# SQF Food Safety Audit Edition 9
## Assemblers, Inc. - Assemblers Inc.

## Summary

**AUDIT DECISION**
CERTIFIED

**CERTIFICATION NUMBER**
23618 | 167247

**AUDIT RATING**
95
Good

**DECISION DATE**
10/28/2022

**AUDIT TYPE**
RECERTIFICATION

**RECERTIFICATION DATE**
09/08/2023

**AUDIT DATES**
09/19/2022 - 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:** 4

## Non-Conforming

## 2.5.4 Internal Audits and Inspections (Mandatory)

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. MINOR: There is no evidence the Quality Manager and participating staff (i.e. HACCP coordinator) performing the onsite facility GMP audits has any training specific to internal auditing.

**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:** MINOR

**EVIDENCE:** There is no evidence the Quality Manager and participating staff (i.e. HACCP coordinator) performing the onsite facility GMP audits has any training specific to internal auditing.

**ROOT CAUSE:** Training requirement in Internal Audit program is not specified for the GMP auditors, only for Food Safety System auditors. SOP will be revised.

**CORRECTIVE ACTION:** Quality manager enrolled in formal Internal Audit training. All participants have been be trained on Internal Audit proceedures by Regulatory Compliance Manager, who has formal training.

Internal Auditing Training Enrollment.pdf

2.5.4.2 Correction IA Training (1).pdf

**VERIFICATION OF CLOSEOUT:** The auditor reviewed the invoice for internal auditing training dated 10/13/2022 and the Order dated 9/28/2022. This submission meets the criteria for the SQF code element 2.5.4.2.

**COMPLETION DATE:** 10/13/2022 **CLOSEOUT DATE:** 10/21/2022

## 2.6.1 Product Identification (Mandatory)

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. MINOR: During the audit of the several Production rooms (MP12, MP16, MP1 + MP5), the auditor observed many containers/bins of raw materials being used for production without any clearly identified lot traceability information.

**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:** MINOR

**EVIDENCE:** During the audit of the several Production rooms (MP12, MP16, MP1 + MP5), the auditor observed many containers/bins of raw materials being used for production without any clearly identified lot traceability information.

**ROOT CAUSE:** Process did not rely on batch sheets for traceability for batched pallets, since all materials are scanned by pallet in the ERP system in real-time. Batch sheets are in use, but batch sheets contain multiple batches and no paper process existed to tie the batch sheet to individual pre-weighed batches.

**CORRECTIVE ACTION:** Placards with Batch number, Formula, Date, and Initials will be used on pre-weighed pallets. This will allow traceability to the ingredient lot information on the batch sheets.

Assemblers - WI - OPS005 - Pre-weighed

Training for Pre-Weighe... Process.pdf

**VERIFICATION OF CLOSEOUT:** The auditor reviewed the Pre-weighed Batch ID Process document and the training record dated 10/18/2022. This submission meets the criteria for the SQF code element 2.6.1.1.

**COMPLETION DATE:** 10/18/2022 **CLOSEOUT DATE:** 10/21/2022

## 11.1.6 Ventilation

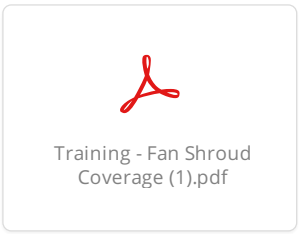
There was adequate ventilation throughout the site observed during the facility audit. The popcorn kettles are covered and have adequate extractor ventilation velocities (no steam). MINOR: During the audit of the MP12 - Batching, MP12-Packing and MP5 Baking rooms, fans blowing on product and food contact surfaces were equiped with fan shrouds too small to effectively cover the entire back of the fan. This situation poses a potential food safety hazard (contamination).

**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.

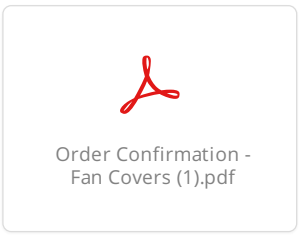
**RESPONSE:** MINOR

**EVIDENCE:** During the audit of the MP12 - Batching, MP12-Packing and MP5 Baking rooms, fans blowing on product and food contact surfaces were equiped with fan shrouds too small to effectively cover the entire back of the fan. This situation poses a potential food safety hazard (contamination).

**ROOT CAUSE:** Employees not properly trained on expectation.




**CORRECTIVE ACTION:** Operations trained on requirements for fans- including being fully covered by the shroud. The plant is purchasing a large size to effectively cover the entire back of the fan. Fans will not be in use unless/until properly covered.




**VERIFICATION OF CLOSEOUT:** The auditor reviewed the Meeting/Training record dated 10/18/20222 and the Order Acknowledgement dated 10/7/2022. This submission meets the criteria for the SQF code element 11.1.6.4.

**COMPLETION DATE:** 10/07/2022 **CLOSEOUT DATE:** 10/28/2022

## 11.1.7 Equipment and Utensils

Equipment are designed with impervious material and ease of cleaning. All overflows are discharged directly to the drain. All utensils are not colored coded and designed for the required task. There is a contracted laundering service used. The site orders supplies of the PPE (frocks) clothing for the company. All processing equipment + utensils are cleaned daily or as needed and stored to prevent microbiological contamination. The auditor reviewed the vendor catalog listings for the following utensils that come into contact with food and food contact surfaces: REMCO Food Grade Scoop, 32 oz.; Item # 6400 and CHOICE 20" x 15", White, Polypropylene plastic Food Storage Box, Item # 176BT20155WH and REMCO Large Hand Scrape 9.7" x 4.4"; Series 6962. All three are FDA compliant for use with food. MINOR: During the audit of the site, the following was observed: 1) MP1 Bar Line: a white long handle paddle (food contact) was observed to be lying on a plastic pallet (non-food contact) under the flooring of the Production platform. 2) Walk-In Freezer: There is an excessive amount of ice buildup over the door and entrance of the freezer.

**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:** MINOR

**EVIDENCE:** During the audit of the site, the following was observed: 1) MP1 Bar Line: a white long handle paddle (food contact) was observed to be lying on a plastic pallet (non-food contact) under the flooring of the Production platform. 2) Walk-In Freezer: There is an excessive amount of ice buildup over the door and entrance of the freezer.

**ROOT CAUSE:** 1) Lack of designated place for out-of-use equipment 2) Ice build up due to drivers leaving door open. Work order created to add remote closure system for door to facilitate closing when not in use.

Training - GMP Utensil Storage Practice (1).pdf

Work Order - Freezer Door Opener.pdf

**CORRECTIVE ACTION:** 1) Corrected at the time of the audit by removing the paddle and taking it to a sanitaiton room for cleaning. Employees in room will be retrained on GMP expectations for food contact equipment. 2) Ice will be cleared and monitored.

**VERIFICATION OF CLOSEOUT:** The auditor reviewed the Meeting/Training record dated 10/18/20222 and the picture of the cleaned Freezer area free of ice. This submission meets the criteria for the SQF code element 11.1.7.2.

**COMPLETION DATE:** 10/04/2022 **CLOSEOUT DATE:** 10/28/2022

## 11.2.3 Calibration

Calibration procedures and responsibilities are outlined in Calibration of Equipment SOP. There is a Master Calibration Matrix maintained by the Quality Manager. The site's CQP is Net Weight. The auditor reviewed the Calibrate Certificates for 2 in-line check weighers (LOMA Model: T16; s/n 1921776 + PEN-TEC Model: HR-600 + s/n P01519 ) dated 2/10/2022; calibration due date 2/10/2023 and batch scales: MP12 (Doran Model 7000XL; s/n 7XL18635 dated 10/4/2021; s/n 7XL12156 dated 8/31/2021 and s/n 7XL11734 dated 2/11/2023) and MP5 (Doran Model 7000XLM; s/n 7XL600497 dated 9/1/2021 and Doran Model: 7000Xl; s/n 7XL600498 dated 10/4/2021). All weights used to verify the onsite scales are calibrated annually by a contracted Scale Service. The auditor reviewed the Calibration Certificates (# 280483 dated 5/28/2021; 280814 dated 6/4/2021 + 281787 dated 6/22/2021. The site uses metal detection and X-Ray onsite. The auditor reviewed the Calibration Certificates for metal detectors and for the Loma Systems and Raycon X-Ray units dated 2/10/2022. All were compliant + within their tolerances. The 3 test wands are calibrated. The auditor reviewed the Certificates of Compliance (cert # 13722, 44174 + 6/13/2017 for stainless steel) regarding the test pieces. The auditor reviewed the Liquid in Glass Thermometer Calibration Report (Report # K6227) for a Thermometer (model ACC6113XXS; s/n 6216) issue dated of 3/18/2022. The MP14 line uses a conveyor oven to bake the crackers batched in the room. The auditor reviewed the Calibration Certificate (cert# 304904) for the conveyor oven dated 6/3/2022. The site calibrates its Luminometer (Hygiena Ensure Touch ATP system) using negative and positive test pieces. The auditor reviewed the calibration results of the ET 2.2 luminometer dated 9/20/2022, 8/11/2022+ 7/20/2022. QA Manager is responsible to make a decision regarding product when calibration is out of spec (place on HOLD). Only authorized/trained personnel are allowed to verify the calibrations of measuring devices. The auditor reviewed the Scale Calibration Logs dated 8/8/2022 + 9/6/2022; the Monthly Temperature Sensor Calibration Forms dated 8/25/2022 + 9/16/2022 and the Thermometer Calibration Logs dated 9/20/2022. All were complete and comprehensive. MINOR: 1) The certified weights used onsite for scale verification and batch scales are calibrated annually by a contracted scale/weight service provider. The Calibration Certificates for these weights are not current (Calibration Due Dates ranging from 5/28/2022, 6/4/2022 and 6/18/2022). 2) The Calibration Certificates for 2 MP5 batch scales are not current (Calibration Due Dates ranging from 8/31/2022 and 9/1/2022).

**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:** MINOR

**EVIDENCE:** 1) The certified weights used onsite for scale verification and batch scales are calibrated annually by a contracted scale/weight service provider. The Calibration Certificates for these weights are not current (Calibration Due Dates ranging from 5/28/2022, 6/4/2022 and 6/18/2022). 2) The Calibration Certificates for 2 MP5 batch scales are not current (Calibration Due Dates ranging from 8/31/2022 and 9/1/2022).

**ROOT CAUSE:** 3rd party was not able to calibrate all devices during the last visit due to staff/scheduling issue. Plant will be more proactive on calibration schedule and to leave some tolerance before the due dates.

**CORRECTIVE ACTION:** Certified weights and batch scales were re-certified by 3rd party at next visit immediately after audit. Plant will be more proactive on calibration schedule and to leave some tolerance before the due dates.

ASSEMBLERS MCCOOK-7XL12156... 309571.PDI

ASSEMBLERS MCCOOK-7XL60034... 309570.PDI

ASSEMBLERS MCCOOK-MCCWT... 308085.PI

ASSEMBLERS MCCOOK-MCCWT... 308086.PI

**VERIFICATION OF CLOSEOUT:** The auditor reviered the Calibration Certificates for the scales and weights. This submission meets the criteria for the SQF code element 11.2.3.2.

**COMPLETION DATE:** 09/29/2022 **CLOSEOUT DATE:** 10/21/2022

## Audit Statements

| | |
|---|---|
| **SQF Practitioner Name** | Name the designated SQF Practitioner<br>**RESPONSE:** Sam Gu |
| **SQF Practitioner Email** | Email of the designated SQF Practitioner<br>**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)<br>**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<br>**RESPONSE:** Assemblers Inc. is located in a commercial park at the southwestside 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 ans 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)<br>**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<br>**RESPONSE:** Maintain Certification |

## Section Responses

### 2.1.1 Management Responsibility (Mandatory)

A Food Safety and Quality Policy dated 9/30/2021 is available and includes the methods of meeting the requirements. The policy is signed by Joel Rosenbacher (President) and Paul Siefert (FSQA Director) and dated 9/30/2021. It is 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 SOP 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 trained. The HACCP certificate is current and dated 5/16/2015. Both SQF Practitioners are full time employees. The SQF practitioners are also trained PCQI: Cert # 308bf29d dated 2/22/2018 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 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

## 2.1.2 Management Review (Mandatory)

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 8/16/2022 to 9/12/2022 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** The SQF System shall be reviewed by senior site management at least annually and include: i. Changes to food safety management system documentation (policies, procedures, specifications, food safety plan); ii. Food safety culture performance; iii. Food safety objectives and performance measures; iv. Corrective and preventative actions and trends in findings from internal and external audits, customer complaints, and verification and validation activities; v. Hazard and risk management system; and vi. Follow-up action items from previous management reviews. Records of all management reviews and updates shall be maintained.

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.1.3 Complaint Management (Mandatory)

The methods and responsibility for handling 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 safety complaint received 8/6/2022 for a 5026 6 oz. birthday cake (Heavenly Hunks Birthday Cake; Lot Not Reported) regarding the consumer reporting they "bit into something strange". The investigation could not determine the validity of the complaint based on the lack of information received. 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 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 Management System is located electronicnically maintained in the SharePoint platform. It summarizes the organization's food safety policies and methods to meet the requirements of the current SQF standard. The organizational chart is current. There is a product 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). Procedures to validate justifiable changes to the food safety plan are present. Plan and personnel revisions were reviewed.

**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)

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

**RESPONSE:** COMPLIANT

## 2.2.3 Records (Mandatory)

The 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 certified (Tania Paz) have the verification responsibility for Batch + Production related records. 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.

**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 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. 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 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:** NOT APPLICABLE

**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:** NOT APPLICABLE

**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:** NOT APPLICABLE

**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:** NOT APPLICABLE

**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:** NOT APPLICABLE

## 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 materrials, 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 Dessicated Coconut; Pack Date: 3/2/2022; Lot # 220610. The COA was available upon request.

**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

The site does not use contract manufacturers.

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

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

**RESPONSE:** NOT APPLICABLE

## 2.3.4 Approved Supplier Program (Mandatory)

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.1 Food Legislation (Mandatory)

The auditor reviewed Food Legislation SOP. All Finished Products are required to be certified as per stated in 21 CFR. The responsibility is of the SQF practitioner for keeping current on all food regulations. 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. The client is registered with the FDA and USDA. The auditor reviewed the FDA Facility Food Registration (last updated 10/8/2020; expiration 12/31/2022; Status - Valid) and the USDA Grant of Inspection: Est. # 45719; Innuaguration Date: 5/22/2017.

**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)

Th auditor reviewed the Good Manufacturing Practices (GMP's) Policy (Doc # 5). The visitor GMP's are posted in English and Spanish. The policy addresses how to control and maintain food safety for the scope of certification. The responsibility is of the senior management and the SQF practitioners to ensure implementation and communicating to management and employee the GMP requirements. The policy addresses how to control and maintain food safety for the scope of certification and maintain the integrity of the customer's products.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.3 Food Safety Plan (Mandatory)

The site has a SQF Food Safety Plan maintained on file. The food safety plan has been developed following the 12-step HACCP method and has been effectively implemented. The auditor reviewed the food safety plan. ALL FINSHED PRODUCTS ARE RTE. LOW RISK. Procedure is FSMA compliant with HACCP Team having the required PCQI training. The HACCP 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 Mendendez, Sanitation/Sanitation Manager = Phillip Woods, Warehouse & Warehouse Manager = Juan Vasquez. The Quality/Quality Manager (Sam Gu) is the HACCP Team Leader. The plans are FSMA compliant with the HACCP Coordinator, FSQA Manager, Regulatory Compliance and Food Safety Manager and the FSQA Director PCQI certified. There are 14 HACCP Plans with 1 CCP 1) Metal Detection/X-Ray and with 2 CQP's 1) Moisture % and 2) Net Weight or Net Quantity. HACCP Plan 1 = Baking Line (COSTCO product): There is 1 CCP = Metal Detection. The critical limits are Pass/Fail using 2.0 mm ferrous, 2.5 mm non-ferrous and 2.5 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 2 = Cracker Line. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0 mm ferrous, 2.5 mm non-ferrous and 2.5 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 3 -MP1 Bar Line. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0 mm ferrous, 2.5 mm non-ferrous and 2.5 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 4 - MP2 Bar Line: CCP 1 = Metal Detection. The critical limits are Pass/Fail using 1.5mm ferrous, 1.5 mm non-ferrous and 2.0 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 5 - MP4 Bar Line: CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0mm ferrous, 2.0 mm non-ferrous and 2.0 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 6 - Protein Snack Bites. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0mm ferrous, 2.0 mm non-ferrous and 2.0 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 7 - Muddy Bites. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0mm ferrous, 2.0 mm non-ferrous and 2.0 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 8- Chubbies Snacks. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0mm ferrous, 2.0 mm non-ferrous and 2.0 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 9: Crepes. CCP 1 = Baking Temperatute. The critical limt = Internal Temperatur > or = 160°F monitored by a trained designee every hour (+/- 30 minutes) using a calibrated thermometer. CCP 2 = Metal Detection. The critical limits are Pass/Fail using 2.0 mm ferrous, 2.5 mm non-ferrous and 2.5 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 10 = USDA Meat Repack. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0 mm ferrous, 2.5 mm non-ferrous and 2.5 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 11 = Vertical Bagger. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0 mm ferrous, 2.5 mm non-ferrous and 2.5 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 12 = Repack of Bulk Shelf Stable RTE Items. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0 mm ferrous, 2.5 mm non-ferrous and 2.5 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the end of the production run by the Operations personnel. 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. HACCP Plan 13 = Bulk Repack of Perishable RTC Products. CCP 1 = Metal Detection. The critical limits are Pass/Fail using 2.0 mm ferrous, 2.5 mm non-ferrous and 2.5 mm stainless steel test pieces that are recorded at Start-up, every hour (+/- 30 minutes) frequency and the

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| | end of the production run by the Operations personnel. 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. HACCP 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. The site has an Allergen related PC. 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. Allergen PC 1 = Label verification. The critical limit = the correct allergen declaration on packaging prior to the start of the line and every hour (+/- 30 minutes) after start-up by a trained Quality person. |
| **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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**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.<br>**RESPONSE:** COMPLIANT |

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| **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).<br>**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.<br>**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.<br>**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.<br>**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).<br>**RESPONSE:** COMPLIANT |
| **2.4.3.16** | Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used.<br>**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.<br>**RESPONSE:** COMPLIANT |

## 2.4.4 Product Sampling, Inspection and Analysis

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 (COA's) with no analysis. There is a QC lab located next to the Maintenance Office soon after you access the Production/Warehouse ares close to the admin offices. The site performs physical attribute testing: water activity (aW) and finished product testing on physical attributes (aW and moisture %) and sensory evaluation. Food safety analysis is continually performed during the daily production runs. The lab has the following diagnostic equipment: 1 Aqualab water activity (aW) and moisture analyzer; 1 Meter water activity (aW) and moisture analyzer; 1 C3 Brookfield Texture Analyzer (COSTCO owned and used only to collect data on a COSTCO product - coconut almond butter chocolate bar); 1 Mettler Toledo HC103 Moisture Analyzer; 1 Thermo incubator and 1 grinder. The lab also stores the Production bechtop scales in a secured cabinet, The same contracted laboratory services are used for environmental and/or product testing and is registered with the FDA. 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. The site performs gluten testing for some of its gluten-free products and perfoms proficiency testing every 2 years to meet the GFCO requirements. The auditor reviewed the GFCO Proficiency Testing 2021 Round - Preliminary Redport Amended (Wheat and Barley Mix) dated 4/22/2021. Both results were acceptable. There are 2 employees (lab technicians) whom perform APC testing in the onsite laboratory. The site used a contracted lab (LGC) to administer the supplies and testing regarding the proficiency of the 2 lab personnel regarding the Hygiens Surface Monitoring. The auditor reviewed the HY1901- Assemblers, Inc. Hygiene Surface Monitoring (Hygiene) Analyte Report; Hy311 - (Round 311); issued 5/18/2022. The results were in the "Green" with a total plate count of 857 cfu/plate with a recovery of 28.6% when compared to the direct count. 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 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. The site performs sensory analysis for the finished products as per the customer's requirements. All were compliant with the SQF practitioner and the employee who generates and labels the product with verification.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.5 Non-conforming Materials and Product

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

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

**RESPONSE:** NOT APPLICABLE

## 2.4.7 Product Release (Mandatory)

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 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

An Environmental Monitoring Program is based upon risk assessment. The Quality Manager/SQF Practitioner is the responsible person. The swabbing frequency is Zone dependent. The auditor reviewed the updated swabbing schedule (Pre-Operational Swab Matrix and the Pathogen Environmental Monitoring Program Matrix) for Zones 1, 2 ,3 + 4. Zone 1 is swabbed during Pre-Operational inspections for non-pathogenic organisms (ATP and APC) and zones 2, 3 + 4 are swabbed for pathogens (Listeria and Salmonella). Depending on the area of the site's production areas, the client swabs at a frequency of 4/week, 1/month and 4/month. The program identifies the pathogens of interest: Listeria and Salmonella. For Zone 1, APC are the organisms of interest. The auditor reviewed the COA's (Report #'s 211203120645, 21211203120645, CHG-45889427-0 and 220815153054) dated 9/13/2021, 12/3/2021, 4/22/2022 and 8/15/2022. All swabs complied with the microbiological requirements. The site changed their contracted laboratory during 2020. 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 standarThe 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.

**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 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** 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 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 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)

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 # 28 (Internal Corrective Action) dated 5/20/2022 regarding sprinkler leak in the Coller getting pallets wet. The affected product was placed on Hold. The Quality Manager determined the root cause to be a "faulty sprinkler head" and was repalced by the contratced service provider. The sprinkler head was replaced.

**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)

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. MINOR: There is no evidence the Quality Manager and participating staff (i.e. HACCP coordinator) performing the onsite facility GMP audits has any training specific to internal auditing.

**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:** MINOR

**EVIDENCE:** There is no evidence the Quality Manager and participating staff (i.e. HACCP coordinator) performing the onsite facility GMP audits has any training specific to internal auditing.

**ROOT CAUSE:** Training requirement in Internal Audit program is not specified for the GMP auditors, only for Food Safety System auditors. SOP will be revised.

**CORRECTIVE ACTION:** Quality manager enrolled in formal Internal Audit training. All participants have been be trained on Internal Audit proceedures by Regulatory Compliance Manager, who has formal training.

Internal Auditing Training Enrollment.pdf

2.5.4.2 Correction IA Training (1).pdf

**VERIFICATION OF CLOSEOUT:** The auditor reviewed the invoice for internal auditing training dated 10/13/2022 and the Order dated 9/28/2022. This submission meets the criteria for the SQF code element 2.5.4.2.

**COMPLETION DATE:** 10/13/2022 **CLOSEOUT DATE:** 10/21/2022

**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)

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. MINOR: During the audit of the several Production rooms (MP12, MP16, MP1 + MP5), the auditor observed many containers/bins of raw materials being used for production without any clearly identified lot traceability information.

**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:** MINOR

**EVIDENCE:** During the audit of the several Production rooms (MP12, MP16, MP1 + MP5), the auditor observed many containers/bins of raw materials being used for production without any clearly identified lot traceability information.

**ROOT CAUSE:** Process did not rely on batch sheets for traceability for batched pallets, since all materials are scanned by pallet in the ERP system in real-time. Batch sheets are in use, but batch sheets contain multiple batches and no paper process existed to tie the batch sheet to individual pre-weighed batches.

**CORRECTIVE ACTION:** Placards with Batch number, Formula, Date, and Initials will be used on pre-weighed pallets. This will allow traceability to the ingredient lot information on the batch sheets.

Assemblers - WI - OPS005 - Pre-weighed

Training for Pre-Weighe... Process.pdf

**VERIFICATION OF CLOSEOUT:** The auditor reviewed the Pre-weighed Batch ID Process document and the training record dated 10/18/2022. This submission meets the criteria for the SQF code element 2.6.1.1.

**COMPLETION DATE:** 10/18/2022 **CLOSEOUT DATE:** 10/21/2022

**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)

Product Identification and Trace SOP outlines responsibilities and methods for traceability throughout the process as well as for recalls and withdrawals (one-up + one-back). The Operations personnel is responsible for the implementation of the program. A trace for a COSTCO finished product selected by the auditor during the facility audit was performed during the audit: Finished Product: Heavenly Hunks Canadian Oatmeal Dark Chocolate 20 oz.; Item code 5014; 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).

**2.6.2.1** 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 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).

**2.6.3.1** 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 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 personnl. 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 tradedmarked product policy was performed (if applicable). The Cooler area was shut down and swabbed for pathogens, A week later, the area was opened afdter 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.

**2.6.4.1** 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 auditor reviewed Food Defense Plan outlines methods and responsibilities for food defense. The Food Safety Team serves as the Food Defense Team are responsible parties, with the Operations Manager (Jonathan Lyon) taking the lead and working with the identified product. Raw material protections in place. The Food Defense Team consist 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 Mendendez, Sanitation/Sanitation Manager = Phillip Woods, Warehouse & Warehouse Manager = Juan Vasquez. The stated procedures address requirements of the SQF code element 2.7.1. The client is registered with the FDA Facility. The auditor reviewed the FDA Facility Food Registration (last updated 10/8/2020; expiration 12/31/2022; Status - Valid) and the USDA Grant of Inspection: Est. # 45719; Innuaguration Date: 5/22/2017. The plant has access control, locked external doors for restricted access to areas of facility; passwords + firewalls used for computer systems with a disaster recovery system. The incoming and outgoing shipments are full loads requiring seals and LTL's requiring locked trailers. The Food Defense Plan was reviewed as part of the site's SQF system on 9/8/2022. A food defense vulnerability assessment was performed on 9/1/2021 and reviewed on 9/6/2022. The site is performed a Food Defense Challenge Exercise on 9/8/2022 regarding an unauthorized access of the site by an unauthorized person (employee from the Chicago site). Three door entrances identified as potential entry points were challenged by this person. The person did get past the receptionist and was stopped once entering the cafateria area. She was also challenged at the other doors. This person was also given access to the warehouse and challenged by a lead. The site required training of door policies and visitor protocols for the applicable personnel on 9/30/2022. The test result was successful with corrective actions and recommendations provided in the exercise's Summary.

**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)

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.

**2.7.2.1** 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)

An Allergen Control Program outlines responsibility and methods for controlling allergens. The Quality Manager/SQF Practitioners are responsible for allergen assessment and the training facilitator is responsible for providing training. The site has all the Big 8 allergens except for shellfish handled onsite in the production and re-pack operations: Tree Nuts (coconut), Soy, Dairy and Wheat (in the Production and in the ambient and cooler warehouse areas). Control of potential cross-contamination is achieved through segregated storage, labeling, employee training + production scheduling (all allergen containing finished products are produced at end of daily schedule). Full cleaning is performed during changeover when required between each product. Risk assessment for allergens was reviewed in the Allergen Cross-Contact Risk Assessment (6/27/2022) listing the onsite allergens by room location. Annual validations regarding residual allergen post-Sanitation are performed for each production area (rooms) using the Neogen 3D Reveal Allergen and or Roemer AGRAStrip gluten testing systems. The auditor reviewed the annual Validation Study results for the lines processing the COSTCO products (MP5 and MP12) for peanuts for the MP12 Line dated 6/20/2022;, 7/5/2022 + 7/15/2022 and the MP5 Line dated 5/17/2021. NOTE: Both lines are dedicated lines for the coconut allergen and deemed a low risk. Therefore, these lines are not validated for coconut. All areas were validated (negative) post sanitation.

**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

**EVIDENCE:** The site does not re-work product.

**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 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** 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)

Employees are 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 Machine Operator 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 Vertical Metal Detector (2.9.3-WI-003) and SP Metal Detector Monitoring (2.9.3-WI-011) for which the Machine Operators was trained on and the Metal Detection Trainung Quizes (MCC-MD-1) and the Meeting/Training Record dated 10/29/2021 for the applicable QA personnel.

**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

Assemblers Inc. is located in a small commercial park at the southwestside 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 ans 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. The site was approved by local authorities: Village of McCook; County of Cook; State of Illinois; License # 2022047; issued 1/3/2022 and expiration date of 12/31/2022. The site re-packs some meat snack products and is registered with the USDA: Grant of Inspection: Est. # 45719; Innuaguration Date: 5/22/2017. The auditor reviewed the FDA Facility Food Registration (last updated 10/8/2020; expiration 12/31/2022; Status - Valid).

**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

All floors in the non-processing (warehouse) and processing areas (baking, hand pack, repack, etc.) are concrete and well maintained. Floor drains are located in appropriate processing areas and capable of accommodating a cleaning washdown. There are no waste trap systems onsite. Walls, ceilings, partitions and doors are properly constructed of concrete and metal. The Processing Rooms walls are insulated metal panels and are well maintained. The ceiling is well maintained. No water piping over production/packing lines. Windows are located in the 2 corners (warehouse + admin office areas of the building). There are no stairs, catwalks, and platforms in food processing and warehouse handling areas.

**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:** NOT APPLICABLE

**EVIDENCE:** There are no waste trap systems onsite.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** There are no stairs, catwalks, and platforms in food processing and handling areas.

## 11.1.3 Lightings and Light Fittings

There is a combination of flourescent and LED shatterproof lighting producing sufficient illumination for workers. All bulbs are covered with shatterproof plastic tubing or shields.

**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

There are no inspection/quality control areas onsite. There are carts that are placed in the applicable areas of production to perform in-process testing (i.e. moisture %, aW, etc.). Inprocess/finished product testing is performed in the onsite QC laboratory.

**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

Doors in both buildings are adequately sealed to protect against dust and pest contamination. Bait stations are located along the exterior perimeters only. External doors (bay doors, emergency exits, employee entrance) are sealed + secure. Electronic insect lighting is strategically located and operational.

**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

There was adequate ventilation throughout the site observed during the facility audit. The popcorn kettles are covered and have adequate extractor ventilation velocities (no steam). MINOR: During the audit of the MP12 - Batching, MP12-Packing and MP5 Baking rooms, fans blowing on product and food contact surfaces were equiped with fan shrouds too small to effectively cover the entire back of the fan. This situation poses a potential food safety hazard (contamination).

**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:** MINOR

**EVIDENCE:** During the audit of the MP12 - Batching, MP12-Packing and MP5 Baking rooms, fans blowing on product and food contact surfaces were equiped with fan shrouds too small to effectively cover the entire back of the fan. This situation poses a potential food safety hazard (contamination).

**ROOT CAUSE:** Employees not properly trained on expectation.

Training - Fan Shroud Coverage (1).pdf

**CORRECTIVE ACTION:** Operations trained on requirements for fans- including being fully covered by the shroud. The plant is purchasing a large size to effectively cover the entire back of the fan. Fans will not be in use unless/until properly covered.

Order Confirmation - Fan Covers (1).pdf

**VERIFICATION OF CLOSEOUT:** The auditor reviewed the Meeting/Training record dated 10/18/20222 and the Order Acknowledgement dated 10/7/2022. This submission meets the criteria for the SQF code element 11.1.6.4.

**COMPLETION DATE:** 10/07/2022 **CLOSEOUT DATE:** 10/28/2022

## 11.1.7 Equipment and Utensils

Equipment are designed with impervious material and ease of cleaning. All overflows are discharged directly to the drain. All utensils are not colored coded and designed for the required task. There is a contracted laundering service used. The site orders supplies of the PPE (frocks) clothing for the company. All processing equipment + utensils are cleaned daily or as needed and stored to prevent microbiological contamination. The auditor reviewed the vendor catalog listings for the following utensils that come into contact with food and food contact surfaces: REMCO Food Grade Scoop, 32 oz.; Item # 6400 and CHOICE 20" x 15", White, Polypropylene plastic Food Storage Box, Item # 176BT20155WH and REMCO Large Hand Scrape 9.7" x 4.4"; Series 6962. All three are FDA compliant for use with food. MINOR: During the audit of the site, the following was observed: 1) MP1 Bar Line: a white long handle paddle (food contact) was observed to be lying on a plastic pallet (non-food contact) under the flooring of the Production platform. 2) Walk-In Freezer: There is an excessive amount of ice buildup over the door and entrance of the freezer.

**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:** MINOR

**EVIDENCE:** During the audit of the site, the following was observed: 1) MP1 Bar Line: a white long handle paddle (food contact) was observed to be lying on a plastic pallet (non-food contact) under the flooring of the Production platform. 2) Walk-In Freezer: There is an excessive amount of ice buildup over the door and entrance of the freezer.

**ROOT CAUSE:** 1) Lack of designated place for out-of-use equipment 2) Ice build up due to drivers leaving door open. Work order created to add remote closure system for door to facilitate closing when not in use.

Training - GMP Utensil Storage Practice (1).pdf

Work Order - Freezer Door Opener.pdf

**CORRECTIVE ACTION:** 1) Corrected at the time of the audit by removing the paddle and taking it to a sanitaiton room for cleaning. Employees in room will be retrained on GMP expectations for food contact equipment. 2) Ice will be cleared and monitored.

**VERIFICATION OF CLOSEOUT:** The auditor reviewed the Meeting/Training record dated 10/18/20222 and the picture of the cleaned Freezer area free of ice. This submission meets the criteria for the SQF code element 11.1.7.2.

**COMPLETION DATE:** 10/04/2022 **CLOSEOUT DATE:** 10/28/2022

**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 grounds surrounding the site is well maintained and free from waste and accumulated debris. Surroundings are kept neat and tidy and do not present a hazard to sanitary operations. There is a designated making area located in the side of the site's grounds area. Eating is not permissible on the outside grounds except in the employees cars. There are some commercial and residential buildings on the 47th street side of the site. There is an open space behind the site and a commercial entity located about .25 miles next to the side of the site and pose no food safety threat.

**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:** There are no paths from amenities leading to site entrances.

## 11.2.1 Repairs and Maintenance

The maintenance procedures and responsibilities are outlined in the Maintenance SOP. The Maintenance Manager (Paul Rivera) is responsible for Preventive Maintenance and all maintenance activities. The company's maintenance systems management platform (eMaint) is used to maintain the Maintenance program. Unscheduled repairs are also maintained in the software. All PM + emergency repairs are communicated to the Maintenance Manager for action and verification. All maintenance and contractors are trained in the company's GMP's and personal hygiene practices. The outside contractors are trained during the signing of the GMP requirements for visitors + contractors at the receptionist desk. Completed work requirements regarding sanitation and food safety are being met. A Preventive Maintenance schedule (Scheduled Activity) is maintained entirely as a calendar form in the software. The software prompts the Maintenance Manager and assistant when the scheduled task requires their attention/action. The PM schedule + associated work orders were reviewed for 2021 + 2022. Lines MP12 and MP are used to produce the COSTCO product (Heavenly Hunks). MP12 Line: There is a horizontal mixer used to batch the product that is serviced monthly, a Handtman Extruder service annually by the manufacturer and 3 Rack (Baxter) ovens serviced weekly. The auditor reviewed the online Work order's for the following: Horizontal Mixer -W/O # 18123 dated 4/5/2022; W/O # 24961 dated 9/10/2022 and W/O #15080 dated 1/4/2022. Baxter Ovens: W/O # 15608 dated 1/19/2022; W/O # 19348 dated 5/11/2022 + W/O # 25123 dated 9/17/2022. Handtman Extruder (Continuos Vacuum Filler): Service Report Letter (Service Ticket # 30980; PO # PO-2767) dated 1/11/2022 regarding the annual "Copmplete Service" of the unit. The Maintenance Manager verifies the completed maintenance work with the applicable Maintenance person(s) in the eMaint program. If work is done on food contact surfaces, the area is also cleaned + sanitized by Sanitation personnel. The site does have a Temporary Repair Policy (section 8.3) in the Maintenance SOP. No temporary repairs were observed during walkthrough. The food-grade and non-food grade chemicals are secured and in the Maintenance storage area as well as some secured cabinets in designated areas of the site. The auditor reviewed the SDS's for Food Grade: Rela Dyne Synthetic Food Grade Air Tool Oil dated 1/1/2021; v1; Dow Corning Compound 4 Electrical Insulating Compound dated 10/16/2015; v2.0; CRC Food Grade Silicone dated 10/18/2018; v5 and Logix Thread Smart Hi-Temp FG Anti-seize dated 5/30/2018 and Non-Food Grade: Hitachi TH-Type A Make-Up dated 11/13/2014; Leibinger Ink 70000-00195 dated 6/18/2015; Goof Off dated 5/21/2020 and Stainless Steel Picking Solution dated 1/16/1996.

**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

Contractor's are required to sign-in and out in a log at the visitor's entrance. Visitors are also required to read and sign the GMP requirements. Appropriate clothing and footwear are covered in the requirements. All visitors are required to follow the employee GMP and clothing requirements. Completed work requirements regarding sanitation and food safety are being met. Maintenance schedule and the completed work orders are maintained in the site's online Maintenance platform (eMaint). All reviewed work orders have the requirement to remove all tools and debris from any maintenance activity once it has been completed. The auditor verified this requirement was performed for each work order reviewed during the interview of the Maintenance Manager.

**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

Calibration procedures and responsibilities are outlined in Calibration of Equipment SOP. There is a Master Calibration Matrix maintained by the Quality Manager. The site's CQP is Net Weight. The auditor reviewed the Calibrate Certificates for 2 in-line check weighers (LOMA Model: T16; s/n 1921776 + PEN-TEC Model: HR-600 + s/n P01519 ) dated 2/10/2022; calibration due date 2/10/2023 and batch scales: MP12 (Doran Model 7000XL; s/n 7XL18635 dated 10/4/2021; s/n 7XL12156 dated 8/31/2021 and s/n 7XL11734 dated 2/11/2023) and MP5 (Doran Model 7000XLM; s/n 7XL600497 dated 9/1/2021 and Doran Model: 7000Xl; s/n 7XL600498 dated 10/4/2021). All weights used to verify the onsite scales are calibrated annually by a contracted Scale Service. The auditor reviewed the Calibration Certificates (# 280483 dated 5/28/2021; 280814 dated 6/4/2021 + 281787 dated 6/22/2021. The site uses metal detection and X-Ray onsite. The auditor reviewed the Calibration Certificates for metal detectors and for the Loma Systems and Raycon X-Ray units dated 2/10/2022. All were compliant + within their tolerances. The 3 test wands are calibrated. The auditor reviewed the Certificates of Compliance (cert # 13722, 44174 + 6/13/2017 for stainless steel) regarding the test pieces. The auditor reviewed the Liquid in Glass Thermometer Calibration Report (Report # K6227) for a Thermometer (model ACC6113XXS; s/n 6216) issue dated of 3/18/2022. The MP14 line uses a conveyor oven to bake the crackers batched in the room. The auditor reviewed the Calibration Certificate (cert# 304904) for the conveyor oven dated 6/3/2022. The site calibrates its Luminometer (Hygiena Ensure Touch ATP system) using negative and positive test pieces. The auditor reviewed the calibration results of the ET 2.2 luminometer dated 9/20/2022, 8/11/2022+ 7/20/2022. QA Manager is responsible to make a decision regarding product when calibration is out of spec (place on HOLD). Only authorized/trained personnel are allowed to verify the calibrations of measuring devices. The auditor reviewed the Scale Calibration Logs dated 8/8/2022 + 9/6/2022; the Monthly Temperature Sensor Calibration Forms dated 8/25/2022 + 9/16/2022 and the Thermometer Calibration Logs dated 9/20/2022. All were complete and comprehensive. MINOR: 1) The certified weights used onsite for scale verification and batch scales are calibrated annually by a contracted scale/weight service provider. The Calibration Certificates for these weights are not current (Calibration Due Dates ranging from 5/28/2022, 6/4/2022 and 6/18/2022). 2) The Calibration Certificates for 2 MP5 batch scales are not current (Calibration Due Dates ranging from 8/31/2022 and 9/1/2022).

**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:** MINOR

**EVIDENCE:** 1) The certified weights used onsite for scale verification and batch scales are calibrated annually by a contracted scale/weight service provider. The Calibration Certificates for these weights are not current (Calibration Due Dates ranging from 5/28/2022, 6/4/2022 and 6/18/2022). 2) The Calibration Certificates for 2 MP5 batch scales are not current (Calibration Due Dates ranging from 8/31/2022 and 9/1/2022).

**ROOT CAUSE:** 3rd party was not able to calibrate all devices during the last visit due to staff/scheduling issue. Plant will be more proactive on calibration schedule and to leave some tolerance before the due dates.

**CORRECTIVE ACTION:** Certified weights and batch scales were re-certified by 3rd party at next visit immediately after audit. Plant will be more proactive on calibration schedule and to leave some tolerance before the due dates.

ASSEMBLERS MCCOOK-7XL12156... 309571.PDI

ASSEMBLERS MCCOOK-7XL60034... 309570.PDI

ASSEMBLERS MCCOOK-MCCWT... 308085.PI

ASSEMBLERS MCCOOK-MCCWT... 308086.PI

**VERIFICATION OF CLOSEOUT:** The auditor reviered the Calibration Certificates for the scales and weights. This submission meets the criteria for the SQF code element 11.2.3.2.

**COMPLETION DATE:** 09/29/2022 **CLOSEOUT DATE:** 10/21/2022

**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

A Pests Control IPM Program Monitoring is on file. The Quality Manager is responsible person onsite. An Organic compliant IPM program is in place with a contracted Pest Control service provider (Illinois Department of Public Health; License Permit; Registration ID # 051-010734; expiration 12/31/2022) and maintains its records and applicable documents on their online portal. The auditor reviewed PCO license; PCO William James; ID # 052-090581 and expiration date of 12/31/2022. The IPM Scope of Service Program is in a binder with the client sign-off dated 2/10/2022. Weekly service for interior and monthly service for the exterior. Targeted pests are rats, mice, cockroaches, flies and ants. An Organic Approved Product List dated 2/10/2022 is in the binder with the Sanitation Manager and service provider's signatures. The auditor reviewed the Device Locator Map dated 2/10/2022 with management sign-off. The PCO performed an Annual IPM Assessment on 9/15/2022. All employees are trained to report any pests sightings. If a sighting, employee will report to management + PCO is contacted. COI is current: 10/1/2021 effective date and 10/1/2022 expiration date. The site uses the Pest Sighting Log in the binder for employees sightings when PCO is offsite. The requirement for identified pest activity do not present a risk of contamination is stated in IPM program. Trending charts exist for all pest of interest. The auditor reviewed the Device Trend Reports for the date range of 2/1/2021 to 12/31/2021. Flying insects (flies, midges, moths, etc.) were the most trended pest. Service reports (hardcopy) are kept in binder and those for 2021 + 2022 were reviewed and found to be compliant + well maintained. The auditor reviewed the SDS's for Terad 3 AG Blox dated Jan 2020 + Talstar Xtra dated 5/26/2016; v1.03.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** There are no pesticides storedm onsite.

**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

Assemblers Inc. has established procedures for cleaning and sanitation of processing and storage areas, food handling equipment and all areas of the facility. The auditor reviewed the Cleaning and Sanitation SOP. Detailed SSOP's regarding the cleaning of equipment have been developed and implemented. There is a Sanitation Department with a designated Sanitation crew (~46 employees). The Sanitation Manager (Phillip Woods) is responsible for the Sanitation program. Daily cleaning/sanitation is verified through the daily pre-operational checks. The auditor reviewed the 2022 Master Sanitation Schedule - McCook and verified the weekly sanitation actions performed on the MP12 Horizontal Mixer and Handtman Extruder and on the MP5 Slab Machine with Cutting blades for the first week of September 2021, second week of January 20212, third week of May 2022 and fourth week of August 2022. maintained as hardcopies and as virtual files on the site's secured shared drive. Employees performing sanitation duties have received specialized training by the sanitation chemical supplier's representative. The auditor reviewed the online Columbus Sanitation Training record dated 2/25/22 for the Alchemy Chemical Safety Sanitation Training. The auditor reviewed the Meeting/Training records for the sanitation personnel perfoming the cleaning actions and handling chemicals with signoff. Cleaning is verified visually and by ATP swabbing during Pr-Operatinal Inspections. There are no CIP systems onsite. All cleaning/sanitizing is COP. The auditor reviewed the SSOP's for the MP5 Slab Cutter Line, MP12 Line (horizontal mixer + Handtman Extruder)and the enrobers on the MP2 line. The auditor reviewed Pre-operational reports for the first week of September 2021, second week of December 2021, the third week of May 2022 and the fourth week of August 2022. The Quality technician uses a flashlight to check visually and verifies the effectiveness of the sanitation via ATP swabbing (Hygiena Ensure Touch system) and captures/analyzes the data in the SureTrend software. Where residual product was observed, the QC technician identified it and had the sanitation crew rectify. Titrations (ppm) of the mixed cleaning and sanitizing chemical are performed daily by the Sanitation Supervisor or Lead and monthly by the cleaning chemical service provider's representative. The auditor reviewed the daily Chemical Concentration Logs records for the titrations of the cleaning and sanitizing chemicals (Advantis FC SM, Quorum Clear V and Quorum Green) for the first week of September 2021, second week of January 20212, third week of May 2022 and fourth week of August 2022. All were compliant. The auditor also reviewed the Customer Service Reports for the titrations performed by the chemical provider's representative onsite for 8/25/2022. There is a Color Code Policy (11.3.3) for the shovels, squeegees, pails and cleaning equipment. All observed to be in proper use and storage during the facility audit. Staff amenities and sanitary facilities are inspected daily by the QA personnel. The client uses 2 sanitizers onsite: ECOLAB Quorum Clear V and ECOLAB Quorum Green/Verde. The auditor reviewed the SDS's for the following stored chemicals: ECOLAB Quorum Clear V dated 5/18/2017; v1.3; ECOLAB Quorum Green/Verde dated 5/10/2017; v1.1; ECOLB Advantis Sot Metal FC dated 10/28/2019; v1.3; ECOLAB SHC Extreme dated 3/19/2020; v1.3; ECOLAB Quorum Clean Surface Sanitizer dated 9/14/2020; v1.4; DrySan Duo 2 Step Cleaner dated 1/22/2021; v1.4; ECOLAB Questar GPC Non-Chlorinated Alkaline Cleaner dated 11/20/2019; v1.4; ECOLAB Hand Sanitizer dated 7/20/2020; v1.2 and Boost 3201 SM dated 1/22/2021; v1.4

**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:** NOT APPLICABLE

**EVIDENCE:** There are no CIP systems onsite.

**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

Employees are trained on infectious disease concerns during their new hire training and in their GMP refresher training. During the audit, there were no employees observed in production areas who showed signs of infectious diseases. Sick personnel are sent home and not allowed to come in contact with product +/or direct contact packaging. Employees are responsible to report to management if they are sick. If sick with a known pathogen, the employee must return to work only with a doctor's note. The site formed COVID Committee comprising of multi-departmental Leadership (President, FSQA Director, Regulatoryv& Compliance Manager, VP Customer Service + CFO) and a webpage. The client has implemented a Coronavirus (COVID-19) Company Policy regarding the where employees are instructed to follow the CDC guidelines and state mandates.The site is presently following the CDC and local health guidelines regarding the pandemic. The site's employees have received Alchemy Bloodborne Pathogen training and have several sanitation personnel designated to cleanup any spilled bodily fluids. The auditor reviewed the Alchemy Traing schedule and roster for Bloodborne pathogen training performed in 2nd quarter of 2022. The auditor reviewed the Bloodborne Pathogen Protection Program (2.4.2.1). The auditor also reviewed the Meeting/Training Records for those Sanitation employees whom are designated to cleanup any bodily fliud spillage incidents. The records reviewed were dated 1/20/2022, 6/23/2022, 7/20/2022 and 8/10/2022. Employees with any cuts, lesions or exposed sores must use metal detectable bandages/band aids to cover. If they are employed to handle product or direct food packaging, they will be required to use company provided gloves and respirator for dust. During the audit, there were no employees observed in the production areas who showed signs of having open wounds or lesions. Water consumption is allowed in the re-pack/warehousing areas; only in the Primary Filling areas/rooms. Use of tobacco, eating, drinking or smoking is not allowed in the facility. A employee breakroom/lunchroom is available to employees for eating and drinking.

**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

Employees are instructed to wash their hands before starting and/or returning to work. Observation of employees during the audit noted adherence to the facility hand wash policy. Hand wash sinks are located at the entrance and inside the Production Room and in the Warehouse bathroom. All hand wash basins are constructed of stainless steel and operated "hands-free" with foot/finger/knee buttons. All wash basins are supplied with water at appropriate temperatures, liquid soap, paper towels and a waste container. Signs are available at all wash stations which are legible and prominently displayed in English and Spanish.

**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:** NOT APPLICABLE

**EVIDENCE:** There are no high risk processing performed onsite.

**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

Facility is not high risk. Personal clothing is worn by staff and properly maintained, clean and did not pose a risk to the product. The site performed a Clothing Food Safety Risk Assessment on 8/18/2021. The Production Line Leads and QC personnel are responsible for the visual inspection of employee apparel. A 3rd party laundering service supplies the employees onsite with the PPE (frocks).The employee's personal clothing do not present a contamination risk. No jewelry allowed to be worn in processing where exposed product exist except for plain ring bands and medical alert neclaces worn under clothing. Small objects (i.e. pens) must be kept below waistline.

**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 sign-in and out in a logbook at the main office entrance. Visitors are also required to read and sign the GMP requirements prior to entering the facility. Appropriate clothing and footwear are covered in the requirements. All visitors are required to follow the employee GMP and clothing requirements (blue hairnets) ansd blue safety glasses. The auditor reviewed the Visitor GMP + Contractor GMP Policies. No jewelry allowed to be worn in plant except for a ring band with no stones and medical alert necklaces. Small objects (i.e. Pens) must be kept below waistline.

**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)

Staff amenities have sufficient lighting and ventilation to accommodate the maximum number of plant personnel. There are 2 lockerooms adjacent to the employee breakroom/bathrooms. There are lockers for employee personal belongings, easy for inspection with hooks for clothing and accommodate the number of employees onsite. Toilets are adequate in number for the maximum number of staff. Toilets are constructed so that they can be easily maintained, tidy and clean. There are four bathrooms: two bathrooms adjacent to the employee lockerooms and two in the admin office. The hand washing sinks are designed and constructed as per section 11.3.2.2. A procedure is in place to manage sewage backups. There is a lunchroom segregated from the production and storage areas. The lunch rooms have sufficient seating, utensil sink, refrigeration, microwaves and temporary storage of personal food items. It is properly ventilated, well lit, have adequate seating, hot and cold water, heating and cooling. Lunch rooms are kept clean and tidy. There are no designated eating areas permitted on the outside premises.

**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:** NOT APPLICABLE

**EVIDENCE:** There are no showers onsite.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.4.1 Staff Engaged in Food Handling and Processing Operations

The site's personnel were observed entering or exiting the facility through the designated employee entrances. Employees have been instructed to keep exterior doors closed when not in use. During the audit, all exterior doors in the production areas were observed to be maintained closed by plant personnel. There were no employees observed wearing false fingernails or fingernail polish in the processing areas of the facility. Trash containers were observed to be properly identified (label) and emptied at a regular frequency. No sensory analysis is performed in a food handling/contact zone. Sensory analysis is performed in the QA laboratory by the QA personnel during finished product testing.

**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:** NOT APPLICABLE

**EVIDENCE:** No sensory analysis is performed in a food handling/contact zone.

## 11.5.1 Water Supply

The facility uses municipal water as their potable water supply. There were no cross connections or observed issues that could affect the quality of the water. The facility tests the water for potability annually by an outside lab. Hot water is supplied. The auditor reviewed the "Arrow/Old World/VFP Pumbing; Backflow Test Report"(job # INR16058/84258) dated 5/23/2022. The 4 assemblies passed; performed by a contracted plumber (Robert Hamling) Certificated Tester # XC3150. The auditor reviewed the Chicago Drinking Water Report 2020. The microbiological and heavy metal contaminants were within the regulatory requirements.

**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:** Non-potable water is not used onsite.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** No water is stored onsite.

## 11.5.2 Water Treatment

The site does not treat its processing or cleaning water.

**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

The site relies upon contracted microbial lab analysis to validate water is potable. The policy dictates the sampling schedule. It is the responsibility of the Quality Manager to ensure the laboratory personnel samples the onsite water for potability testing annually. Ther auditor reviewed the contracted laboratory's Certificate of Accreditation (Matix Sciences International) (Cert # AT-1491; valid to 10/22/2022) meeting the ISO/IEC 17025:2017 standard. The site test for potability quarterly at certain site locales where the 4 quarters satisfy the annual testing requirements (annual). The auditor reviewed the Analytical Test Report (Batch # Assembler_22072015) dated 8/1/2022 for MP9 and the COA (CHG-45839328-0) dated 4/6/2022. The site test for Coliforms and Total Heterotropic Count (THC). All locations sampled were either <1.1/100 ml for pathogens and <1.0/ml for the THC.

**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

The site has a commercial ice maker that makes ice used to cool the dough used for crackers and the mix used for the COSTCO Heavenly Hunks product line. The site tests the ice for potability annually. Ther auditor reviewed the COA (COA # CHG-45566475-0) dated 1/22/2022 for spigot #4 of the ice maker. The site test for Coliforms and Total Heterotropic Count (THC). All locations sampled were either <1.1/100 ml for pathogens and <1.0/ml for the THC.

**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:** COMPLIANT

**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:** COMPLIANT

**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:** COMPLIANT

## 11.5.5 Air and Other Gasses

Compressed air is used on several Production lines to blow product off of the conveyor belts at the metal detection/X-Ray equipment. Compressed liquid nitrogen is used to flush the headspace of the product pouches for several products at the packaing lines. There are 2 air compressors onsite that use food grade rated air filters. The auditor reviewed the Technical Data Sheet for the Grade H - Hifg Efficiency Oil Removal Filter rated ay 0.01 micron. The air compressors are on the site's PM schedule and service by the onsite Maintenance staff every 3 months. The auditor reviewed the Work Order # 16781 dated 3/1/2022; W/O # 20307 dated 6/4/2022 and W/O # 24615 dated 9/1/2022. The compressed air is tested in the onsite laboratory annually for APC and Yeast & Mold using the 3M petri film systems. Ther air in specified locations of the site is tested quarterly on a rotating test schedule. By the end of the year, all sections of the site. The auditor reviewed the second and third quarter results for the compressed air. For the second quarter, the auditor reviewed the Analytical Test Report (Report # Assemblers_211007151947) dated 10/12/2022. Th test results were withijn the alloted tolerances. The auditor reviewed the Praxair Certificate of Conformance dated 3/18/2022 for the Extendpak 1 & 2 Nitrogen gas stating the gas is tested and meets or exceeds the requirements of the Food Chemical Codex and recognized as the minimum acceptance for use in the food industry.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.6.1 Receipt, Storage and Handling of Goods

There is 1 walk-in Cooler and 1 Freezer onsite. The majority of the storage area is for ambient storage of shelf stable raw materials and finished goods. All allergen containing and organic raw materials that are received, processed or stored onsite require segregated storage. All products/packaging/super sacks/bins are on pallets and stored off the floor. The company practices FIFO and periodic inventory of raws, product and packaging occurs. There is a secured equipment storage cage area onsite. Most processing equipment is repaired "in-place" or in maintenance shop. No raw materials, ingredients, packaging, equipment and chemicals are held under temporary or overflow conditions that are not designed for the safe storage of goods.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** There is no temporary storage that occurs onsite.

**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

The methods and responsibilities of Safe, Proper Handling & Storage SOP meets the SQF requirements for clause 11.6.2. There is 1 walk-in cooler for storing raws (eggs, cheese, yogurt, milk) and some finished product and 1 walk-in freezer for storing both raws and finished product. The rest of the warehousing/repack areas is maintained at ambient temperatures. The auditor observed sufficient cooler/freezer capacity for the raw materials. The auditor system monitors the cooler temperatures and notifies (email) the applicable onsite personnel if there is a temperature non-conformance and sends a continuous temperature monitoring data to the Quality, Facility, Warehouse and Maintenance managers. The auditor reviewed the Daily Temperature Log Coolers dated from 3/7/2022 to 3/11/2022. All were compliant with the designated temperature ranges. The site has 16 seated forklifts and 4 stand-up forklifts.

**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

All packaging is properly stored on racks in the ambient warehousing areas. There are no wet areas in the warehousing areas or near storage racks. Warehouse transportation vehicles did not pose a contamination risk. There are ~ 30 forklifts exist onsite. All are on a PM schedule and serviced by a contracted service provider, as well as daily safety checks. The auditor verified during walkthrough.

**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

The methods and responsibilities of Storage of Hazardous Chemicals and Chemical Substances are listed in the SOP. Daily supplies of chemicals are properly stored in a secured cabinets in the Maintenance area as well in other cabinets at other site locations. No risk to food products was observed. No pesticides are stored on site. Chemicals have adequate storage for their use and facility's needs. The cabinet is secured via a lock and accessible by authorized personnel only (combination). The cleaning/sanitizing chemicals are stored on chemical spill containment pallets in a secured cage area with signage, a spill kit and a wall mounted emergency eye wash bottle station. There are wall-mounted emergency eye wash stations positioned in strategic areas of the site. SDS's for the cleaning/sanitizing chemicals are maintained and assessable upon request. The auditor reviewed the SDS's for the following cleaning/sanitizing chemicals: The auditor reviewed the SDS's for Food Grade chemicals: CRC Food Grade Machine Oil (aerosol) dated 8/45/2016; v3 and Synco Super Lube Silicone Lubricant (aerosol) dated 4/25/2018 and Non-Food Grade: Super Industrial Gear Lube dated NU Calgon EVAP Foam No Rinse (aerosol) dated 2/26/2018 and CRC White Lithium Grease dated 1/16/2015; v1. The auditor reviewed the SDS's for Food Grade: Rela Dyne Synthetic Food Grade Air Tool Oil dated 1/1/2021; v1; Dow Corning Compound 4 Electrical Insulating Compound dated 10/16/2015; v2.0; CRC Food Grade Silicone dated 10/18/2018; v5 and Logix Thread Smart Hi-Temp FG Anti-seize dated 5/30/2018 and Non-Food Grade: Hitachi TH-Type A Make-Up dated 11/13/2014; Leibinger Ink 70000-00195 dated 6/18/2015; Goof Off dated 5/21/2020 and Stainless Steel Picking Solution dated 1/16/1996.

**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 auditor reviewed the Shipping & Receiving SOP. There are 23 manual bay doors for shipping and receiving of raw materials, packaging and finished goods and 3 Access doors for large equipoment + access to the outside areas. The site's Shipping and Receiving "Truck Drivers" receive the raw materials and other materials (cleaning chemicals, etc.) at the docks. Raw materials/ingredients/packaging are received at ambien, refrigerated and frozen temperatures which are received and stored under refrigeration or freezer. All finished products shipped form the site are shipped by ambient and refrigerated temperature transport. The trailer and product temperatures are montored nusing calibrated thermometers. The audtor reviewed the calibration records for those thermometers used on the docks (see 11.2.3). All transport is arranged and managed by the site's customers using independent transport vehicles. The auditor reviewed the Inbound and Outbound Trailer Inspection Records for received goods and finished products for the first week of September 2021, second week of December 2021, third week of April 2022 and the fourth week of August 2022. All were complete with the recorded GMP concerns (trailer condition, damage, pest activity, etc.) and trailer and product temperatures (when applicable).

**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 site's Packaging room for the Crepe Line (MP8 RTE) is a high risk area. The ambient air is tested annually for APC and Yeast & Mold in the onsite QC lab for this area. The auditor reviewed the test results for the 3rd quarter. The APC test results were 2 cfu/exposure time and 0 cfu for yeast & mold. Ther employees in the high risk areas wear PPE (rubber shoe covers + frocks).

**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:** COMPLIANT

**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:** COMPLIANT

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

**RESPONSE:** COMPLIANT

**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:** COMPLIANT

**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:** COMPLIANT

## 11.7.2 Thawing of Food

No need for thawing of any raws/ingredients. This clause is not applicable.

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

**RESPONSE:** NOT APPLICABLE

**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:** NOT APPLICABLE

**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:** NOT APPLICABLE

## 11.7.3 Control of Foreign Matter Contamination

Methods and responsibility for the prevention of foreign matter contamination are documented in several documents such as the Glass, Brittle Plastic, Ceramics and Similar Materials Policy and the Knives and Sharp Object Program. Responsible personnel are the FSQA Manager and Production personnel. Employees are trained regarding foreign material contamination (auditor reviewed the 2022 3rd quater training records in the Alchemy Training Log). Preventative maintenance and internal audits are performed to ensure plant and equipment remains in good condition. Temporary fasteners are allowed. Company maintains a Glass & Brittle Material Register broken down by plant areas. Onsite inspection is performed by the Quality personnel on a monthly basis. The auditor reviewed the Glass & Brittle Material Register dated 9/17/2021, 9/21/2021, 1/11/2022, 1/18/2022, 5/3/2022, 5/10/2022, 8/4/2022 and 8/15/2022. Pre-Op Inspections are performed regarding any glass/plastic instrument covers and loose metal objects. Wooden pallets are in good condition and are usually swapped out for plastic pallets for storage and transport. Knives are assigned to employees by their Production supervisor and inspected for any noncompliance (broken, missing pieces) when returned at the end of the shift. Any broken blades are reported to the Supervisor and Quality personnel. The Production Manager maintains the utility knife logs. The auditor reviewed the Knoves and Sharp Objects Register dated form 5/20/2022 to 8/28/2022.

**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

The site uses 12 metal detectors (2 used for COSTCO product) and 4 X-Ray units onsite to run all packaged product through. There are 2 dedicated metal detectors on the RTE Heavenly Hunks (MP5 + MP12) lines used to pack the COSTCO finished baked products (Heavenly Hunks brand). Metal detection/X-Ray is also one of the site's CCP's (CCP 1). The Packaging personnel perform a metal detector check at startup, every hour for all the products packaged onsite after a changeover and at the end of the production run. On 9/19/2022, the auditor witnessed 3 metal detector checks performed on the MP12 + MP5 Baking lines, the MP16 Room and 1 X-Ray check on the MP10A Gummy Hand Pack lines by the trained machine operators during the facility audit. The test piece sizes are: Ferrous = 2.0 mm; Non-Ferrous = 2.5 mm and 316 Stainless Steel = 2.5 mm. The checks are documented on the CCP - Metal Detector Monitoring and Verification Record. The critical limit (test piece size) = 7 mm. There-check was compliant with the Metal Detection Procedure. The auditor reviewed the Work Instructions for the Vertical Metal Detector (2.9.3-WI-003) and SP Metal Detector Monitoring (2.9.3-WI-011) for which the Machine Operators was trained on and the Metal Detection Trainung Quizes (MCC-MD-1) and the Meeting/Training Record dated 10/29/2021 for the applicable QA personnel. The auditor reviewed the CCP 1 related document (CCP - Metal Detector Monitoring and Verification Record) regarding Metal Detection and X-Ray checks for the first week of September 2021, second week of December 2021, third week of April 2022 and third week of August 2022.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.8.1 Waste Disposal

The responsibility and methods are outlined in the Waste Management & Disposal SOP. All trash from production, packaging, administration, etc. are removed at end of shift, day, or batch to a dumpster by trained personnel. There is a waste compactor for trash and a bailer for recycled secondary packaging. No areas observed with waste accumulation. Containers for waste are properly maintained and vehicles and equipment used for waste are properly cleaned. All waste/trash is removed by an outside contracted waste disposal provider and is removed weekly or on an as needed basis. Daily monitoring of the control of waste materials is performed. The site does generate inedible waste designated for animal feed that are collected and stored in white bins supplied by a 3rd party service that removes the waste when the designated service trailer is full. There are trademarked materials onsite. The auditor reviewed section 5.1 (General and Food Waste Handling) of the Waste Management & Disposal SOP regarding the controlled disposal of trademarked or sensitive packaging. The site will dispose in the compactor or use a 3rd party disposal service if a compactor is not available or sufficient and receive a Certificate of Disposal (COD).

**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

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| **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.<br><br>**RESPONSE:** NOT APPLICABLE<br><br>**EVIDENCE:** There is no waste held on-site prior to disposal. |
| **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.<br><br>**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.<br><br>**RESPONSE:** COMPLIANT |