SQF Quality Audit Edition 9
Assemblers, Inc. - Assemblers Inc.

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
23618 | 168867

DECISION DATE
10/28/2022

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
09/08/2023

AUDIT DATES
09/22/2022 - 09/22/2022

EXPIRATION DATE
11/22/2023

ISSUE DATE
11/02/2022

Facility & Scope

Assemblers, Inc. (44719)
Assemblers Inc.
8601 w 47st
McCook, IL 60525
United States

Food Sector Categories:
13. Bakery and Snack Food Processing
25. Repackaging of Products Not Manufactured On Site

Products:
Cookies, Crepes, Snack Bar. Gift Baskets, Seasonal Bundled Displays.

Scope of Certification:
The manufacture and baking of snack bars, cookies, and snacks. The manufacture and heat treatment of crepes. The repackaging of sealed food items and consumer items into gift baskets and seasonal bundled gift sets.

Certification Body & Audit Team

DNV GL
1400 Ravello Drive
Katy, TX 77449
United States

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

Lead Auditor: Arrighi, Wayne (123246)
Technical Reviewer: Szulczewski, Eric (131290)

Hours Spent on Site: 28
Hours of ICT Activities: 0
Hours Spent Writing Report: 2

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Sam Gu
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** Sam@assemblers.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Wayne J. Arrighi: SQF Lead Auditor, Brian Lotz: Regulatory & Compliance Manager, Paul Siefert: FSQA Director, Sam Gu: Quality Manager, Joel Rosenbacher: President, Kevin Menendez: Production Manager, Phillip Woods: Sanitation Manager and Paul Rivera: Maintenance Manager.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** Assemblers Inc. is located in a commercial park at the southwest side of Chicago at 8601 West 47th Street, McCook, Illinois. The company is exclusively a co-manufacturer and co-packer of an assortment of products (crackers, cookies, extruded protein & snack bars, crepes, cereal and repack operation of cereals and meat snack products) to retail establishments provided in various package configurations. The facility has established and implemented a Food Safety & Quality Program based on the requirements of the GFSI standard and maintains the requirements of the standard through Food Safety auditing and training and is SQF certified for FSC 13. Bakery and Snack Food Processing and FSC 25. Repackaging of Products Not Manufactured on Site. The site consist of 1 main building (~360,000 sq. ft.) dedicated for the scope of certification and warehousing where finished product is stored. There are ~500 employees that work 3 staggered Production shifts and Sanitation as needed. The manufacturing site has Processing and Packaging departments with warehousing areas and several Shipping/Receiving docks. The products within the scope of this audit are Cookies, Crepes, Snack Bars and repacking of products not manufactured on site: Gift Baskets, Seasonal Bundled Displays.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Wayne J. Arrighi: SQF Lead Auditor, Brian Lotz: Regulatory & Compliance Manager, Paul Siefert: FSQA Director, Sam Gu: Quality Manager, Paul Sowizraz: Plant Manager: President, Kevin Menendez: Production Manager and Phillip Woods: Sanitation Manager.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Maintain Certification

Section Responses

2.1.1 Management Responsibility

A Food Safety and Quality Policy dated 8/5/2020 is available and includes the methods of meeting the requirements. The policy is signed by Joel Rosenbacher (President) and Paul Siefert (FSQA Director) and date3d 9/13/2021. It posted in main entrance/employee entrance and employee breakroom area in English and Spanish. Pre-requisite programs are in place and address the relevant SQF code's elements. The company policy includes a commitment to establish and review food safety and quality objectives using the established food safety culture. There is a Management Responsibility that details the Management reporting process. There is an organizational chart dated 7/15/2021 in the Food Safety manual. The company has designated the site's Quality Manager as the primary SQF practitioner (Sam Gu) and FSQA Director (Paul Siefert) is the substitute SQF Practitioner. The primary SQF practitioner is HACCP certified. The HACCP certificate is current and dated 9/23/2018. Both SQF Practitioners are full time employees. The SQF practitioners are also trained PCQI: Cert # 47f4cbe6 dated 11/8/2018 and Cert # 98b89237 dated 2/23/2016 for the FSQA Director The Regulatory Compliance Manager is also HACCP and PCQI trained. The senior management supported the documented procedures, training, policy improvements and capital improvements to ensure the food safety practices were adopted and maintained. No blackout periods exist.

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines the site's commitment to quality and includes at a minimum: i. Establishment and maintenance of a quality management system; ii. Compliance with customer, regulatory, and company quality requirements; iii. Identification of quality objectives and the methods used to measure them; and iv. Continuous improvement of its quality performance.

RESPONSE: COMPLIANT

2.1.1.2 The policy statement shall be displayed in a prominent position and communicated to all staff. It may be included in or separate from the organization's food safety policy.

RESPONSE: COMPLIANT

2.1.1.3 Senior site management shall implement, maintain, and continuously improve the quality culture within the site that ensures at a minimum: i. Quality objectives and key performance indicators are communicated to all staff; ii. Provision of adequate resources to meet the objectives and key performance indicators; iii. Awareness by all staff of their quality responsibilities and their accountability in meeting the requirements of the SQF Quality Code; iv. Responsibility to notify management of actual or pending quality issues and empowerment to resolve quality issues within their scope of work; and v. Education of all staff to understand the importance of quality controls and deviation consequences.

RESPONSE: COMPLIANT

2.1.1.4 Senior site management shall ensure the personnel performing key process steps and responsible for achieving quality objectives and meeting customer, regulatory, and company quality requirements are identified in the reporting structure and have the required competencies to carry out these functions.

RESPONSE: COMPLIANT

2.1.1.5 Job descriptions for personnel performing key process steps and responsible for achieving quality requirements shall be documented and include provisions for coverage in the absence of key personnel.

RESPONSE: COMPLIANT

2.1.1.6 Senior site management shall designate an SQF quality practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review, and maintenance of the SQF Quality System, including quality fundamentals outlined in 2.4.2 and the quality plan outlined in 2.4.3; ii. Take appropriate action to ensure the integrity of the quality system; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the quality system.

RESPONSE: COMPLIANT

2.1.1.7 The SQF quality practitioner shall: i. Be competent to implement and maintain food quality plans using a risk-based methodology such as HACCP; ii. Understand the Quality Code and the requirements to implement and maintain a quality management system; and iii. Be competent, through training or experience, in process control and/or other quality tools to reduce process variation impacting quality and achieve customer requirements.

RESPONSE: COMPLIANT

2.1.1.8 Senior site management shall develop and implement a quality communication program to ensure all staff: i. Know the site's quality statement, quality objectives, and the process by which quality performance is measured; and ii. Understand the methods by which customer, regulatory, and company quality requirements, where applicable, are met.

RESPONSE: COMPLIANT

2.1.1.9 Senior site management shall establish a process to trend progress in quality performance against agreed measures. Benchmarking shall be part of this process, and the performance data shall be reported at least annually, and communicated to all staff, to demonstrate effectiveness of the quality management system.

RESPONSE: COMPLIANT

2.1.1.10 Sites that are certified to the SQF Quality Code may use the SQF Quality Shield. The use of the quality shield shall follow the requirements outlined in Appendix 4: SQF Quality Shield Rules of Use.

RESPONSE: NOT APPLICABLE

2.1.2 Management Review

Typically, the site has monthly meetings on the 2nd Mondays of each month. They discuss the topics pertinent to the SQF system and daily production/customer concerns. The Regulatory Compliance Manager, the FSQA Manager and the SQF Practitioner meets with management regarding pertinent topics (training, internal audits, customer complaints, etc.). The site keeps records on file. Validation of all record changes are documented on the document register. The auditor reviewed the monthly manager meeting notes (11/8/2021, 3/14/2022, 6/8/2022 and 8/15/2022) and an annual SQF System Verification dated 9/17/2021 to 9/24/2021 with the management sign-off. Facility complies with this SQF code requirement for FSC 13 - Bakery and Snack Food Processing and FSC 25. Repackaging of Products Not Manufactured On Site.

2.1.2.1 Senior site management shall be responsible for reviewing the performance of the SQF Quality System. Reviews shall include actions required to: i. Monitor compliance to specifications; ii. Measure and reduce process and product variation; iii. Meet customer requirements; iv. Take appropriate corrective action where applicable; and v. Ensure sufficient resources are allocated to maintain and improve the performance of the quality system.

RESPONSE: COMPLIANT

2.1.2.2 The SQF quality practitioner(s) shall update senior site management monthly at a minimum on matters impacting the implementation and maintenance of the SQF Quality System. The updates and management responses shall be documented. The SQF Quality System in its entirety shall be reviewed at least annually.

RESPONSE: COMPLIANT

2.1.2.3 The quality system, including food quality plans, shall be reviewed when any changes are implemented that have an impact on the site's ability to meet customer requirements and/or corporate quality requirements where applicable.

RESPONSE: COMPLIANT

2.1.2.4 Senior site management shall ensure the integrity and continued operation of the quality system in the event of organizational or personnel changes within the company or associated facilities.

RESPONSE: COMPLIANT

2.1.2.5 Senior site management shall document and implement a change management process that details how changes in specifications, materials, equipment, or resources are evaluated for their impact on quality, communicated to customers, and effectively implemented.

RESPONSE: COMPLIANT

2.1.2.6 Records of all quality system reviews, reasons for amending documents, and changes to the SQF Quality System shall be maintained. Records shall include decisions for actions related to the improvement of the quality system and process effectiveness.

RESPONSE: COMPLIANT

2.1.3 Complaint Management

The methods and responsibility for handling and investigating the cause and resolution of complaints from customers are documented in Complains Management SOP. The consumer contacts the customer personnel and complaint is sent to the SQF Practitioner for an investigation and root cause analysis. The site would then fill out a Complaint Investigation Record. The vast majority of complaints are quality related. The auditor reviewed a food quality complaint received 6/16/2022 for a 5022 20 oz. Oatmeal Dark Chocolate (Canada; Lot# 060822 2159 MP12) regarding the consumer reporting an "too many oats in the cookie". The investigation could not determine any significant difference from their retain samples. The root cause was due to the customer supplying a different type of oat than previous and the lack of a standard for this ingredient. Based on the results shared with the customer, the quality team at the customer will standardize the oat ingredient for future production. The SQF practitioner determines who needs to be involved and performs the Root Cause Analysis (RCA). The auditor reviewed the year over year trending graphics and complaint categories.

2.1.3.1 The methods and responsibilities for the complaint management process shall be documented and implemented. They shall include: i. A mechanism to collect and record all quality complaints resulting from activities at the site; and ii. Communication processes for reporting and follow-up with senior management and customers.

RESPONSE: COMPLIANT

2.1.3.2 Trends from quality complaints shall be included in the performance measures established for the quality system.

RESPONSE: COMPLIANT

2.1.3.3 Corrective and preventative action shall be implemented based on the seriousness of the incident and identified trends and shall be completed as outlined in 2.5.3.

RESPONSE: COMPLIANT

2.1.3.4 Records of quality complaints, their investigation and resolution, if applicable, shall be maintained.

RESPONSE: COMPLIANT

2.2.1 Quality Management System

The Quality Management System is electronicnically maintained in the SharePoint platform. It summarizes the organization's quality policies and methods to meet the requirements of the current SQF standard (version 9.0). The organizational chart is current with the scope and listing of the products of interest (FSC 13 - Bakery and Snack Food Processing and FSC 25. Repackaging of Products Not Manufactured On Site). The binders do have the documentation necessary to support the development, implementation, maintenance and control of the SQF System Procedures to validate justifiable changes to the food safety plan are present. The quality plans, GMP's and all relevant aspects of the SQF System are reviewed, updated, and communicated to management as needed by the FSQA Manager/SQF Practitioner on a monthly basis.

2.2.1.1 Electronic and/or hard copy documentation that outlines the methods and procedures the site shall use to meet the requirements of the SQF Quality Code shall be current and maintained. It shall be made available to staff and include: i. A summary of the organization's quality policies and the methods it will apply to meet the requirements of the SQF Quality Code; ii. The policy statement and site organization chart; iii. A list of the products covered under the scope of certification; iv. Finished product specifications that agree with customers' requirements and/or meet the site's corporate quality requirements, where applicable; and v. A description of the applications of process control methods and other quality tools that are used to control and reduce process variation and meet customer specifications. The quality system manual may be incorporated into or be independent of the food safety system manual.

RESPONSE: COMPLIANT

2.2.2 Document Control

The auditor reviewed the Document Control SOP. It states the methods + responsibilities for maintaining document control + employee access. All documents are controlled with Document #'s, dates and version #'s. All docs are stored on a secured company SharePoint online platform with restricted access and the hardcopies stored in a locked cabinet. Employees have access (Read Only). A electronic document register exist on the company's secured shared drive and available to employees (Read Only). The auditor reviewed the Document Register.

2.2.2.1 The methods and responsibility for maintenance, storage, and distribution of quality documents shall be documented and implemented.

RESPONSE: COMPLIANT

2.2.2.2 A register of current SQF Quality System documents and amendments to documents shall be maintained. Documents shall be safely stored and readily accessible.

RESPONSE: COMPLIANT

2.2.3 Records

The auditor reviewed the Document Control SOP where the record storage and retention section resides. Record types and their verification and storage practices are listed in SOP. The QA personnel whom are HACCP trained (Tania Paz) have the verification responsibility for Batch + Production related records for quality. The auditor reviewed the following CQP related records (Net Weight Verification Forms) and the Shipping/Receiving records for the first week of September 2021, second January 2022, third week of May 2022 and fourth week of August 2022.

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 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. Records shall be retained in accordance with periods specified by customers or regulations or, at a minimum, no less than the product shelf- life.

RESPONSE: COMPLIANT

2.3.1 Product Formulation and Realization

The auditor reviewed the Product Design, Development and Realization SOP. The site does not perform any designing or developing new product formulations and converting product concepts to commercial realization. There is no R&D team onsite. There are active R&D related projects for this site's customers. Customers are responsible for initiating the overall product development process and performing shelf life trials. Mostly, the site's R&D projects consist of matching a customer's sample submission and then scaling up into Production runs.

2.3.1.1 The methods for designing, developing, and converting product concepts to commercial realization shall include a comparison of process controls with specification limits (i.e., process capability analysis) to ensure that processes can consistently supply products that meet customer specifications.

RESPONSE: COMPLIANT

2.3.1.2 Product formulation, manufacturing processes, and the fulfillment of product quality requirements shall be validated by facility trials and product testing.

RESPONSE: COMPLIANT

2.3.1.3 Shelf life trials shall be conducted for new products, or when there are changes in materials, ingredients, or equipment, to establish and validate a product's packaging, handling, storage, and customer-use requirements through the end of its commercial life and consumer use.

RESPONSE: COMPLIANT

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

Specifications of raw and packaging materials and approved suppliers are maintained in the company's secured SharePoint. Suppliers in emergency situations will be required to provide the same documentation as approved suppliers to assure adherence to specifications. No receipts from non-approved suppliers were observed. All suppliers are validated via documentation review (LOG's, COA's, GFSI certificate, etc.) and must meet the established FDA regulations/specifications. Microbiological analysis is infrequently performed unless requested by the customer. The site uses several lab's performing microbiological analysis depending upon the customer's request. The auditor reviewed the contracted lab's (Matrix) Certificate of Accreditation (cert # AT-1491; valid till 10/22/2022) meeting the ISO/IEC 17025:2017 standard and the Certificate of Accreditation (Silliker) (Cert # 1105.01; valid to 3/31/2024) meeting the ISO/IEC 17025:2017 standard. All suppliers are monitored and re-assessed annually. The auditor also reviewed the COSTCO Product Specification Sheet for Item # 5022 Heavenly Hunks 20 oz. Oatmeal Dark Chocolate (Finished Food Spec # 5022V8). The auditor reviewed the EPAC Flexible Packaging Letter of Guarantee/Certification dated 4/2/2018 stating the metallic packaging film used onsite comply with FDA regulations regarding direct food contact. The auditor also reviewed the Form Plastics Company Continuing Guarantee letter dated 10/17/2018 and Pactiv Food Service/Food Packaging FDA/USDA Compliance Statement: Polystyrene Products dated 10/22/2018 for the plastic preformed trays used for the crepe finished products meeting FD&C regulations. All finished products are packed or re-packed into bottles, pouches and poly bags. All packaging are preprinted and supplied by the customers. Case labels and Pallet placards are printed inhouse using the Bartender software program. The auditor reviewed the listing of raw materials, labeling and packaging for the COSTCO cookie product (Item # 5022) as well as the listing of the site's finished products produced and repacked meat products (Conagra) onsite. The auditor reviewed the Contracted Service Register where the site maintains the list of contracted service providers and the GMP guidelines for Service Providers, Outside Construction and Maintenance Workers SOP which list the training requirements for the contractors/visitors. The auditor requested the COA for a raw material selected during the facility audit: Medium No Sulphites Desiccated Coconut; Pack Date: 3/2/2022; Lot # 220610. The COA was available upon request.

2.3.2.1 Specifications for all raw materials and packaging, including but not limited to ingredients, additives, agricultural inputs (where applicable), hazardous chemicals, and processing aids that impact finished product quality shall be documented and kept current.

RESPONSE: COMPLIANT

2.3.2.2 Raw and packaging quality parameters shall be verified upon receipt to ensure they meet specifications.

RESPONSE: COMPLIANT

2.3.2.3 Product labels that are designed or specified by customers shall be approved by those customers. Records shall be maintained of customer approvals.

RESPONSE: COMPLIANT

2.3.2.4 The register of current raw material and packaging specifications shall include those raw material and packaging materials that impact product quality and customer labels.

RESPONSE: COMPLIANT

2.3.2.5 Finished product specifications shall be documented, current, approved by the site and its customers when required, and accessible to relevant staff. The specifications shall include product quality attributes, service delivery requirements, and labeling and packaging requirements.

RESPONSE: COMPLIANT

2.3.2.6 Customer product specifications and delivery requirements shall be communicated to appropriate departments and staff within the site.

RESPONSE: COMPLIANT

2.3.2.7 Specifications for contract services that have an impact on in-process or finished product quality shall be documented, current, include a full description of the service to be provided, and detail relevant training requirements of contract personnel. The register of contract service specifications shall list those services impacting product quality

RESPONSE: COMPLIANT

2.3.3 Contract Manufacturers

The site does not use contract manufacturers.

2.3.3.1 The methods and responsibility for ensuring all agreements with contract manufacturers relating to quality, site/customer product requirements, their realization, and delivery shall be specified, documented, agreed upon, and implemented.

RESPONSE: NOT APPLICABLE

2.3.3.2 The site shall: i. Ensure that the processes in place at the contract manufacturer are capable of consistently meeting customer and/or corporate quality requirements, where applicable; ii. Verify compliance with the SQF Quality Code and that all customer requirements are being met; iii. Audit the contract manufacturer annually, at a minimum, to verify compliance to the SQF Quality Code and with agreed arrangements, or accept the manufacturer's certification to the SQF Quality Code or equivalent; and iv. Ensure changes to contractual agreements are approved by both parties, agreed with customers when necessary, and communicated to relevant personnel.

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

2.3.4 Approved Supplier Program

The auditor reviewed the Supplier Approval Program and it is current. For the major materials (Raw Materials, Primary Packaging), the customers are responsible for ensuring these materials meet the required GFSI requirements while the site performs a review of the customer's documentation and process. Raw materials and primary packaging are subject to document review and microbiological testing (if requested). Questionnaires and a selected document review are used. Records of raw and packaging materials are maintained in the company's secured SharePoint system. No non-approved supplier materials were observed. The site has a Submitted document log for the ingredients and packaging vendors information and is current. The auditor reviewed the questionnaire dated 7/3/2020 for oats supplied by Bay State Milling.

2.3.4.1 Raw materials, ingredients, packaging materials, processing aids, and services, including co-manufactured products, that impact finished product quality shall be supplied by an approved supplier.

RESPONSE: COMPLIANT

2.3.4.2 Material suppliers shall be selected and approved based on their ability to supply materials that meet quality specifications. The evaluation program shall require suppliers to: i. Maintain controlled and current copies of specifications; ii. Have processes that are capable of consistently supplying materials that meet specification and other defined quality metrics (e.g., delivery, service, etc.); iii. Provide evidence that the supplied product meets agreed specifications and metrics; and iv. Have a complaint management system in place that includes corrective actions processes.

RESPONSE: COMPLIANT

2.3.4.3 Materials supplied shall only be accepted by the site based on either a certificate of analysis for each lot received, or inspection of the lot at receipt, to ensure materials comply with specifications. All receipts shall be visually inspected for damage and product integrity.

RESPONSE: COMPLIANT

2.3.4.4 The approved supplier program shall include an agreement with suppliers for the return or disposal of materials that fail to meet specifications or are damaged or contaminated.

RESPONSE: COMPLIANT

2.3.4.5 Any supplier audits performed shall be conducted by individuals knowledgeable of applicable regulatory and food quality requirements and trained in auditing techniques.

RESPONSE: COMPLIANT

2.4.1 Customer Requirements

The Regulatory Compliance Manager is responsible for keeping current on all food regulations. Local management were able to name the principles to contact in case of as regulatory event. The notification email addresses for both SQFI + the certification body are listed in the policy and in the site's Product Withdrawal and Recall Emergency Contact Listing.

2.4.1.1 The methods and responsibilities for managing customer requirements and/or consumer expectations shall be documented and implemented. They shall include at a minimum: i. A review and approval process for all new or updated customer requirements, as they occur; ii. A process for collection and analysis of data for product quality attributes to ensure specifications continue to meet consumer expectations; and iii. A communication process to notify identified customers when the ability to supply compliant products is temporarily halted.

RESPONSE: COMPLIANT

2.4.1.2 Where customer products, materials, or equipment are used within the facility, the site shall have measures in place to safeguard customer property and ensure its correct and proper use.

RESPONSE: COMPLIANT

2.4.2 Quality Fundamentals

The GMP policy is posted at several locations onsite and on the TV screen located in the employee lunchroom and stated on the document. The policy addresses how to control and maintain food quality for the scope of certification. The methods and responsibility for the calibration of measuring, test, and inspection equipment are stated in the Calibration SOP. The methods + responsibility for storage and transport of raw materials, work-in-progress and finished product are stated in the Storage and Handling Procedure and the Outbound Finished Product Trailer Inspection Procedure documents.

2.4.2.1 The buildings and equipment shall be constructed, designed, and maintained to facilitate the manufacture, handling, storage, and/or delivery of food that meets customer specifications, regulatory requirements, and/or company quality requirements.

RESPONSE: COMPLIANT

2.4.2.2 The methods and responsibility for the calibration of measuring, test, and inspection equipment used for quality testing of raw materials, work-in-progress, and finished product, for food quality 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

2.4.2.3 Storage and transport of raw materials, work-in-progress, and finished product shall be suitable to maintain the integrity of the product without loss, waste, or damage and to meet customer requirements for inventory management and transportation, where applicable.

RESPONSE: COMPLIANT

2.4.3 Food Quality Plan

The site has a SQF Quality Plan maintained on file as part of the site's HACCP plans. The food quality plans have been developed following the 12-step HACCP method and has been effectively implemented. The auditor reviewed the food quality plans. ALL FINSHED PRODUCTS ARE RTE. LOW RISK. The Quality team is comprised of the Quality/Quality Manager = Sam Gu, Quality/HACCP Coordinator = Miguel Arechiga, Regulatory Compliance and Food Safety Manager = Brian Lotz, Quality/FSQA Director = Paul Siefert, Quality/Quality Supervisor = Soco Resendiz, Operations/Production Manager = Paul Sowizrai, Maintenance/Maintenance Manager = Paul Rivera, Production/ Production Manager = Kevin Menendez, Sanitation/Sanitation Manager = Phillip Woods, Warehouse & Warehouse Manager = Juan Vasquez. The Quality/Quality Manager (Sam Gu) is the HACCP Team Leader. There are 14 Quality Plans with 2 CQP's 1) Moisture % and 2) Net Weight or Net Quantity. Quality Plan 1 = Baking Line (COSTCO product): There are 2 CQP's: CQP 1 = Moisture %. The critical limit = a moisture % = 4% to 8% monitored by a trained designee at the beginning, middle and end of the shift. CQP 2 = Net Weight: The critical limit is meeting the weight requirements per the NIST Handbook 133 and is monitored every hour (+/- 15 minutes) by trained designee. Sanitation PC 1 = Allergen changeover cleaning. The critical limit = visual inspection of the equipment between changes from allergen containing products to non-allergen containing products by a trained Quality person. Quality Plan 2 = Cracker Line. CQP 1 = Moisture %. The critical limit = a moisture % = 4% to 8% monitored by a trained designee at the beginning, middle and end of the shift. CQP 2 = Net Weight: The critical limit is meeting the weight requirements per the NIST Handbook 133 and is monitored every hour (+/- 15 minutes) by trained designee. Quality Plan 3 -MP1 Bar Line. CQP 1 = Net Weight. The critical limit is meeting the net quantity requirements per the NIST Handbook 133 and is monitored every hour (+/- 30 minutes) by Quality person. Quality Plan 4 - MP2 Bar Line: CQP 1 = Net Weight. The critical limit is meeting the net quantity requirements per the NIST Handbook 133 and is monitored every hour (+/- 30 minutes) by Quality person. Quality Plan 5 - MP4 Bar Line: CQP 1 = Net Weight. The critical limit is meeting the net quantity requirements per the NIST Handbook 133 and is monitored every hour (+/- 30 minutes) by Quality person. Quality Plan 6 - Protein Snack Bites. CQP 1 = Net Weight. The critical limit is meeting the net quantity requirements per the NIST Handbook 133 and is monitored every hour (+/- 30 minutes) by Quality person. Quality Plan 7 - Muddy Bites. CQP 1 = Net Weight. The critical limit is meeting the net quantity requirements per the NIST Handbook 133 and is monitored every hour (+/- 30 minutes) by Quality person. Quality Plan 8- Chubbies Snacks. CQP 1 = Net Weight. The critical limit is meeting the net quantity requirements per the NIST Handbook 133 and is monitored every hour (+/- 30 minutes) by Quality person. Quality Plan 9: Crepes. CQP 1 = Net Weight: The critical limit is meeting the weight requirements per the NIST Handbook 133 and is monitored every hour (+/- 15 minutes) by trained designee. Quality Plan 10 = USDA Meat Repack. CQP 1 = Net Weight: The critical limit is meeting the weight requirements per the NIST Handbook 133 and is monitored every hour (+/- 15 minutes) by trained designee. Quality Plan 11 = Vertical Bagger. CQP 1 = Net Weight: The critical limit is meeting the weight requirements per the NIST Handbook 133 and is monitored every hour (+/- 15 minutes) by trained designee. Quality Plan 12 = Repack of Bulk Shelf Stable RTE Items. CQP 1 = Net Weight: The critical limit is meeting the weight requirements per the NIST Handbook 133 and is monitored every hour (+/- 15 minutes) by trained designee. Quality Plan 13 = Bulk Repack of Perishable RTC Products. CQP 1 = Net Weight: The critical limit is meeting the weight requirements per the NIST Handbook 133 and is monitored every hour (+/- 15 minutes) by trained designee. Quality Plan 14 = Secondary Lines. There are no CCPs or CQPs. There are several PC's based on the product being processed or repacked (allergen labeling, etc.). The HACCP plans were approved by 5 members of the HACCP Team on 9/9/2022.

2.4.3.1 A food quality plan shall be developed, effectively implemented, and maintained in accordance with a risk-based method such as HACCP. The food quality plan may be combined with or independent from the food safety plan, but either way it must identify quality threats and critical quality points and their controls.

RESPONSE: COMPLIANT

2.4.3.2 The food quality plan shall outline how the site controls and assures the quality attributes of the products or product groups and their associated processes.

RESPONSE: COMPLIANT

2.4.3.3 The food quality plan shall be developed and maintained by a multidisciplinary team that includes the SQF quality practitioner and those site personnel with technical, production, and marketing knowledge of the relevant products and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food quality team. The composition of the food quality team may be different from the food safety team.

RESPONSE: COMPLIANT

2.4.3.4 The scope of the food quality plan shall be developed and documented, including the start and endpoints of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

2.4.3.5 Product descriptions shall be developed and documented for all products included in the scope of the food quality plan. This shall include information in the finished product specifications (refer to 2.3.2.1) plus any additional quality or service attributes established by agreement with the customers.

RESPONSE: COMPLIANT

2.4.3.6 The intended use of each product shall be determined and documented. This shall include, as appropriate, target consumer groups, ease of use by consumers, consumer instructions, evidence of tampering , and other applicable information affecting product quality.

RESPONSE: COMPLIANT

2.4.3.7 The food quality team shall review the flow diagrams developed as part of the food safety plan and confirm and ensure process steps, process delays, and inputs and outputs that impact product quality are included.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.9 The food quality team shall conduct a quality threat analysis for every identified quality threat to identify which threats are significant, i.e., their elimination or reduction to an acceptable level is necessary to ensure or maintain product quality. The methodology for determining threat significance shall be documented and used consistently to assess all potential quality threats.

RESPONSE: COMPLIANT

2.4.3.10 The food quality team shall determine and document the control measures that must be applied to all significant quality threats. More than one control measure may be required to control an identified threat, and more than one significant threat may be controlled by a specific control measure.

RESPONSE: COMPLIANT

2.4.3.11 Based on the results of the threat analysis (refer to 2.4.3.9), the food quality team shall identify the steps in the processes where control must be applied to eliminate a significant threat or reduce it to an acceptable level. These steps shall be identified as Critical Quality Points or CQPs.

RESPONSE: COMPLIANT

2.4.3.12 For each identified CQP, the food quality team shall identify and document the quality limits that separate acceptable from unacceptable product. The food quality team shall validate the critical quality limits to ensure the designated level of control of the identified quality threat (s), and that all critical quality limits and control measures individually or in combination effectively provide the level of control required.

RESPONSE: COMPLIANT

2.4.3.13 The food quality team shall develop and document procedures to monitor CQPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.15 The documented and approved food quality plan shall be fully implemented. The effective implementation shall be monitored by the food quality team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, specifications or inputs occur which may affect product quality.

RESPONSE: COMPLIANT

2.4.3.16 Implemented food quality plans shall be verified as part of SQF Quality System verification (refer to 2.5).

RESPONSE: COMPLIANT

2.4.4 Product Sampling, Inspection, and Analysis

The auditor reviewed the Product Sampling, Inspection + Analysis SOP. The site performs no testing of raws/packaging except for quality/sensory analysis. The site accepts products/packaging based upon document review with no analysis. There is an onsite laboratory. The site performs inprocess chemical and physical attributes: water activity (aw) and finished product testing on physical attributes (aw and moisture %). Food safety analysis is continually performed during the daily Production runs. The same contracted laboratory services are used for environmental and/or product testing and is registered with the FDA. For the moisture % and water activity (aW) testing, the site uses a SKALA program in accordance to the AquaLab testing equipment for both physical attributes. The auditor reviewed the HACCP related Daily Quality Data Sheets and SKALA product specific production records with water activity (aw) and moisture % analysis results for the finished products (including COSTCO products). The auditor reviewed the HACCP related Label Verification Form and product specific production records with Water Activity (aw) and Moisture % analysis results for the first week of September 2021, second January 2022, third week of April 2022 and fourth week of August 2022. All were compliant with the SQF practitioner and the employee who generates and labels the product with verification. All were compliant with the SQF practitioner and the employee who generates and labels the product with verification. The site performs sensory analysis for the finished products as per the customer's requirements. The auditor reviewed the Finished Product Requirements and Specification document (section 6.1 Organoleptic Testing) and the customer specifications regarding the sensory analysis of its product [RXBAR Image and Defect Reference Manual (IDRM)]. The auditor reviewed the Kellogg Product Management Review Forms (RX BAR) dated form 1/7/2022 to 9/16/2022. All product attributes were evaluated and scored.

2.4.4.1 Processing parameters or in-process measurements shall be established, validated, and verified at a determined frequency to meet all customer, regulatory, and/or company requirements.

RESPONSE: COMPLIANT

2.4.4.2 On-site laboratories and inspection stations shall be equipped and resourced to enable testing of in-process and finished products to meet customer, regulatory, and/ or company requirements and meet quality objectives. 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 2.3.2.7).

RESPONSE: COMPLIANT

2.4.4.3 Process control methods shall be used to effectively control and optimize production processes to improve process efficiency, product quality, and reduce waste. Control charts and/or other quality tools shall be used for control of key processes

RESPONSE: COMPLIANT

2.4.4.4 A sensory evaluation program shall be in place to ensure alignment with agreed customer and/or company requirements. Sensory evaluation results shall be communicated with relevant staff and with customers where appropriate.

RESPONSE: COMPLIANT

2.4.4.5 Records of all quality inspections and analyses and statistical analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Product or Equipment

The auditor reviewed Quarantine and Non-Conformance Policy. It outlines the methods and responsibilities for handling non-conforming products. Any raw materials, packaging and finished products that do not have the required paperwork are NOT permitted to enter or leave the facility. Responsible persons are the FSQA personnel and the applicable onsite personnel. The site uses a Red HOLD tag and enter the non-compliance into the QA Quarantine Log if there is a non-conformance. Almost all of the recorded non-conformances are related to quality issues. The auditor reviewed the QA Quarantine Log regarding incident # 22-557 dated 9/2/2022 for 2 pallets of a Muddy Bites finished product (White Chocolate Pouches; Hold Tag 221202; Item # 24522) due to a potential contamination (plastic filings from a scraper). The product was quarantined and awaiting further actions and feedback from the customer.

2.4.5.1 Non-conforming product shall include products that fail to meet in-process or product requirements for quality. Non-conforming product shall be suitably identified, segregated, and appropriately dispositioned with records maintained.

RESPONSE: COMPLIANT

2.4.5.2 Non-conforming equipment shall include equipment that is not suitable for use and/ or is not capable of producing products that meet in-process or product requirements for quality. Non-conforming equipment shall be identified and segregated from production areas, if possible, with appropriate documentation maintained.

RESPONSE: COMPLIANT

2.4.5.3 The site shall document and implement a procedure to accept returned product that does not meet finished product specifications. The procedure shall include identification, handling, and disposition of returned goods to prevent redistribution or contamination of other products.

RESPONSE: COMPLIANT

2.4.6 Product Rework

The auditor reviewed the Rework Product SOP. Rework is not performed onsite.

2.4.6.1 Procedures shall be documented and implemented to ensure product quality or formulation is not compromised by the rework process. Material to be reworked shall be identified and traceable. Rework operations shall be overseen by qualified personnel.

RESPONSE: NOT APPLICABLE

2.4.7 Product Release

The auditor reviewed Finished Product Release SOP. The QA Supervisor and/or designees are the responsible persons. Incoming raws and packaging documentation (COA's, COC's) are required and reviewed. The case label review is performed by the Production and Quality personnel. The applicable Daily Production reports are reviewed by the Document Review/QA Lead (Tania Paz) for customer specification and CCP compliance (chemical, physical, Metal Detection/X-Ray Logs) and approved before the finished products can be released to the customer. For noncompliant product, the Document Review/QA Lead will notify Customer Service and the product will be "flagged" in the site's inventory management system, which is part of the site ERP system (PackManager). The product cannot be scanned into the PackManager system and is placed in Quarantine until it is either "reworked/ rerun" and released. The Quality personnel are the only persons authorized to release product that have been on HOLD. Now those products previously on Hold can be shipped. If still nonconforming results are observed, additional sampling and evaluation is performed. If product passes, it is released for shipment. Records are entered in the appropriate hardcopy documents.

2.4.7.1 The site shall document and implement a positive product release procedure to ensure that, at the time of delivery to its customer, the food supplied complies with all agreed customer, regulatory, and/or company requirements, including but not limited to product specifications, sensory attributes, packaging and package integrity, labeling, delivery, and service requirements.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release or disposition shall be maintained

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness

The auditor reviewed Verification and Validation SOP. Flow charts, product descriptions, raw material assessment and process flow were verified. 2 CCP's, 2 CQP's and 4 PC's exist. The Quality Manager/SQF Practitioner is responsible for documenting and implementing the methods, responsibility and criteria for validating. Records are maintained by the Quality Manager/SQF Practitioner. The Quality Manager uses internal audits, GMP audits, HACCP review and annual validations of metal detection devices (metal detectors) and X-Ray units. Auditor reviewed records of annual SQF System Verification dated 8/16/2022 to 9/12/2022 with the management sign-off and HACCP validation which was conducted on 9/9/2022.

2.5.1.1 Validation activities shall include those necessary to authenticate critical quality limits, process controls, and other quality tests established to meet customer requirements.

RESPONSE: COMPLIANT

2.5.1.2 Records of validation of quality criteria shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities

The auditor reviewed the Verification and Validation SOP. The Document Review (daily HACCP related records), SQF Practitioner (internal + GMP audits), Quality personnel (daily GMP audit/ Pre-Operational Inspections) and Compliance personnel (Supplier Approval) are responsible for verification activities. Client has work instructions for all test and products. Annual Verification records are performed on a continual basis throughout the year. Records of Complaint logs; Cleaning logs; GMP/Pre-Op Inspections, etc. The auditor reviewed the following HACCP/CCP related Ray and Metal Detection records and the Shipping/Receiving records for the first week of September 2021, second January 2022, third week of May 2022 and fourth week of August 2022. The auditor reviewed the following HACCP/CCP related Ray and Metal Detection records and the Shipping/Receiving records for the first week of September 2021, second January 2022, third week of May 2022 and fourth week of August 2022. The auditor reviewed the HACCP related Label Verification Form and product specific production records with Water Activity (aw) and Moisture % analysis results for the first week of September 2021, second January 2022, third week of May 2022 and fourth week of August 2022. All were compliant with the SQF practitioner and the employee who generates and labels the product with verification. All were compliant with the SQF practitioner and the employee who generates and labels the product with verification.

2.5.2.1 The verification schedule shall include activities designed to ensure the effectiveness of process controls and quality tests.

RESPONSE: COMPLIANT

2.5.2.2 The methods, responsibility, and criteria for verifying the effectiveness of monitoring critical quality points and other process and quality controls shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each record.

RESPONSE: COMPLIANT

2.5.2.3 Verification activities shall include a comparison between process control limits and specification limits to ensure alignment and appropriate process control corrections.

RESPONSE: COMPLIANT

2.5.2.4 Records of the verification of quality activities shall be maintained.

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action

The auditor reviewed the Corrective and Preventive Action Program which details root cause analysis and resolution of non-conforming products and the responsibility is of the SQF Practitioner (Sam Gu with the department managers assisting him in the applicable investigations). The auditor reviewed the ICA # 18 (Internal Corrective Action) dated 3/21/2022 regarding shipping/receiving product temperatures not being taken at the nose, middle and tail of the trailers. The root cause was determined to be that the applicable program was not updated to meet GFSI standards. The corrective action was to update the Trailer inspection forms.

2.5.3.1 Corrective and preventative action methods shall include the identification of the root cause(s) and the resolution of non-compliance of critical quality limits and deviations from quality requirements.

RESPONSE: COMPLIANT

2.5.4 Internal Audits

The auditor reviewed the Internal Audits SOP. Batch processing is performed; each product specific. The FSQA Director and Compliance Manager are responsible for the overall Internal audit program. The Quality Manager is responsible personnel is responsible for SQF system/program reviews and the Quality personnel for the onsite GMP and Pre-Operational audits. The Document Review (Tania Paz) is responsible for doc review of all applicable Production related and CCP/CQP related records. The Compliance department is responsible for review of the raw materials (COA's, COC's + lot #'s). Applicable finished product lots are tested offsite for microbiological analysis (APC, yeast/mold, total coliforms, and pathogens). All records of inspections maintained on a online platform (iAuditor) and virtual documents (SOP's, Policies, etc.) are stored in the SharePoint. The raw material and finished product testing focusses on the physical, chemical, appearance and organoleptic attributes. All applicable personnel (lab technicians) perform onsite inprocess and product testing related to the quality of the finished products processed onsite. The auditor reviewed the Certificate of Participation for Internal Auditor dated 5/22/2015 for the FSQA Director; Certificate of Completion for Internal Auditing- Basics dated 9/10/2019 for the Regulatory & Compliance Manager and AIB email as the proof of attendance and completion of GFSI Internal Auditing Webinar dated 4/21/2021. The auditor reviewed the Training Record dated 2/7/2022. The auditor reviewed records of annual SQF system audit performed 8/16/2022 to 9/12/2022 and HACCP validation which was conducted on 9/9/2022. The site performs weekly GMP facility audits on the 4 identified areas of the site's building. The auditor reviewed the weekly facility GMP audits captured using a virtual iAuditor platform for Area 1 dated Area 1/18/2022, Area 2 dated 4/19/2022, Area 3 dated 6/21/2022 and Area 4 dated 8/23/2022.

2.5.4.1 Internal audit plans and methods shall include assessments of food quality plans, process controls, quality tests, and other activities implemented to meet finished product specifications as well as customer and company requirements.

RESPONSE: COMPLIANT

2.5.4.2 Staff conducting the quality internal audits shall be trained and competent in internal audit procedures and have knowledge and experience in quality processes and process control methods as they relate to the scope of certification. Where practical, staff conducting internal audits shall be independent of the function being audited.

RESPONSE: COMPLIANT

2.6.1 Product Identification and Traceability

The Product Identification and Traceability SOP addresses methods and responsibility for product identification at all stages. Customer Service/Sales are the responsible persons who set up all food items and raw materials in the inventory control platform (PackManager). Master case labels are applied to some finished product cases. Records of product identification are maintained in the PackManager database and on the recorded production records. The lot coding system (PackManager) for each received raw material/packaging uses the vendor's lot # to identify the received products and is traced throughout the entire process. The Best By dates for most of the Finished Products used onsite are customer specific. The auditor reviewed the COSTCO Coding of Finished Product Listing which is quite prescriptive. An example of a COSTCO finished product (Heavenly Hunks) packed on MP12 on first shift dated 9/20/2022 would be 092022 263 MP12. The auditor observed online personnel and stored product using this format to comply with SQF requirements. A trace for a COSTCO finished product selected by the auditor during the facility audit was performed during the audit: Finished Product: Heavenly Hunks Oatmeal Dark Chocolate 20 oz.; Item code 5022; Lot # 090122 2244 MP12; Best by Sep 1, 2023. 2,304 eaches were produced from 9/1/2022; 0 eaches shipped and 2,304 eaches were in inventory. All product were accounted for (100% accountability). Primary Packaging: Oatmeal Dark Chocolate 20 oz. CDA; Item # 3143; Lot # 129092. Received 207,900 eaches; Used 166,790 eaches; Inventory 40,882 eaches (99.9% accountability). Raw Materials: 1) Oats; Item # 1001-102490) Lot #: MGM2152022. Received 52,000 lb.; Used 48,804 lb.; Inventory 0 lb.; Transferred 4,000 lb. to customer (101.5 % accountability). 2) Chocolate Chips: Item # 1023-53385; Lot # 2162T530CL14. Received 49,350 lb.; Used 47,941.9423 lb.; Inventory 144.4 lb. (97.3 % accountability).

2.6.1.1 Finished product shall be labeled to the agreed customer, regulatory, and/or company requirements.

RESPONSE: COMPLIANT

2.6.1.2 Product changeover procedures shall include verification of quality attributes required to meet finished product specifications and customer requirements.

RESPONSE: COMPLIANT

2.6.1.3 Finished product shall be traceable forward to the customer, such as the retailer, distributor, or manufacturer (one forward).

RESPONSE: COMPLIANT

2.6.1.4 All raw materials, ingredients, and packaging materials used in manufacturing a finished product and processing aids associated with the product shall be identified with the finished product lot number and traceable back to the supplier (one back).

RESPONSE: COMPLIANT

2.6.2 Product Withdrawal and Recall

The mock recalls are conducted one forward and one back by the management team. No actual recalls in 2021 or 2022. Only mock recall exercises have been performed by the site. Requirement to inform FDA, CB, SQFI and customer(s) are located in the Recall Emergency Contact List. The responsible personnel are the FSQA Director and the Regulatory & Compliance Managers. The procedure states investigation to determine root cause of a recall shall be undertaken and action documented. The auditor reviewed the Trace Report for Finished Product: Bottle 350 ml OLLY Goodbye Stress 42 ct/12 pk case (Material # 700075.01; Lot # 1277A 5723); Produced 1311 cases; Shipped 1311 cases; Inventory: 0 cases; (100% accountability).

2.6.2.1 The site’s recall and withdrawal procedures shall apply to product recalled or withdrawn due to failure to meet customer specifications or corporate quality requirements. Records shall be maintained and meet customer, regulatory, and company requirements, as applicable.

RESPONSE: COMPLIANT

2.6.3 Crisis Management

The auditor reviewed the Crisis Management SOP on file. The responsible personnel are the FSQA Director and directs the CMT. The Regulatory & Compliance Manager is the CMT leader's backup. The FSQA Director is responsible for all internal communications and communication with regulatory agencies and the VP of Customer Service is responsible for communicating with the media. The auditor reviewed the Crisis Management Exercise dated 9/12/2022. The plan was tested regarding a water leak. At 10:15 AM the fire alarm was triggered by a low pressure in the sprinkler system in the Cooler ceiling. The root cause (faulty sprinkler head) was identified by the onsite personnel. The Maintenance team powered down the equipment near the Cooler. After the water was shut off, it was determined 65% of the stored product was affected. All affected product was assessed and disposed of if required. The trademarked product policy was performed (if applicable). The Cooler area was shut down and swabbed for pathogens, A week later, the area was opened after the results of the swabbing were received. Three opportunities for improvement were generated. The CMT addressed the scenario and satisfied the SQF code requirement for clause 2.6.4.

2.6.3.1 The crisis management plan prepared by senior site management shall include the methods by which the site shall, in the event of a crisis, maintain continuity of supply that meets customer, regulatory, and/or company product and service quality requirements.

RESPONSE: COMPLIANT

2.6.3.2 The site shall contact its customers in the event of a crisis that impacts its ability to supply quality product.

RESPONSE: COMPLIANT

2.7.1 Food Fraud

Plan is in place. It is listed in the Food Fraud Mitigation Plan and states the methods, responsibility and criteria for identifying vulnerability to food fraud. The Regulatory & Compliance Manager is responsible for the Food Fraud program and the Food Safety Team is responsible for leading the mitigation plan and conducting the annual assessment. The auditor reviewed Food Fraud Assessment - McCook document with the overall food fraud vulnerability rating being 'Low". The EMA was accessed during the Food Safety hazard analysis. Report contained conclusions, proposed mitigation and summary. Food fraud vulnerability assessment and mitigation plan was reviewed and verified on 12/9/2021. Records are maintained in the site's SQF SharePoint program.

2.7.1.1 The food fraud vulnerability assessment shall include the site’s susceptibility to ingredient or product substitution, mislabeling, dilution, and counterfeiting that could adversely impact food quality. This assessment may address both food safety and quality.

RESPONSE: COMPLIANT

2.7.1.2 A food fraud mitigation plan shall be developed and implemented that specifies the methods to be used for controlling identified food fraud vulnerability that could adversely impact food quality.

RESPONSE: COMPLIANT

2.8.1 General Requirements for Identity Preserved Foods

The SOP for management of these products are detailed in the Identity Preserved Foods SOP. The client is certified to handle and process Gluten-Free and Organic products. While the site does process Kosher and Non-GMO products, they are audited by all the relevant Kosher/ Non-GMO certification representatives and listed as the manufacturing site for the applicable customers. The SOP for management of these products are detailed in the Identity Preserved Foods SOP. Specified receiving, handling and segregated storage procedures are in place. Not all finished products are certified for all these identity categories. There is a mixture of products certified to a specific identity or identities. The segregation concerns is related to the allergens, gluten-free, Non-GMO and Organic ingredients (a requirement). The Kosher preserved status is managed by the Regulatory & Compliance Manager along with the Warehouse Manager. The auditor reviewed Kosher Certificate for Ratio Dairy Snack Granola Overcap Bulk (OUD3-FXVEGEW) dated 7/13/2022 certified by the Kosher is Orthodox Union (OU). The site is not certified for the Non-GMO preserved status. The customers facilitates certification by the Non-GMO Project. The Organic preserved status is managed by the Regulatory & Compliance Manager along with the Warehouse Manager and the certification body that verifies the Organic claim is OTCO Certification Services (Cert # Z-67854-2008; Customer ID # OT-019725; effective date 6/9/2015 and issue date 8/31/2022). The label identifier is Certified Organic. When organic products are scheduled to be produced, non-dedicated equipment are used. All organic products are scheduled for the first production run or the only run for that day. No rework of any finished product is allowed onsite. All organic products are labeled with labels under the control of the customer and verified onsite by the Receiving and Quality personnel. All organic finished products are in segregated storage area of the warehouse and undergo pre-shipment review checks before release for shipment.

2.8.1.1 The methods and responsibility for the identification, label approval, and processing of food and other products requiring the preservation of their identity preserved status (e.g., Kosher, Halal, organic, GMO free, regional provenance, free from, free trade, etc.) shall be documented and implemented.

RESPONSE: COMPLIANT

2.8.1.2 Identification shall include a statement of the product's identity preserved status of all ingredients, including additives, preservatives, processing aids, and flavorings.

RESPONSE: COMPLIANT

2.8.1.3 Raw material and ingredient specifications for identity preserved foods shall include requirements for their handling, transport, storage, and delivery prior to use.

RESPONSE: COMPLIANT

2.8.1.4 Assurances concerning the raw material or ingredient's identity preserved status shall be by agreement with the supplier of the material.

RESPONSE: COMPLIANT

2.8.1.5 The process description shall allow for a product's identity preserved status to be maintained during manufacturing.

RESPONSE: COMPLIANT

2.8.1.6 The processing of identity preserved foods shall be conducted under controlled conditions such that: i. Ingredients are physically separated from ingredients identified as incompatible with the identity preserved food; ii. Processing is completed in separate rooms, scheduled as the first production run, or carried out after completion of thorough sanitation of the processing area and equipment; and iii. Finished product is stored and transported in separate units or isolated by a physical barrier from the non-specialty product.

RESPONSE: COMPLIANT

2.8.1.7 The identity preserved status shall be declared in accordance with regulatory requirements.

RESPONSE: COMPLIANT

2.8.1.8 Additional customer-specific requirements for identity preserved foods shall be included in the finished product specification, as described in 2.3.2.5, or the label register and implemented by the site.

RESPONSE: COMPLIANT

2.9.1 Training Requirements

The Training of Personnel addresses requirements of employee training regarding Assemblers Inc. Policies, SOP's, Plant Programs and food regulations to be implemented and maintained onsite. The responsible person is the Training Coordinator. Food safety topics are determined by SQF food safety codes and regulatory requirements. Competencies and methods are detailed in the training documentation and quizzes given to every employee post-training. The client uses the online Alchemy Training platform to train its onsite employees regarding food safety/quality topics, GMP's and SQF topics. Area/process/ equipment specialized training is performed by the area/departmental management. Appropriate personnel are trained regarding the food safety requirements (CCP's, HACCP, SQF/PCQI Training certificates).

2.9.1.1 Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the SQF Quality System and the maintenance and improvement of quality requirements.

RESPONSE: COMPLIANT

2.9.1.2 Instructions shall be available explaining how all tasks critical to meeting customer and company specifications and quality and process efficiency are to be performed.

RESPONSE: COMPLIANT

2.9.2 Training Program

Employees trained on required food safety criteria and personal safety. The Training of Personnel addresses requirements of employee training regarding Assemblers Inc. Policies, SOP's, Plant Programs and food regulations to be implemented and maintained onsite. The responsible person is the Training Coordinator. The site utilizes the Alchemy Training program to train and record required employee training. All training records are being stored on the company's secured Alchemy Training Matrix 2022. The auditor reviewed the refresher training records for the Lab that performed the metal detector checks in the Popcorn Rooms during the facility audit and the forklift driver interviewed during the facility audit. The auditor reviewed the Work Instructions for the Moisture Analyzers (WI-QA015) and the Meeting/Training Record dated 8/11/2022 for which is performed on finished product by trained QA personnel.

2.9.2.1 The employee training program shall include the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Process control and monitoring of critical quality points (CQPs); ii. Steps identified as critical to effective implementation of the food quality plan and the maintenance of food quality; and iii. Product inspection and testing.

RESPONSE: COMPLIANT

2.9.2.2	The employee training program shall include: i. Applicable process control and quality tools training for those responsible for operating, inspecting, and overseeing key manufacturing processes; ii. Training, calibration, and proficiency testing of internal laboratory personnel; iii. Training of personnel responsible for sensory evaluations; iv. Training in the application of risk-based principles, such as HACCP, used for the identification and control of quality threats for staff involved in developing and maintaining the food quality plan; and v. Provision for identifying and implementing the refresher training needs of site personnel. **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