chris's Cookies
100 Hollister Road
Unit C1
Teterboro, NJ 07608
United States

Web Site: http://www.chriscookies.com

Food Sector Categories:
13. Bakery and Snack Food Processing

Products:
Cookies, brownies

Scope of Certification:
Packaged and Bulk cookies and brownies

Certification Body & Audit Team

WQS, LLC.
Quail Plaza - 7621 Little Avenue
Suite 200
Charlotte, NC 28226
United States

Phone #: 980-218-9151
Email: sqf@wqscert.com
Web Site: http://www.wqscert.com

CB#: CB-1-WQS
Accreditation Body: ANSI
Accreditation Number: 1226

Lead Auditor: Gonzalez Prego, Pavel (123392)
Technical Reviewer: Nolte, Fred (130321)

Hours Spent on Site: 16
Hours of ICT Activities: 0
Hours Spent Writing Report: 4

Non-Conforming

11.1.2 Building Materials

The auditor inspected both the internal and external premises as part of this audit. The facility and exterior environment were maintained in a sanitary manner. Floors were constructed of concrete. Floors were graded to prevent pooling during sanitation. The waste trap was located away from the food handling area and entrance to the facility. The floor was found in good condition. No risks associated with the location or construction of the premises were observed by the auditor at the time of the audit. The construction and ongoing operation of the premises on site are approved by the relevant authority, the New Jersey Department of Agriculture. The current business permit was provided for auditor review. The most recent FDA inspection was conducted in 2018. A narrative of the inspection was provided to the facility. The letter shows any adverse observations made by the inspector. Facility interior walls were light in color and maintained in a sanitary manner. Wall-to-wall and wall-to-floor junctions were maintained with no accumulation of debris noted. Corrective actions from the last SQF audit were completed. Windows have been covered. Overhead ducts are routinely dusted to keep accumulation from occurring. All areas of the facility are equipped with ceilings. No evidence of past or present leaks was observed on the ceiling surface. The drop ceiling is used in some production and office areas. Ceiling panels do provide access for maintenance of facility utilities.

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: During the floor inspection, the auditor sighted the wall-to-wall and the floor-wall junctions have a long gap in the ambient cooling room.

ROOT CAUSE: A contractor was hired to seal all walls in the bakery few months back. However one portion was overlooked. Moving forward all walls will be properly monitored on GMP, monthly inspections.

CORRECTIVE ACTION: The gap was sealed the second day of the audit and as a prooof of the action picture is attached as 11.1.2.4

VERIFICATION OF CLOSEOUT: A picture was provided showing the crack being fixed.

COMPLETION DATE: 10/11/2022 **CLOSEOUT DATE:** 11/02/2022

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: MINOR

EVIDENCE: The dry warehouse and the packing room have exposed fiberglass over the product zone.

ROOT CAUSE: Ovlooked during monthly inspection. All celings will be properly inspected for any exposed materials during monthly inspections.

CORRECTIVE ACTION: All exposed fiberglass are covered with a suitable material. As a proof picture is attached names as 11.1.2.8

VERIFICATION OF CLOSEOUT: The provided picture shows the exposed fiberglass being fixed.

COMPLETION DATE: 10/11/2022 **CLOSEOUT DATE:** 11/02/2022

11.2.4 Pest Prevention

There is a pest control policy SOP# 54 of 3/4/22. The annual review was done on 3/3/22 by the area manager. The pest review of pest records audit observed the following non-conformances: Written Integrated Pest Management Service Program was last updated on 3/3/22. The authorized product list for this location was last updated on 3/1/2017. The service report for 2022 was found complete and in compliance. When there are activities, they are followed up. The site uses the first strike as bait. Invade Bio Foam is applied to facility drains. Materials applied were not listed on the authorized product list their SDS was available. SPP moth trap is also included in map 1/6/22. Trend reports have been provided for services in 2022. The liability expires on 8/31/22. 42 mechanical traps, 3 pheromones, 7 insect lights, and 13 bait stations.

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

RESPONSE: MINOR

EVIDENCE: The main entrance has two control devices for ants, that are not included in the map.

ROOT CAUSE: Not creating a temporary map for the devices. Going forward the Pest control company is strictly instructed to create a temporary map if any short term devices are to be used as prevetive measure.

CORRECTIVE ACTION: Both ant control devices have been removed . Please refer to picture 11.2.4.2

VERIFICATION OF CLOSEOUT: The provided picture shows that the units were removed.

COMPLETION DATE: 10/13/2022 **CLOSEOUT DATE:** 11/02/2022

11.8.1 Waste Disposal

No uncontrolled accumulation of waste was observed inside or outside of the plant. The contracted service provider removes solid waste from the facility routinely. Liquid waste is removed through the city sewer system. All trash receptacles were labeled and maintained in a sanitary manner. A daily inspection program is used to ensure the proper level of housekeeping is being conducted and that the facility is being maintained in a condition that is adequate and sanitary for safe and quality food manufacturing. Self-inspection monitoring records provided for auditor review were dated.

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: MINOR

EVIDENCE: Sighted the outside garbage container open.

ROOT CAUSE: Associates being careless in replacing the cover after using the dumster for waste. The cover was put back immediately on 10/11/22, and all associates handling the dumster have been trained on 10/27/22 to put the cover in correct position after its use.

CORRECTIVE ACTION: The cover has been replaced. Refer to picture 11.8.1.8 & Training record 11.8.1.8

VERIFICATION OF CLOSEOUT: The picture shows compliance and the training will prevent future issues.

COMPLETION DATE: 10/11/2022 **CLOSEOUT DATE:** 11/02/2022

Section Responses

Audit Statement	Audit
SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Christian Gargiulo
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** chris@chriscookioes.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Christian Gargiulo: President/CEO, Kapila Devkota: Consultant Certified Food Scientist, Pavel Gonzalez Prego: Auditor.

Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** This cookie manufacturing plant is in operation Monday - Friday from 5 AM - 10 PM. Additional production may be carried out on weekends during the peak holiday season due to heavy customer orders. The baked cookie production area is 30,400 square feet. This facility employs 35 full-time employees composed of production, management, and drivers. Temporary employees may be used during the peak holiday season. There are two production lines. Employees are scheduled on two 10-hour shifts. The two shifts overlap from 1-3 PM. Most of the production is carried out on the first shift. The second shift will finish production and spend the remainder. There is a shipping/receiving area with 2 bays, there are 7 production rooms, 1 storage freezer (5,000 square feet), 1 storage area, 3 lunchrooms, office spaces, there are 7 toilets, and 9 hand washing stations.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Christian Gargiulo: President/CEO, Kapila Devkota: Consultant Certified Food Scientist, Pavel Gonzalez Prego: Auditor.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Certify the Site as soon as the findings are corrected, and approved by the auditor and WQS.

2.1.1 Management Responsibility (Mandatory)

Food Safety Management Mission and Vision statement was most recently updated on 10/3/22 and signed by the company president. The statement is posted in the employee breakroom and the front of the building. Food Safety Management Mission and Vision statement is provided in both English and Spanish as the facility has 50% of the workforce speak Spanish. Additionally, about 25% of the workforce also speaks Hindi. However, those who speak Hindi are also fluent in English. The CEO, who is ultimately responsible for the maintenance and implementation of the food safety policy statement signed the posted policy. The CEO accompanied the auditor throughout the facility inspection and participated in the records and policy review portion of the audit. The policy statement includes management commitment to the production of fine desserts using high-quality ingredients with a commitment to excellence, innovation, enhancing the customer experience, creating and maintaining food safety objectives, and a food safety culture. Continual improvement of the food safety management system is carried out using: monitoring of key process indicators to measure whether food safety objectives are being met. The communication of the importance of meeting and maintaining the SQF standard -following applicable regulatory requirements -compliance with customer food safety requirements -compliance to documented food safety policy -conducting management reviews -ensuring the availability of resources Any changes made to the Food Safety Management System Manual must be approved by the CEO. Records of all amendments are to be maintained. The SQFP and the backup are full-time employees of the company. The SQFP Backup is in training (QA Tech) at this moment; however, the current backup is a shareholder. He is holding that position until the QA is finally trained to maintain the SQF system integrity. The organizational chart 7/1/22 for this facility was most recently updated. Annual GMP training on 9/21/22 conducted with employees includes the concept that all employees are responsible for food product safety. Slides and employee sign-in sheets were used on 9/21/22. GMP refresher training was provided. This plant has designated the Quality Tech as the SQF Practitioner Backup. The CEO is the Practitioner for this location should the designated Practitioner be absent. These individuals have read the SQF code. The SQFP is HACCP Certified from AIB International on 10/9/22. Examples of written job descriptions provided for auditor, the review included: CEO, Food Safety and Quality Technician, Production Manager, Receiving Supervisor, Maintenance Supervisor, and Order Processing Supervisor. This is an initial audit, so a blackout or unannounced audit is cannot be permitted. Blackout dates will be set 30 before the 60 days audit window.

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:** Initial audit.
2.1.2	**Management Review (Mandatory)** The food safety system manual was most recently updated on 10/3/22 as a result of the annual review process. The review process, quality-food safety manual, and internal audit were done at the same time. They were done every week for 4 months using the SQF Checklist. Right after each audit, a review meeting was conducted. An example of the internal audit done on 6/8/22 (management commitment section 2.1), on 9/7/22 the product traceability and Crisis Management were conducted, and on 10/4/22 the Receipt, Storage, and transport were done. The review of the policy manual, and internal, and external audit findings include corrective actions, investigation, and resolution. Also, customer complaints and their resolution and investigation are included in the review. The weekly management meetings are conducted. Participants in the weekly meetings are the CEO, QA Manager, and Production Supervisors. Weekly self-audits which are used to monitor the maintenance of the Food Safety Management System programs are reviewed during these meetings. In addition to the weekly meetings, the entire Food Safety Management System is reviewed at least annually. Changes to the food safety management system are required to be validated by the QA Manager. Records of reviews, amendments, and validations are to be maintained for a minimum of two years.
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)** SQFP is responsible for handling and investigating customer complaints. Complaints may be received via phone call or email system. If a non-conforming product is returned to the manufacturer it is placed on hold, and investigated by the Quality Department, findings are reported to Senior Management who will make the decision for the disposition of the product. Trends of customer complaints are analyzed by personnel from the quality department. Corrective actions taken are commensurate with the seriousness of the incident. Records are to be maintained for a minimum of 2 years. For example, there are three customer complaints. The 2022 records were reviewed. 2 were related to foreign material and one related to dark products.
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)** The Food Safety Manual 5/22/22 is reviewed at least annually. The policies, procedures, and programs reviewed during the course of the audit indicated this facility has an established food safety management system. Copies of the Food safety system manual are maintained in both electronic and hard copy formats. The Hard copy is maintained in the QA Office. The Q-drive is where the electronic copy of the manual is stored. The SQF Practitioner / QA Manager at this location has been given responsibility for ensuring programs are reviewed, verified, and validated at least annually. Records of these activities are to be maintained according to the established records retention program. The food safety management system includes food safety plans and prerequisite programs used to support the plans. The system identifies the scope of this certification and the products covered. The scope of certification is the manufacturing of baked goods from the receipt of raw materials, through manufacturing to the distribution of finished goods
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)** A document control policy is included in the SQF manual issue date of 3/4/22. All documents about the food safety management system are identified by the name of the person implementing with the issue date as they are implemented in the process every day. All documents are maintained as electronic files. A backup of all electronic files is maintained. Control of documents ensures that all proposed changes are reviewed before implementation to determine their effects on food safety and their impact on the food safety management system. All records are to be maintained in the office for a minimum of one year and in storage for up to five years or as per regulatory / or customer requirements. The document register is maintained by the SQF Practitioner. Document register provided for auditor review lists the name of the document, SSOP, or SOP, version, last updated, and approved by. Additional amendment record is maintained. Distribution lists indicate a hard copy is maintained in the QA office and an electronic copy is maintained on the computer Qquality drive.
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)** Reviewed SOP # 10, which covers the records. The auditor requested the 2022 records to verify food safety and quality records. They are being maintained. Dates of records requested and provided promptly were properly reviewed. The 2022 records complied. For Example, Screws removable parts count, inbound products inspection, Allergen cleaning verification, Daily Pre-operational Inspection, temperature monitoring, and freezer and cooler logs. Packaging area checks from Finished product weight checks. Metal detector check form All records are to be maintained in the office for a minimum of one year and in storage for up to two years or as per regulatory / or customer requirements.
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** The CEO of the company is in charge of product development. Product development and realization programs for designing new products, product formulation, manufacturing processes, and the fulfillment of product requirements are always validated by facility trials, shelf life trials, and product testing. SOP #31 details the steps to be taken during the implementation of a new product. Nutra coster software program is used for nutritional and cost evaluations for proposed products. Shelf life evaluations are based on sensory taste and micro tests. Trial runs samples are evaluated daily to establish shelf life standards. Micro tests are conducted on the day of the trial run and every week to establish the end of shelf life. The list of products developed for 2022 indicates multiple products have been developed. Most of the products are developed by the customers and they conduct their own shelf life.
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)** Raw materials register and specifications have been compiled by the SQF Practitioner. Supporting documents obtained from raw materials suppliers includes third-party audits, SDS, product specifications, kosher certifications, allergen statement, certificate of liability insurance, continuing food guarantee, crisis management contact information, bioterrorism, a summary of quality assurance programs, preventive control plan summary, country of origin statement, GMO statement, nutritional statement, lot/batch code format, and a recall plan. Auditor referenced Blue Diamond Growers to verify specifications are maintained on file for approved ingredients suppliers. Supporting documents obtained from packaging suppliers included a certificate of guarantee, an FDA 21 CFR compliance statement, and current third-party audit certification. The auditor referenced Supply One food product packaging approved supplier to verify packaging specifications are maintained on file. A packing area check form is used to document monitoring that finished product labels are complete, legible, and applicable to the product produced. The packaging area check form provided for auditor review details the time, product name, visual sensory evaluation of the product produced, package weight, sealing, supervisor initials, finished product lot number, correct packaging material used, all allergens listed on the label, quantity in case, quantity in the tray and QA initials. The contract service provider register is maintained in two parts, contract services listing details of the service to be provided, and the frequency of service to be rendered. Contact information for the contracted service is maintained on the approved supplier register. Challenged the label of several products and found them in compliance. For example, the Honolulu Cookie Company 4 Oz Mini Bites Guava, item # 127-004GS lot # 20230618. The ingredients and sub-ingredients were correctly stated from the predominant to the least amount.
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 manufacturer.
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)** Finished products specifications detail the product name, product brand, product type, item number, physical characteristics, microbial characteristics, chemical attributes, ingredients, allergen status, pack size, item net weight, case net weight, gross weight, production code format, lot code example, storage condition, shelf life, primary packaging, primary packaging UPC, secondary packaging, UPC, box dimensions, issued by, and revision date. Auditor referenced the finished product Mini Macaroons, Chocolate Chunks Cookies, and Assorted Butter Cookies to verify specifications are maintained on file.

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)** SQF Manual places responsibility for food legislation on the Food Safety and Quality Manager. FSMA implementation for this facility is in place. The food legislation policy does include the requirement for SQFI and the certification body to be notified should a food safety event that requires public notification occur. This facility did experience such an event the week before this audit. Further details are included under the recall/withdrawal. The site is registered with the FDA xxxxxxx4012 expiring on 12/31/22. The Business License 12731 expires on 3/31/23. The last inspection assignment 9285 on 10/17/18 without any finding.
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)

Auditor was required to review GMP expectations at the time of arrival at the plant. Entrances to production areas are posted to remind employees and visitors they are entering a GMP-required area. Records of the most recent GMP training conducted with employees were provided for auditor review. The most recent GMP refresher training was conducted on 9/21/22.

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)

Food safety program places responsibility for the development and implementation of food safety plans on a multi-disciplinary food safety team. This team is led by the QA Manager. The food safety team for this location is comprised of the QA Manager, CEO, CFO, Production Manager, Maintenance Manager, and QA Technician. A food safety plan is supported by documented pre-requisite programs for Master cleaning schedule and SSOPs GMPs Pest Management Chemical control Consumer complaint program Traceability and Recall Program Allergen Control program Approved Supplier Program Equipment / Lab Calibration Receiving Inspection Program Preventive Maintenance Program HACCP plans provided for auditor review were most recently reviewed and approved by the food safety team on 10/6/22. This facility has developed 15 different plans to cover all types of cookies produced by this site. Plans include a product description that details the product name, process category, how it is to be used, type of package, preservative tolerance, water activity, storage and distribution, where it will be sold, case code requirements, labeling instructions if special distribution control is needed, formula number, product common name, shelf life, and packaging size. Plans include flow charts. Hazard analysis identifies potential hazards introduced, controlled, or enhanced at each step in the process. Hazards are classified as biological, chemical, or physical. Consideration is also given to the likelihood of risk or severity of risk involved. All plans' hazard analysis identifies only one CCP. CCP identified is metal detectors. Plans include a science base used for the establishment of critical control limits. Control is to pass all products produced through a metal detector as close to the end of the packaging process as possible. Metal detector functionality is verified daily using Fe, Non-Fe, and Stainless Steel test pieces. All test pieces are >/= to 2mm. Metal detector functionality is verified at start-up, every 60 minutes during production, every changeover of product, and at end of production. The production manager, QA manager Operations manager, or a CCP-trained employee is responsible for performing metal detector verifications. Should the metal detector be found not to be functioning properly, corrective action is to put all products produced since the last good check on hold. Investigate the cause of metal detector malfunction and correct it. All products placed on hold must be re-run through a properly functioning metal detector. The last one was done on 10/6/23.

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** Finished product weight checks are performed on each product, and each production is run by QA staff. The weight check form details the sample number, product name, lot number, SKU number, shelf life, unit of measure used, and time sample taken. If 2 or more out of 5 packages are underweight, they are placed aside and a new 5-sample lot is taken. If still have two or more weights, all packages since the last good check are to be put on hold for the underweight product. QA Manager, Production Supervisor, and managers are responsible for ensuring necessary corrective actions are taken. The finished product grading form is used to document the sensory evaluation of the finished product produced. Grading of products is conducted by QA staff daily. The finished product form is used to evaluate products for shape, size, color, texture, flavor, and aroma. Products are evaluated using a 1-5 grading scale. If the product is awarded a 1, the product is considered a fail. The product evaluated as a 5 is considered excellent. A product that receives a score of 2 needs improvement, 3 is acceptable and 4 is good. Weight before and after baking is monitored on each production run by QA staff. The acceptable range is defined as the +/- 5 grams from the specific target weight detailed in product specifications. If 2 or more out of 3 units are underweight or overweight, put aside these packages and check 3 more units. Notify QA Manager or production supervisors if the second sampling set is also found non-conforming. Before and after baking form details the time sample taken, product name, lot number, unit of measure, weight range before baking, sample weight in triplicate, after weight range, after baking weight in triplicate, and QA staff initials.
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

Written SOP details the steps to be taken when a non-conforming product, raw material, or equipment is identified to minimize the risk of cross-contamination or usage. The quality department is to be responsible for the hold and release program. Form #55 is completed for each rack or pallet that is to be placed on hold. This completed form is then used to tag the non-conforming item. Form #55 states in big red letters, "PRODUCT ON HOLD DO NOT USE." This tag is applied to 2 or 4 sides of the pallet, basket, or rack to ensure the item is identified as being on hold. SQF Practitioner maintains a hold log. Hold log details the date hold was initiated, product, lot number, quantity, manufacturing date, use by date, reason for being on hold, disposition action to be taken, and initials of the person placing on hold. Hold logs for 2021 and 2022 were provided for auditor review. The auditor observed the product on hold in the cooler at the time of the facility tour. At the time of observation, the product was identified and isolated from other conforming products.

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

The rework log details the date product originated, description of the item to be reworked, original pack size, lot number of item to be reworked, quantity, the item being reworked into, new pack size, new lot number, quantity reworked, shipped quantity and initials of QA staff release. 2022 rework records were provided to review. QA is responsible for visually inspecting products for rework and notifying production when rework is to be used.

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

RESPONSE: COMPLIANT

2.4.7 Product Release (Mandatory)

The Quality Manager or another member of the Quality staff is the only one authorized to release the product for shipment. Once all inspections and analyses are successfully completed and documented to verify legislative and food safety controls have been met the product is eligible for release to the distribution chain. A flexible software program is used to note product is on hold or has been released for shipment. Warehouse staff interviewed at the time of the audit demonstrated how software program is used to monitor stock rotation and shipping records. The 2022 outbounds inspection was reviewed, for example, form # 3 of the outbounds inspections of 9/14/22 shows compliance. The product was shipped frozen at -10 degrees Fahrenheit. The trailer inspection for the same day (Form # 50) showed compliance.

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** The environmental program was reviewed on 3/4/22. The Risk Assessment was done on 8/2/22. Five swabs are collected each month and sent to an outside reference lab for Listeria genus analysis. Testing results provided for auditor review were dated. The 2022 results passed the tests. The last tests were done on 10/5/22 for Listeria in zone 3. The site conducts 4 tests of listeria monthly from random areas of zone 3. The site conducts 2 APC tests quarterly on zone 1 and 2. No failure has been reported. The test result is verified by the SQFP about the next day after the result arrives. The SQFP prints and initials the tests. CAPA is required on failed desired results. Re-test swab for the area that fails is required after it is cleaned.
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)** The SQF Practitioner is responsible for ensuring all validation activities are conducted and documented. The schedule details the frequency and methods used to validate and verify food safety fundamentals, food safety limits, and quality controls. Monthly reviews of customer complaints are used to validate programs are effective at controlling the hazards. Annual validation records were provided. The CCPs were validated: The validation was done during the annual HACCP review. The pre-requisite programs were validated during the internal audit to cover those sections. The GMP was validated using the 21CFR110, 21CFR117, and 21CFR136, the preventive controls, and module 11 of the SQF V9 Code. The sanitation was validated using environmental, ATP, and regulatory guidance. The guidance 555.425 was used to validate the glass and similar material control programs, also, it was used to validate the metal control program. The electronic data and documentation is validated using the 21CFR subpart 11 of an electronic record and electronic signature.
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)** The verification plan has been documented in table format. The verification schedule defines the activity/prerequisite program to be verified, the frequency of verification, the records maintained, and who is responsible for ensuring verification is completed. Verification plan has been applied to Customer complaint/feedback - monthly Process flow - annual Hazard analysis / CCPs - annual CCP monitoring records - daily Process and supply records - daily CAPA records - each occurrence Metal detector calibration- yearly Cleaning - monthly Pre-requisite programs - yearly Pest control - quarterly. All records are verified within 7 days.

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)** CAPA reports are maintained by the SQF Practitioner. The 2022 CAPA records were provided and reviewed. The CAPA reports detail the findings of the incident, define immediate corrective actions to be taken, the root cause of the incident, long-term corrective actions, preventive actions, and expected date of completion. Reviewed the 2022 corrective action on non-conformance, internal audit, and customer complaints.
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 are conducted by the SQFP as they are independent of all other areas being audited. Form # 26 is used to document internal audits which are similar and reflect the SQF V9 checklist. The form has been designed so that all areas of the facility are being monitored for compliance with all elements of the SQF v9 code. Internal audits include the ID of staff conducting the internal audit, date of audit, observations made and location, corrective actions taken, staff responsible for corrective action, and date completed. Records of internal audit findings provided for auditor review covered from July 2022 to October 2022. The GMP Audit is done monthly and covers the entire facility and the equipment.
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)

Assembly form is used to document the item numbers, item names, and lot codes of individual baked goods to maintain their traceability to produced manufacturing when several products are put together to create a combination of products for a private label entity. Assembly also details the name of the finished product produced, lot code for the new finished product, number of units made, production supervisor initials / or QA tech initials, and any additional comments. The comments section is used to record the customer ID, net weight statement, and sell-by code. SQF Practitioner is responsible for verifying that assemble forms are being completed. During the flow inspection, all sighted items were properly ID (Packed materials, packaging, and final products).

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)

The traceability policy states the responsibility and the control method used throughout the operation and the process steps. The Assembly form was challenged during the audit, along with the operator, 2022 receiving, shipping, and label accuracy records of the ingredients, packaging, and final products. The traceability is maintained on products and materials on hold. No expiration or allergen segregation issue was sighted. The traceability/recall/counted-for mock was conducted during the audit and twice a year (see 2.6.3).

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 product recall/withdrawal policy provided for auditor review was most recently revised on 2/1/22. The policy establishes are recall team which is composed of the CEO, Production Manager, Quality Representative, Legal Counsel, and Maintenance Supervisor. The CEO is a member of senior management who leads the recall team. The policy requires at least two mock recall exercises to be conducted annually. The most recent mock recall exercise was conducted on 10/2/22. Records of the exercise were maintained on file. The program includes the responsibilities of the recall team. The program also includes the recall class I, II, III, Market Withdrawal, and Stock Recovery. During the audit, the site conducted a mock recall of 179 cases of Honolulu Cookie Mini Lemon Bites lot # 20230317. The raw materials and packaging were traced back to the suppliers. The final product was recalled and traced to Costco Van Burn Dry Storage Center. 100% of the raw and packaging materials and the final product were counted for 100%. Conducted in 54 minutes.

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** The Crisis Management Policy Revision date 7/22/22 was provided for auditor review. The policy establishes a Crisis Management Committee which is composed of the President, CFO, Production Manager, Maintenance Supervisor, Food Safety and Quality Assurance Manager. The policy outlines the responsibilities of each of the Crisis Management Committee members. Contact information for committee members (5) and legal and expert advice are included in the policy. This facility has made arrangements with an alternate bakery operation to produce products for them should a crisis occur which would render the plant unable to produce its own products. In the event of a recall, the QA Manager is given responsibility for informing essential bodies including FDA, SQFI, and the certification body. The policy requires a test of the crisis management plan to be conducted at least annually to ensure the plan is effective at controlling risks identified by the plan. The most recent test of the business continuity plan was conducted on 7/22/22. The scenario was the main power outage of 2 or more days. Once power is restored, maintenance staff assess the plant equipment for damage triggered by power loss. A summary of actions that would be taken had this been real was provided for auditor review. The crisis management team was activated. The decision was made to contact an alternate manufacturer to produce 510 packs of Trader Joe's Sutters Peanut Butter V2. CEO for this facility would travel to the alternate manufacturing site to oversee the production of products until production at this plant could be restored. A written agreement to act as a backup manufacturing site for this plant was issued on 2/20/2018. Records of crisis management mock events are maintained for a minimum of two years per the records retention policy. The threats identified for the site are Power Outages, Water shortages, Floods, Labor Strikes, Vandalism, Bomb Threats, Natural Disasters, and Pandemics. The method is included in each threat. The site uses the mock crisis test as training for the team.
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)** The food defense team meets at least annually to review the program and conduct a reassessment. The food defense team is made up of the CEO, CFO, QA Manager, Production Manager, and Maintenance Manager. In addition to the annual review, weekly inspections are conducted by QA personnel. Weekly food defense inspections were provided for review. The assessment was done on 8/5/22 and the challenge was done on the doors' lock on 9/3/22.
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)** SQFP monitored regulatory and industry websites for incidents of food fraud as a means of figuring out what risks could apply to this facility. Based on their research findings, no raw materials used by this facility nor the approved suppliers used by this facility are considered high risk for food fraud. A review of COAs is being conducted to monitor approved supplier performance and to ensure products purchased meet agreed-upon specifications. At the time of audit risk assessment indicates all materials used by this facility are low risk for food fraud. The site identified Honey, Spices, Vanilla Extract, and Canola Oil. The mitigation includes 3rd party audit, COA, Letter of Guarantee, and inspection at receiving.
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)** Raw materials have been evaluated for the presence of allergen sub-ingredients. Allergens identified are milk, soy, tree nuts, and ground nuts. Hygiena swabs are used every day to test equipment post-sanitation for allergenic proteins. Once per year post sanitation swabs are taken and sent to a reference lab and tested for specific allergens using the Neogen Veratox test kit. Reference lab test results provided for the auditor reviewed the last tests on 10/4/22 the file for peanuts on Guava. Also, other tests were done on almonds, hazelnut, macadamia nut, and pistachio. Samples are collected both pre-sanitation and post-sanitation. Test results indicate the sanitation steps carried out effectively removed the allergenic proteins. Daily Hygienic test results are completed on key pieces of equipment, such as mixers. Daily allergen verification swab results were provided for review.

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** The written work instructions at workstations were available in production areas at the time of the facility tour. SSOPs and SOPs are provided for the training of employees. Employees interviewed at the time of the audit showed the auditor where written procedures are stored at workstations to provide staff with access as needed. Training and training materials are available in English and Spanish as these are the languages used by the workforce.
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)** Training sessions are followed by a quiz which is used to determine the employee's level of understanding. Copies of participants' quizzes are maintained on file by the SQF Practitioner. Training and training materials are available in English and Spanish as these are the languages used by the workforce. The most recent GMP training was conducted on 9/29/22. The most recent Recall training was conducted during the last mock recall. The most recent QA training was conducted on 9/29/22. The most recent ingredient receiving and allergen storage training was conducted on 9/29/22. The most recent ATP training was conducted on 9/29/22. The most recent post-operation inspection training was conducted on 9/29/22. The most recent hand washing requirements training was conducted on 9/29/22. The most recent pre-operational process training was conducted on 9/29/22. The most recent cleaning procedure and proper way of cleaning equipment training were conducted on 9/29/22. The most recent metal detector CCP training was conducted on 9/29/22. The most recent SQF training was conducted on 9/29/22..
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** The training binder is used as the training register. Training sign-in sheets identify the date of training, subjects covered during training, who the instructor is, and persons completing the training. All training sessions are concluded with a quiz that each participant is required to take. The results of quizzes are used to determine the participant's level of understanding of the materials covered.
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

The auditor inspected both the internal and external premises as part of this audit. The facility and exterior environment were maintained in a sanitary manner. Floors were constructed of concrete. Floors were graded to prevent pooling during sanitation. The waste trap was located away from the food handling area and entrance to the facility. The floor was found in good condition. No risks associated with the location or construction of the premises were observed by the auditor at the time of the audit. The construction and ongoing operation of the premises on site are approved by the relevant authority, the New Jersey Department of Agriculture. The current business permit was provided for auditor review. The most recent FDA inspection was conducted in 2018. A narrative of the inspection was provided to the facility. The letter shows any adverse observations made by the inspector. Facility interior walls were light in color and maintained in a sanitary manner. Wall-to-wall and wall-to-floor junctions were maintained with no accumulation of debris noted. Corrective actions from the last SQF audit were completed. Windows have been covered. Overhead ducts are routinely dusted to keep accumulation from occurring. All areas of the facility are equipped with ceilings. No evidence of past or present leaks was observed on the ceiling surface. The drop ceiling is used in some production and office areas. Ceiling panels do provide access for maintenance of facility utilities.

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: During the floor inspection, the auditor sighted the wall-to-wall and the floor-wall junctions have a long gap in the ambient cooling room.

ROOT CAUSE: A contractor was hired to seal all walls in the bakery few months back. However one portion was overlooked. Moving forward all walls will be properly monitored on GMP, monthly inspections.

CORRECTIVE ACTION: The gap was sealed the second day of the audit and as a prooof of the action picture is attached as 11.1.2.4

VERIFICATION OF CLOSEOUT: A picture was provided showing the crack being fixed.

COMPLETION DATE: 10/11/2022 **CLOSEOUT DATE:** 11/02/2022

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:** MINOR **EVIDENCE:** The dry warehouse and the packing room have exposed fiberglass over the product zone. **ROOT CAUSE:** Ovlooked during monthly inspection. All celings will be properly inspected for any exposed materials during monthly inspections. **CORRECTIVE ACTION:** All exposed fiberglass are covered with a suitable material. As a proof picture is attached names as 11.1.2.8 **VERIFICATION OF CLOSEOUT:** The provided picture shows the exposed fiberglass being fixed. **COMPLETION DATE:** 10/11/2022 **CLOSEOUT DATE:** 11/02/2022
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:** NOT APPLICABLE **EVIDENCE:** This operation is carried out on one floor only. No catwalks, platforms or stairs are used by this facility.
11.1.3	**Lightings and Light Fittings** Light fixtures were maintained in a sanitary manner throughout the facility. Light fixtures used shatterproof bulbs and had protective covers in place. Light intensity was sufficient for employees to carry out production and sanitation tasks assigned to them. No risks associated with lighting were observed by the auditor at the time of the facility tour.
11.1.3.1	Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light-intensity regulations or industry standards. **RESPONSE:** COMPLIANT
11.1.3.2	Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling. Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program. **RESPONSE:** COMPLIANT
11.1.3.3	Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination. **RESPONSE:** COMPLIANT
11.1.4	**Inspection/ Quality Control Area** The inspection of products is provided in a separate room. Sensory evaluation inspection is not located in the open product zone. The auditor observed the sensory evaluation of products during the production run in a segregated room. No risks to products being produced were observed by the auditor.
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 doors observed were sealed tightly at the time of the audit. Personnel doors provided were fitted with a self-closing device. External doors were kept closed when not in use at the time of the audit. An insect light device is used and located so as not to draw insects into the plant.

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** No condensation or mold growth was noted in packaging or food processing areas. Fans and exhaust equipment used were maintained in a sanitary manner.
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** Overall equipment and utensils observed at the time of the facility tour were designed, constructed, and operated so as not to contaminate the products being produced. The auditor observed the post-operation cleanup of the kitchen and processing equipment as part of this audit. The auditor observed equipment being broken down to its smallest element to provide effective cleaning. Most cleaning for this operation is manual. Processing equipment and utensils are mostly composed of stainless steel or other metal surfaces. Containers used for the inedible product were labeled waste only.
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** The plant is located at one end of a commercial plaza-style building. A paved parking lot is provided in front of the building. The outside was adequate, clean, and maintained. No vegetation issue was observed around the building. No accumulation of trash was observed around the plant perimeter. No equipment or other potential pest harborage points were observed on exterior grounds. Auditor toured both the internal and external premises as part of this audit. The facility and exterior environment were maintained in a sanitary manner. No risks associated with the location or construction of the premises were observed by the auditor at the time of the audit. The construction and ongoing operation of the premises on site are approved by the relevant authority, the New Jersey Department of Agriculture. The current business permit was provided for auditor review. The most recent FDA inspection was conducted in 2017 and 2022 without findings. The Narrative of the inspection was provided to the facility. The letter does not indicate any adverse observations were made by the inspector.
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:** NOT APPLICABLE **EVIDENCE:** No outside amenities.

11.2.1	**Repairs and Maintenance** The maintenance program and the PM Schedule were reviewed. A printed form for the work order is used. The facility is also using a computerized system. For examples of handwritten work orders provided for auditor review at the time of audit covered the 2022 records. They provided for review indicate the manual system has been applied to the building, equipment, and external premises. Most maintenance at this facility is carried out by one maintenance staff member or the production manager. These individuals have received training on proper procedures to follow when performing maintenance in production areas, GMP, allergens, and chemicals. A dedicated storage cabinet is provided for the storage of food-grade lubricants. No product contact surfaces observed by the auditor at the time of the facility tour were painted. The site does not allow temporary repair; however, a log is available in case it is needed. The work order includes the signing-off of the area supervisor and the maintenance personnel to account for the area and equipment cleanup, removal of debris, spare parts, and tool removal.
11.2.1.1	The methods and responsibility for the maintenance and repair of plant, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination. **RESPONSE:** COMPLIANT
11.2.1.2	Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety. **RESPONSE:** COMPLIANT
11.2.1.3	Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule. **RESPONSE:** COMPLIANT
11.2.1.4	Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling, or storage areas. **RESPONSE:** COMPLIANT
11.2.1.5	The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance activities pose a potential threat to product safety (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside operating times. **RESPONSE:** COMPLIANT
11.2.1.6	Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions. **RESPONSE:** COMPLIANT
11.2.1.7	Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product. **RESPONSE:** COMPLIANT
11.2.1.8	Paint used in a food handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces. **RESPONSE:** COMPLIANT
11.2.2	**Maintenance Staff and Contractors** All Maintenance staff, visitors, and contractors shall sign off at the office. They have to go through the site GMP and Food Defense before are allowed to get in the facility. The signing-off is a contract between the visitor and the site that they will follow and be in compliance with the site policy. The GMP training goes directly to the point without ambiguity. The Work Order System is designed to follow up on the removal of debris, spare parts, tools, etc., and cleaning by signing off of the area supervisor and the contractor/maintenance personnel. During the audit the site did not perform any maintenance activity; however, the 2022 records (visitor log, visitor GMP, and work order) show compliance.
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** The Calibration policy was reviewed and includes a documented calibration schedule and calibration logs. The Policy also includes the contracted service providers that are used for calibration activities. Calibration records provided for auditor review as part of this audit included: Plant scales are calibrated at least every six months by a contracted service provider. The 2022 records for the internal daily calibration/verification of the scales were provided and reviewed. The ATP swab machine and the allergen incubator were calibrated by the manufacturer. The metal detectors and rejection systems are calibrated annually by a contracted service provided. The 2022 records show that the site verifies and challenges the metal detectors hourly when they are in use. Thermometers are calibrated annually by a contracted service provider. The 2022 records show that the daily verification/calibration is conducted as required. Ovens are calibrated annually by a contracted service provided. The 2022 records were provided and reviewed. Metal Detector and Rejection System were calibrated on 3/15/22 by Fortress Technology. Scales were calibrated by Arlinton Scale Company on 3/28/22. The master thermometer (Control Company, Serial # 221283788) expires on 2/23/23. The water activity meter (Rotonic) is calibrated using the calibration kit. The moisture analyzer is calibrated before it is used. The backflow certification is current as of 7/7/22, the landlord is responsible, and it is done every quarter.
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** There is a pest control policy SOP# 54 of 3/4/22. The annual review was done on 3/3/22 by the area manager. The pest review of pest records audit observed the following non-conformances: Written Integrated Pest Management Service Program was last updated on 3/3/22. The authorized product list for this location was last updated on 3/1/2017. The service report for 2022 was found complete and in compliance. When there are activities, they are followed up. The site uses the first strike as bait. Invade Bio Foam is applied to facility drains. Materials applied were not listed on the authorized product list their SDS was available. SPP moth trap is also included in map 1/6/22. Trend reports have been provided for services in 2022. The liability expires on 8/31/22. 42 mechanical traps, 3 pheromones, 7 insect lights, and 13 bait stations.

11.2.4.1	A documented pest prevention program shall be effectively implemented. It shall: i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods and the appropriate documentation for each inspection; v. Outline the frequency with which pest status is to be checked; vi. Include the identification, location, number, and type of applied pest control/monitoring devices on a site map; vii. List the chemicals used. The chemicals are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available; viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests and to identify trends. **RESPONSE:** COMPLIANT
11.2.4.2	Pest contractors and/or internal pest controllers shall: i. Be licensed and approved by the local relevant authority; ii. Use only trained and qualified operators, who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.2.8), which includes a site map, indicating the location of bait stations traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; vi. Provide regular inspections for pest activity with appropriate action taken if pests are present, and vii. Provide a written report of their findings and the inspections and treatments applied. **RESPONSE:** MINOR **EVIDENCE:** The main entrance has two control devices for ants, that are not included in the map. **ROOT CAUSE:** Not creating a temporary map for the devices. Going forward the Pest control company is strictly instructed to create a temporary map if any short term devices are to be used as prevetive measure. **CORRECTIVE ACTION:** Both ant control devices have been removed . Please refer to picture 11.2.4.2 **VERIFICATION OF CLOSEOUT:** The provided picture shows that the units were removed. **COMPLETION DATE:** 10/13/2022 **CLOSEOUT DATE:** 11/02/2022
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** The cleaning program includes cleaning procedures, training, and a cleaning schedule. There is a designated equipment and tools cleaning room at the corner of the kitchen for cleaning of utensils, pans, and other large movable processing equipment. Sanitation inspections are conducted daily by QA Manager and Production Manager to evaluate the effectiveness of cleaning. The auditor observed the pre-production inspections including monitoring the equipment to ensure that all removable parts are secured and in place. The same form is also used to verify if the safety mechanism is working. The auditor observed the pre-operational inspections, the second day of the audit, which is done through visual inspection of areas to ensure they are hygienically in compliance before production begins. The ATP and Hygiena allergen swabs are also conducted before production on each piece of equipment to be used during that production day. Pre-operational inspection includes monitoring of the warehouse racks, floors and walls, shipping / receiving area, restrooms, lunch room, hand wash sinks, coolers/freezers, trash removed, enrobing/decorating area, packaging area, production room, and equipment. Pre-production inspections are signed by the QA or Plant Supervisor conducting the pre-production inspection. The QA Manager / SQF Practitioner reviews the daily records to verify they are complete. The auditor did not find any concerning issues during the preoperational inspection. The 2022 records show correction on non-conformances, for example, when the residual dough is found post-sanitation during the pre-operational inspection, the site re-cleans it. Also, when there is a failure during the ATP swab, the site recleans it and re-tests it before the equipment or utensil is released.
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** All employees observed at the time of the facility tour appeared to be in good health. No evidence of infectious diseases, cuts, abrasions, or sores was observed on exposed body parts. No evidence of smoking, chewing, eating, or drink consumption was observed by the auditor in production or food handling areas.
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** The hand wash stations are provided in the first packaging room and in the kitchen. Hands-free wash stations are constructed of stainless steel and maintained in sound construction. Hand wash stations were provided with liquid soap, sanitizer, disposable paper towels, and hot and cold water supplies. Signs reminding employees of the requirement to wash their hands were posted at hand wash stations. The auditor observed facility staff washing their hands upon returning to the production facility after breaks. Disposable gloves are provided for use in the kitchen area. No bare-hand-to-product contact was observed. The auditor observed kitchen staff changing out their gloves whenever their activities could have caused gloves to become damaged or sanitarily compromised. No non-conformance was sighted at the time of inspection. The trash receptacles were observed properly identified, clean, and not overflowed.
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** The Staff is provided with company-issued clothing which is worn by employees entering the product manufacturing and storage areas. All smocks and aprons observed being worn by employees at the time of the facility tour were maintained in a sanitary manner. Smocks and aprons construction was maintained so as not to present to the manufacturing of products. Employees interviewed at the time of the audit indicated smocks and aprons are not taken home but are put on once they report on site. Reusable gloves are provided for employee use in the kitchen area. Heavier latex-style gloves are provided for use during sanitation activities. GMP training conducted with employees includes a requirement for jewelry and other loose objects to be excluded from food handling and processing areas. No jewelry or other loose objects were observed on employees working in food manufacturing and storage areas at the time of facility inspection. Visitors are required to wear garments and footwear which will not pose a risk to the manufacturing of safe, quality foods. Upon arrival at the facility, all visitors are required to sign in and review facility GMP expectations.
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 are required to wear garments and footwear which will not pose a risk to the manufacturing of safe, quality foods. Upon arrival at the facility, all visitors are required to sign in and review facility GMP expectations. Only visitors with no obvious signs of illness and those who agree to comply with GMP expectations will be escorted into food manufacturing areas. Visitors, like employees, are required to wash their hands and follow personnel practice requirements while in production areas. No deviations were observed by the auditor while in food manufacturing areas.
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)** The Staff amenity areas were supplied with sufficient lighting and ventilation. Staff amenities were available for use by staff and visitors. Changing rooms were maintained in a sanitary manner. No food or drinks were observed in changing rooms. The changing room is provided for employee use as employee uniforms are put on upon arrival at the facility. Lockers are provided for staff to store their items away from food contact and storage areas. The attire required for employee use in production areas is supplied by a contracted service provider. This same contracted provider is responsible for the laundering of employee uniforms. Employees are given enough uniforms so that they can be changed out should they become excessively soiled during the work shift. A daily restroom cleaning log is used to document the sanitation of restroom facilities by the sanitation crew each day. A dedicated sanitation crew is responsible for servicing the restroom every three hours from 8 AM - 3 AM, Monday - Saturday. Restroom facilities are provided by the break room, off of the warehouse, and in the office area. Examples provided for auditor review included the SQF Practitioner verification signature. The 2022 daily cleaning logs were reviewed. A lunch room is provided for employee use separate from food manufacturing areas of the plant. The lunch room was equipped with tables, chairs, a microwave, refrigerated storage, sink supplied with hot and cold water. Signs reminding employees to wash their hands before reporting back to their workstations were not provided at the exits of the lunch room. Lighting and ventilation provided in the lunch room were sufficient. The lunchroom was maintained in a sanitary manner at the time of facility inspection.
11.3.5.1	Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product. **RESPONSE:** COMPLIANT
11.3.5.2	Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean. **RESPONSE:** COMPLIANT
11.3.5.3	High-risk change areas shall be provided for staff engaged in the processing of high-risk foods or processing operations in which clothing can be soiled. **RESPONSE:** COMPLIANT
11.3.5.4	Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, food contact zones, food, and packaging storage areas. **RESPONSE:** COMPLIANT

11.3.5.5	Where required, a sufficient number of showers shall be provided for use by staff. **RESPONSE:** COMPLIANT
11.3.5.6	Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and vi. Kept clean and tidy. Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas. **RESPONSE:** COMPLIANT
11.3.5.7	Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations. **RESPONSE:** COMPLIANT
11.3.5.8	Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.3. **RESPONSE:** COMPLIANT
11.3.5.9	Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests. **RESPONSE:** COMPLIANT
11.3.5.10	Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for the introduction of contamination, including pests to the site. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** There is no outside eating area.
11.4.1	**Staff Engaged in Food Handling and Processing Operations** Employees observed at the time of facility inspection were following established foot traffic patterns and GMP requirements. All employees were wearing clean uniforms and proper hair restraints. No false eyelashes or false fingernails were observed being worn by employees. No raw materials or finished products were observed in contact with the floors. All doors were kept closed. Waste containers were identified as waste. Sensory panels are conducted continuously during each operational shift. Sensory panels of the product's freshness are conducted to identify problems early enough to make corrections. Staff conducting sensory evaluations includes at a minimum the production supervisor and lead packers. Production analyzes pH, case inspection, and pre-shipment of each shift, and each production. The 2022 sensory analysis records were reviewed. The Wash-down hoses were being stored off of the floor at the time of facility inspection.
11.4.1.1	All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor. **RESPONSE:** COMPLIANT
11.4.1.2	Personnel working in or visiting food handling or processing operations shall ensure that: i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 11.4.1.4; ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food; iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed. iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage. **RESPONSE:** COMPLIANT

11.4.1.3	The flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized. **RESPONSE:** COMPLIANT
11.4.1.4	In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone, the site shall implement controls and procedures to ensure: i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel only; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; and v. Equipment used for sensory evaluations is sanitized, maintained, and stored separately from processing equipment. **RESPONSE:** COMPLIANT
11.5.1	**Water Supply** City water supply. The contracted laboratory service provider comes on-site once per year and collects city water supply samples at the point of use for analysis. The site is a low risk since the product is shelf stable and baked; however, it uses water as an ingredient in at least one product (Not done during the last 12 months), for that reason the site conducts at least two tests annually, the last two water potability tests passed the federal guidelines. The 2021 water potability certificate states "water supply meets the bacteriological standards for potable water as promulgated by the U.S. Public Health Service, Department of Health, Education, and Welfare". Test results indicate the water was tested for free chlorine, total coliform, and heterotrophic plate counts. Test results reported fall below maximum contaminant levels allowed by state and federal agencies. The backflow certification is current as of 7/7/22, the landlord is responsible, and it is done every quarter. The site test of the water has been conducted a minimum of once a year. The last test was done on March 2022.
11.5.1.1	Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility. **RESPONSE:** COMPLIANT
11.5.1.2	Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use. **RESPONSE:** COMPLIANT
11.5.1.3	Supplies of hot and cold water shall be provided, as required, to enable the effective cleaning of the premises and equipment. **RESPONSE:** COMPLIANT
11.5.1.4	The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained. **RESPONSE:** COMPLIANT
11.5.1.5	The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent backflow or back-siphonage. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** The site only uses potable water.
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:** The site does not store water
11.5.2	**Water Treatment** The water is not 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** A contracted laboratory service provider comes on-site twice a year and collects city water supply samples at the point of use for analysis. The most recent water potability test was conducted in March 2022. Test results reported fall below maximum contaminant levels allowed by state and federal agencies. The method of testing listed on analysis records is included in the current revision of standard methods for water analysis.
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** No ice is used.
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 is not applied to any product or product contact surfaces. APC, yeast, and mold plates are exposed to ambient plant air at least once monthly in four sampling locations. Sampling locations are the mixing room, decoration room, packing room, oven room, and cutting area. Plates are exposed to air for 15 minutes. The expected result is <5 colonies. Test results for 10/4/22 indicate air supply tested met the expected result in all areas tested.
11.5.5.1	Compressed air or other gases (e.g., nitrogen or carbon dioxide) that contact food or food contact surfaces shall be clean and present no risk to food safety. **RESPONSE:** COMPLIANT **EVIDENCE:** Compressed air was done on 10/4/22.

11.5.5.2	Compressed air systems and systems used to store or dispense other gases that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually. **RESPONSE:** COMPLIANT
11.6.1	**Receipt, Storage and Handling of Goods** Separate areas are provided within the manufacturing plant for storage of raw materials which require ambient temperatures, refrigerated or frozen storage temperatures. No temporary storage facilities are used by this facility. Racks used in warehouse and cold storage areas were maintained in sound construction and in a sanitary manner at time of facility tour. Keeping a small inventory of materials on hand is one of the methods used to ensure stock rotation is being maintained. Incoming goods observed at time of facility inspection included date of receipt. This date of receipt is monitored to ensure raw materials are used First in / First out. Daily walk through inspections monitor housekeeping and proper storage of equipment and containers in warehouse areas and throughout production. Inspections and cleaning records were reviewed. No deviations were noted by auditor at time of facility tour and during interviews with staff responsible for maintaining dry warehouse and staging of materials for production use.
11.6.1.1	The site shall document and implement an effective storage plan that allows for the safe, hygienic receipt and storage of raw materials (i.e., frozen, chilled, and ambient), ingredients, packaging, equipment, and chemicals. **RESPONSE:** COMPLIANT
11.6.1.2	Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-contamination risks. Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk. **RESPONSE:** COMPLIANT
11.6.1.3	The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented. **RESPONSE:** COMPLIANT
11.6.1.4	Procedures shall be in place to ensure that all ingredients, materials, work- in-progress, rework, and finished product are utilized within their designated shelf-life. **RESPONSE:** COMPLIANT
11.6.1.5	Where raw materials, ingredients, packaging, equipment, and chemicals are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there are no risks to the integrity of those goods, no potential for contamination or adverse effect on food safety. **RESPONSE:** COMPLIANT
11.6.1.6	Records shall be available to verify the effectiveness of alternate or temporary control measures for the storage of raw materials, ingredients, packaging, equipment, chemicals, or finished products. **RESPONSE:** COMPLIANT
11.6.2	**Cold Storage, Freezing and Chilling of Foods** Temperature monitoring log freezer and coolers form is used by QA department staff to document monitoring of temperatures every two hours. The acceptable range for freezers is between 20 F maximum to a minimum of 5 F. Acceptable temperature for coolers is between 40 F maximum and 28 F minimum. Cold storage and frozen storage temperature logs for 2022were reviewed.
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** Racks used in warehouse areas were maintained in sound construction and a sanitary manner at the time of facility inspection. Daily walk-through inspections monitor raw material/ingredient storage areas for potential risks of contamination and proper rotation of stock. Daily Inspections and cleaning records were reviewed.
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** No packaging, ingredients nor utensils were observed being stored in the chemical storage cage. The cage is secured from unauthorized access with a padlock. No pest control chemical supplies were observed being stored on-site at the time of the facility tour other than those in use in pest control devices. Daily inspections include monitoring of chemical storage areas. The chemicals cage is ventilated has a warning sign, the SDS is available, and all chemicals were properly labeled, and secured.
11.6.4.1	Hazardous chemicals and toxic substances with the potential for food contamination shall be: i. Clearly labeled, identifying and matching the contents of their containers; ii. Included in a current register of all hazardous chemicals and toxic substances that are stored on-site; and iii. Supplemented with current Safety Data Sheets (SDS) made available to all staff. **RESPONSE:** COMPLIANT
11.6.4.2	Storage of hazardous chemicals and toxic substances shall be: i. Located in an area with appropriate signage indicating that the area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii. Adequately ventilated; iv. Stored where intended and not comingled (e.g., food versus non-food grade); v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces. Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances. **RESPONSE:** COMPLIANT
11.6.4.3	Hazardous chemicals and toxic substances shall be correctly labeled and: i. Used only according to manufacturers' instructions; ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-inprogress, finished product, or product contact surfaces; iii. Returned to the appropriate storage areas after use; and iv. Be compliant with national and local legislation. **RESPONSE:** COMPLIANT
11.6.4.4	Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of food processing equipment and surfaces in food contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel. **RESPONSE:** COMPLIANT

11.6.4.5	Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals,: i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use; ii. Be provided first aid equipment and personnel protective equipment (PPE); and iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements. **RESPONSE:** COMPLIANT
11.6.4.6	The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are: i. Not reused; ii. Segregated and securely stored prior to collection; and iii. Disposed through an approved vendor. **RESPONSE:** COMPLIANT
11.6.4.7	In the event of a hazardous spill, the site shall: i. Have spillage clean-up instructions to ensure that the spill is properly contained; and ii. Be equipped with PPE, spillage kits, and cleaning equipment. **RESPONSE:** COMPLIANT
11.6.5	**Loading, Transport, and Unloading Practices** The outbound Inspection and Shipment Procedure outlines the methods and responsibility for loading and receiving of raw materials and finished goods. The Dock area was equipped with curtains and bumper pads maintained in sound construction to protect products during loading and unloading. railer inspection program monitors transport security measures taken, evidence of pest activity, and if the transport is maintained in good repair and maintained in a sanitary manner. Trailer inspection records were reviewed. Products produced by this facility require ambient temperatures only. Customers pick up products, or contracted service LTL carriers are used for the transport of these finished products. Company-owned and operated vans are used for delivery to local markets. The inbound products inspection form is used by facility staff to document the vendor's name, PO or BOL, date, carrier, driver's name, and verification of driver ID. The same form is used to document a description of the materials being received including lot number, quantity, temperature (if applicable), expiration date, allergen (s), and approved kosher symbol. Incoming transports are inspected to ensure the receiving area is maintained in a sanitary manner and adequately lighted. Temperature is recorded for incoming refrigerated load set temperature and actual truck temperatures. The condition of trucks and pallets is evaluated. The truck security seal is verified. Products are inspected for any sign of pest activity if any non-food items are in the truck, any off odors, or any evidence of tampering. This form is also used to verify that COA is received and reviewed for all ingredients. The signature of the inspector was recorded on inbound inspections provided for auditor review.
11.6.5.1	The practices applied during loading, transport, and unloading of food shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination. **RESPONSE:** COMPLIANT
11.6.5.2	Vehicles (e.g., trucks/vans/containers) used for transporting food within the site and from the site shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the product. **RESPONSE:** COMPLIANT
11.6.5.3	Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems. **RESPONSE:** COMPLIANT
11.6.5.4	Loading and unloading docks shall be designed to protect the product during loading and unloading. Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity during loading and transport. **RESPONSE:** COMPLIANT
11.6.5.5	Refrigerated units shall maintain the product at the required temperature. The unit’s temperature settings shall be set, checked, and recorded before loading, and the product temperature shall be recorded at regular intervals during loading, as applicable. **RESPONSE:** COMPLIANT

11.6.5.6	The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals, and the storage temperature at regular intervals during transit. **RESPONSE:** COMPLIANT
11.6.5.7	On arrival, prior to opening the doors, the food transport vehicle's refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently, and product temperatures shall be recorded at the start of unloading and regular intervals during unloading. **RESPONSE:** COMPLIANT
11.6.5.8	Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity. **RESPONSE:** COMPLIANT
11.7.1	**High-Risk Processes** The is no High-Risk Process or area.
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** Materials removed from the freezer are moved into a refrigerated storage area for thawing/tempering prior to use. No water-thawing processes are used in this location. Waste is removed by a contracted service provider through the same channel used for all solid production waste materials.
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:** COMPLIANT
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** Pre-operational visual inspection of equipment is conducted at the start of each shift each production day. Pre-operational inspection includes inspection for monitoring wooden pallets, metal, glass and brittle plastics are stored properly and maintained in sound condition. 2022 pre-operational inspections were reviewed. Glass and brittles plastics register is used to document monthly inspections conducted by QA. The 2022 inspections were provided for auditor review.
11.7.3.1	The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff. Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants. **RESPONSE:** COMPLIANT
11.7.3.2	Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation). Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition. **RESPONSE:** COMPLIANT
11.7.3.3	Regular inspections of food handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory. **RESPONSE:** COMPLIANT
11.7.3.4	Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged. **RESPONSE:** COMPLIANT
11.7.3.5	In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, thoroughly inspected (including cleaning equipment and footwear), and cleared by a suitably responsible person prior to the start of operations. **RESPONSE:** COMPLIANT
11.7.3.6	Wooden pallets and other wooden utensils used in food processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection. **RESPONSE:** COMPLIANT
11.7.3.7	Loose metal objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard. **RESPONSE:** COMPLIANT
11.7.3.8	Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas. **RESPONSE:** COMPLIANT
11.7.3.9	Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3). **RESPONSE:** COMPLIANT

11.7.4	**Detection of Foreign Objects** All products produced pass through metal detectors at end of the production line just before final packaging for consumer use. Metal detector hourly verifications are conducted on each production line that is run by QA staff daily. In addition to hourly verifications, metal detector functionality is verified every product changeover, at the start of the run and end of the run. Metal detector check form used to document these verifications includes tie verification was performed, item number being produced, weight, brand, lot number, and result for ferrous, non-ferrous, and stainless steel. Metal detector logs include what shift is responsible for conducting the verification and the initials of the person completing the task. 2022 metal detector records were provided for the auditor to review. The lead line packer demonstrated metal detector verification monitoring for the auditor at the time of facility inspection. Metal detectors detected all stainless, non-ferrous, and ferrous test pieces. Line flow was diverted during each detection so that no finished product produced at the time of detection proceeded down the production stream. If foreign material is detected the supervisor is notified, maintenance is notified, and corrective actions are taken. The production lead is responsible for verifying corrective actions are taken and effective before the resumption of production.
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** No uncontrolled accumulation of waste was observed inside or outside of the plant. The contracted service provider removes solid waste from the facility routinely. Liquid waste is removed through the city sewer system. All trash receptacles were labeled and maintained in a sanitary manner. A daily inspection program is used to ensure the proper level of housekeeping is being conducted and that the facility is being maintained in a condition that is adequate and sanitary for safe and quality food manufacturing. Self-inspection monitoring records provided for auditor review were dated.
11.8.1.1	The responsibility and methods used to collect and handle dry, wet, and liquid waste and how to store it prior to removal from the premises shall be documented and implemented. **RESPONSE:** COMPLIANT
11.8.1.2	Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken. **RESPONSE:** COMPLIANT
11.8.1.3	Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements. **RESPONSE:** COMPLIANT
11.8.1.4	Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin. **RESPONSE:** COMPLIANT

11.8.1.5	Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging. **RESPONSE:** COMPLIANT
11.8.1.6	Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance. **RESPONSE:** COMPLIANT
11.8.1.7	Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health. **RESPONSE:** COMPLIANT
11.8.1.8	Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards. **RESPONSE:** MINOR **EVIDENCE:** Sighted the outside garbage container open. **ROOT CAUSE:** Associates being careless in replacing the cover after using the dumster for waste. The cover was put back immediately on 10/11/22, and all associates handling the dumster have been trained on 10/27/22 to put the cover in correct position after its use. **CORRECTIVE ACTION:** The cover has been replaced. Refer to picture 11.8.1.8 & Training record 11.8.1.8 **VERIFICATION OF CLOSEOUT:** The picture shows compliance and the training will prevent future issues. **COMPLETION DATE:** 10/11/2022 **CLOSEOUT DATE:** 11/02/2022
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