SQF Food Safety Audit Edition 8.1
Tessemaes LLC - Tessemaes LLC

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
13770 | 101225

AUDIT RATING
93
Good

DECISION DATE
10/09/2020

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
09/28/2021

AUDIT DATES
09/09/2020 - 09/10/2020

EXPIRATION DATE
12/12/2021

ISSUE DATE
10/09/2020

Facility & Scope

Tessemaes LLC (46795)
Tessemaes LLC
8805 Kelso Drive
Baltimore City, MD 21221
United States

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

Food Sector Categories:
18. Preserved Foods Manufacture
19. Food Ingredient Manufacture

Products:
18. Preserved Food Manufacture: Salad Dressings 19. Food Ingredient Manufacture: Marinades

Scope of Certification:
18. Preserved Food Manufacture: Salad Dressings 19. Food Ingredient Manufacture: Marinades

Certification Body & Audit Team

SAI Global
680 George Street
Sydney, NSW
Australia

CB#: CB-1-SAI
Accreditation Body: JAS-ANZ
Accreditation Number: Z1440295AS

Lead Auditor: Kabir, Humayun (129404)
Technical Reviewer: Janicka, Justyna (206926)

Hours Auditing: 16
Hours Writing Report: 6

Non-Conforming

2.4.3 Food Safety Plan (Mandatory)

The facility has a documented food safety HACCP program reviewed on 08/03/2020. The food safety plan has been prepared in accordance with the steps identified in the Codex Alimentarius Commission HACCP guidelines, and based on a thorough analysis of the process, identifying each step in the process and completing a "hazard analysis" of hazards -Radiological; Biological (Salmonella, E.coli 0157H:7, Listeria, C. Botulinum); Chemical (allergen -soy, milk, egg, and tree nut); Physical- Foreign objects such as metal, wood, glass/brittle plastic) each step in the receiving, processing , packing, storage, and transport of the products. The HACCP team consists members from various departments. There is 1 HACCP plan. There is 1 CCP in HACCP plan which is maintaining product pH below 4.5 monitored by QA technician prior to release of each batch. Reviewed CCP monitoring records from randomly selected dates from 08/17/2020, 08/24/2020, 08/31/2020, and 09/02/2020. A raw product (incoming) risk analysis including allergen is included in the HACCP program. Corrective actions related to the HACCP plan include stopping production, isolation of affected product, and determination of the source of the foreign material. A preventive Control Plan is in place and is in compliant with FSMA. When asked/interviewed (QA technician) the employee was knowledgeable about the CCP.

2.4.3.6 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 use of the product.

RESPONSE: MINOR

EVIDENCE: The HACCP program is not complete and did not identify Vulnerable group in the product information.

ROOT CAUSE: Misinterpretation of the SQF requirements. Intended use was identified; however, vulnerable groups were not conisdered.

CORRECTIVE ACTION: Vulnerable groups were researched. Infants and persons susceptible to allergens were identified.

VERIFICATION OF CLOSEOUT: Reviewed the updated HACCP corrective action. Accepted and complete. Humayun Kabir

COMPLETION DATE: 09/10/2020 **CLOSEOUT DATE:** 10/07/2020

2.8.1 Allergen Management for Food Manufacturing (Mandatory)

An allergen program SOP 2.8.2 updated 06/01/2020 is in place and include instructions on how to identify, handle, label, receive, store and segregate raw materials containing allergens. Allergens present at the site are dairy, soy, eggs, coconut, and tree nut. Allergen validation for cleaning is done by using specific allergen tests. Control measures are in place for handling ingredients to prevent cross contact. During the site audit it was observed that products containing allergen were clearly labelled and stored in designated areas. Allergen validation for cleaning is done by using specific allergen tests after each batch preparation or changeover from allergen to non-allergen products. Reviewed allergen test results during changeover for randomly selected dates of 08/29/2020, 09/08/2020, and 09/09/2020. Also reviewed label for Avocado Ranch Dressing. The label comply with regulatory guidelines. A MINOR non-conformance has been cited in section 2.8.1.2 of this audit: Allergen training has been provided to all employees how to handle products containing allergen. However, observed a damaged bottle of finished product (dressing) containing allergen in the finished product cooler. There were spills on the pallet from the damaged bottle. All products on that pallet contained like/similar allergen and were sealed. There were no other product spills or possible of contamination in or around the surrounding areas of that pallet. The finished products stored in adjacent areas were also sealed and contained inside the cases. The sanitation or cleaning team did not manage the allergen spills effectively.

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 containing allergens.

RESPONSE: MINOR

EVIDENCE: Allergen training has been provided to all employees how to handle products containing allergen. However, observed a damaged bottle of finished product (dressing) containing allergen in the finished product cooler. There were spills on the pallet from the damaged bottle. All products on that pallet contained like/similar allergen and were sealed. There were no other product spills or possible of contamination in or around the surrounding areas of that pallet. The finished products stored in adjacent areas were also sealed and contained inside the cases. The sanitation or cleaning team did not manage the allergen spills effectively.

ROOT CAUSE: Warehouse overcrowding caused a pallet to be damaged.

CORRECTIVE ACTION: The damaged product should have had a Reject tag on it; however it was missed during a walkthrough. The damaged bottle/packaging was disposed of in the dumpster upon discovery.

VERIFICATION OF CLOSEOUT: Reviewed the plan of action for handling partial and damaged bags. Accepted and complete. Humayun Kabir

COMPLETION DATE: 09/09/2020 **CLOSEOUT DATE:** 10/07/2020

11.2.2 Floors, Drains, and Waste Traps

Drains are constructed and located so they can be easily cleaned and not present a hazard. Floors are constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

11.2.2.1 Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

RESPONSE: MINOR

EVIDENCE: Floors is constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned. However, observed standing water on the floor in the cooler directly under both the refrigeration units. Pallets of finished products have been stored in the standing water area. All products were contained in sealed boxes. There were no direct product contamination.

ROOT CAUSE: The cooler fan was malfunctioning due to a damaged fan blade.

CORRECTIVE ACTION: The standing water on the floor was due to the malfunctioning cooler fan. Upon discovery, the standing water was immediately cleaned up.

VERIFICATION OF CLOSEOUT: Reviewed the plan and action taken to fix cooler fan and atanding water. Accepted and complete.

COMPLETION DATE: 09/14/2020 **CLOSEOUT DATE:** 10/07/2020

11.2.10 Premises and Equipment Maintenance

The methods and responsibility for the maintenance and repair of plant, equipment and building is documented in the Maintenance program SOP 11.2.10 updated 06/24/2020. The program includes daily, weekly, monthly and less frequently maintenance schedule. The Maintenance Manager was interviewed and reviewed the maintenance program and the daily maintenance work request process. Maintenance follow food safety and hygiene practices after conducting maintenance activities. Reviewed maintenance records for July through September 2020. Upon review of records, there was evidence that all maintenance tasks have been completed as per schedule and signed off by the Maintenance Manager.

11.2.10.2 Routine maintenance of plant and equipment in any food processing, handling or storage area shall be performed according to a maintenance-control schedule and recorded. The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality.

RESPONSE: MINOR

EVIDENCE: A program is in place for routine maintenance of plant , equipment in any food processing, and handling and storage areas (coolers and freezers). During the walkthrough it was noticed that there was dripping of water/condensate from both the overhead refrigeration units in the finished product cooler. The force of the air from the units was forcing water/condensate droplets to fall over boxes (approximately up to 10 feet) from the overhead cooler units. There was evidence that some boxes were wet. All products were contained inside the box. There was no direct product contamination.

ROOT CAUSE: The cooler fan was malfunctioning due to a damaged fan blade. The door had been left open due to a damaged door pulley. Both have been repaired.

CORRECTIVE ACTION: The cooler fan was malfunctioning due to a damaged blade which allowed for increased condensation. Albright's (contracted freezer/cooler repairs) came on site 9/10/20 and repaired the fan. The door pulley was also repaired so that the door remains closed at all times.

VERIFICATION OF CLOSEOUT: Reviewed the root cause analysis and corrective action for standing water. Accepted and complete. Humayun Kabir

COMPLETION DATE: 09/14/2020 **CLOSEOUT DATE:** 10/07/2020

11.4.1 Staff Engaged in Food Handling and Processing Operations

It is the policy of the site that all personnel engaged in any food handling, preparation or processing operations ensures that products and materials are handled and stored in such a way as to prevent damage or product contamination. Sensory evaluations are performed in designated area. All wash down hoses were observed to be stored on hose racks after use and not left on the floor.

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. Packaging material, 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; v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2; vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food; and vii. Hair restraints are used where product is exposed.

RESPONSE: MINOR

EVIDENCE: Observed damaged cases (2 areas) and leaky boxes (6 areas) in the finished products storage cooler. The damaged boxes and leaky boxes have been left unattended.

ROOT CAUSE: The cooler fan was malfunctioning due to a damaged fan blade. The door had been left open due to a damaged door pulley. Both have been repaired.

CORRECTIVE ACTION: The leaking damaged cases and leaking products were missing QA Hold/Rejection tags and were not in the Hold area due to warehouse overcrowding.

VERIFICATION OF CLOSEOUT: Reviewed the action taken for the cooler fan. Accepted and complete. Humayun Kabir

COMPLETION DATE: 09/10/2020 **CLOSEOUT DATE:** 10/07/2020

11.6.2 Cold Storage, Freezing and Chilling of Foods

There are 2 coolers and one freezer. Sufficient refrigeration capacity is available to store chilled products. A minor non-conformance has been cited in section 11.6.2.3 of this audit: MONIR non-conformance has been cited in section 11.6.2.3 of this audit: Observed discharge of frost the overhead freezer unit. Frost was noticed on the pipe of freezer units, on the floor inside the room, and on the outer cases of products that have been stored under the overhead freezer unit. All products were contained inside sealed boxes. There was no direct product contamination when this observation was made.

11.6.2.3 Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.

RESPONSE: MINOR

EVIDENCE: Observed discharge of frost from the overhead freezer unit. Frost was noticed on the pipe of freezer units, on the floor inside the room, and on the outer cases of products that have been stored under the overhead freezer unit. All products were contained inside sealed boxes. There was no direct product contamination when this observation was made.

ROOT CAUSE: Frost developed on the freezer pipes and floors due to the door being left open for organization

CORRECTIVE ACTION: The frost buildup was removed all surfaces wtihin the freezer.

VERIFICATION OF CLOSEOUT: Reviewed the plan of action taken for removing damaged cases and future plan to avoid damages, and frost build-up. Accepted and complete. Humayun Kabir

COMPLETION DATE: 09/09/2020 **CLOSEOUT DATE:** 10/07/2020

11.6.8 Unloading

During receiving, it was observed that the refrigeration unit was on (for products that require refrigeration). Employee was observed to follow guidelines of checking incoming product temperature. Through record review there was evidence that receiving temperature of the refrigerated product was observed to be between 39°F - 40°F. Receiving information is documented on the receiving/unloading form.

11.6.8.1 Prior to opening the doors, the 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 commencement of unloading and at regular intervals during unloading.

RESPONSE: MINOR

EVIDENCE: A procedure is in place documented in "Transportation and Storage" updated 07/10/2020. The site's procedure states that temperature of the product during unloading should be: Fresh Products- <40 Degree F Frozen products- <26 Degree F 1. The procedure did not address that prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature to be checked and recorded which is required as per SQF code section 11.6.8.1 2. The unloading for states as follows: TEMPERATURE Ambient Y/N Refer <40F Freezer <32 F The unloading form did not match with the site's documented/established procedure. It was also noticed that the receiving person was not properly documenting if the load was ambient or not ambient.

ROOT CAUSE: The shipping and receiving team did not reiceve proper training on completing the trailer inspection sheet. The procedure didn't take into consideration all requirements.

CORRECTIVE ACTION: The procedure 11.6 Storage and Transport was revised to reflect SQF unloading requirements to state the following: 1. "Prior to opening the doors of full trailers, the seal will be checked to ensure that it's intact, if applicable. The refrigeration unit's storage temperatures and settings will be checked and recorded on the Trailer Inspection Sheet" 2. "Product will be inspected by receiving personnel or their designee during the unloading process. In the event a deficiency is identified, the QA is to be notified to determine the disposition." The Trailer Inspection Sheet was revised in order for the team to better understand the receiving and unloading requirement

VERIFICATION OF CLOSEOUT: Reviewed the action taken to train and monitor trailer inspection. Accepted and complete.

COMPLETION DATE: 09/16/2020 **CLOSEOUT DATE:** 10/07/2020

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Kristen Dittami
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** chef@tessemaes.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Kristen Dittami: VP R&D, Joseph Bero: VP Manufacturing, Matt Vetter: Chief Marketing Officer, Sarah Harmon: QA Manager, Humayun Kabir: SAI Global SQF Auditor.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** The site is located in Essex, Maryland. The processing area is 36,000 Square feet manufacturing of natural, organic certified salad dressings and marinade. The facility operates 6 days a week in one shift, Monday through Saturday and currently employs 83 employees. There are 3 main manufacturing lines. One for bottles, one for pouches, and a cup line. There is another cup line which is being tested and is not in operation yet. Products manufactured at this facility are distributed domestically in USA.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Kristen Dittami: VP R&D, Joseph Bero: VP Manufacturing, Matt Vetter: Chief Marketing Officer, Sarah Harmon: QA Manager, Humayun Kabir: SAI Global SQF Auditor.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Recommend to issue certificate after all non-conformances have been corrected and accepted.

Section Responses

2.1.1 Food Safety Policy (Mandatory)

The facility Senior management has prepared and implemented a policy statement that outlines: the organization's commitment to supply safe food; the methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; the organization's commitment to establish and review food safety and quality objectives. The policy statement has been signed the President/COO and the QA Manager dated 06/25/2020 It was found to be posted in English at the entrance and at the employee break room.

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines as a minimum the: i. The site's commitment to supply safe food; ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; and iii. The site's commitment to establish and review food safety objectives.

RESPONSE: COMPLIANT

2.1.1.2 The policy statement shall be: i. Signed by senior site management; ii. Made available in language understood by all staff; iii. Displayed in a prominent position; and iv. Effectively communicated to all staff.

RESPONSE: COMPLIANT

2.1.2 Management Responsibility (Mandatory)

The senior management has designated SQF practitioner for the site with responsibility and authority to oversee the development, implementation, review and maintenance of the SQF System. The food safety and quality manual is available to management and employees in electronically and in hard copy. It is stored in a binder located at the SQF Practitioner's office. It outlines the methods by which the organization will use to meet the requirements of the SQF Standards. The SQF practitioner is employed by the supplier as a company employee on a full-time basis, hold a position of responsibility in relation to the management of the supplier's SQF System, have completed a HACCP-based training course on 05/14/18, FSPCA training on 05/11/18 and is competent to implement and maintain HACCP-based food plans, have an understanding of the SQF Edition 8.1 and the requirements to implement and maintain SQF Systems relevant to the supplier scope of certification. The back up SQF Practitioner has obtained PCQI certification on 09/26/2016. Job descriptions for those responsible for food safety and quality have been documented and include provision to cover for the absence of key personnel. The organization chart was last updated on 08/31/2020.

2.1.2.1 The reporting structure describing those who have responsibility for food safety shall be identified and communicated within the site.

RESPONSE: COMPLIANT

2.1.2.2 The senior site management shall make provision to ensure food safety practices and all applicable requirements of the SQF System are adopted and maintained.

RESPONSE: COMPLIANT

2.1.2.3 The senior site management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System.

RESPONSE: COMPLIANT

2.1.2.4 Senior site management shall designate an SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF System, including good manufacturing practices outlined in 2.4.2, and the food safety plan outlined in 2.4.3. 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

2.1.2.5 The SQF practitioner shall: i. Be employed by the site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation 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 for Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

2.1.2.6 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 have met the required competencies to carry out those functions affecting the legality and safety of food products.

RESPONSE: COMPLIANT

2.1.2.7 Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements of the SQF Food Safety Code for Manufacturing, and are informed of their responsibility to report food safety problems to personnel with authority to initiate action.

RESPONSE: COMPLIANT

2.1.2.8 Job descriptions for those responsible for food safety shall be documented and include a provision to cover for the absence of key personnel.

RESPONSE: COMPLIANT

2.1.2.9 Senior site management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement.

RESPONSE: COMPLIANT

2.1.2.10 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

2.1.2.11 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

2.1.3 Management Review (Mandatory)

Senior management is involved in reviewing the SQF system. The last annual review was conducted on 09/03/2020. The review team included CEO, CFO, CTO, Chief Manufacturing Officer, EVP Supply Chain, Director of Finance, HR, General Council, VP Marketing, Chief Strategy Officer, EVP Sales. Upon review of records there was evidence the reviews were conducted which included results of previous audits, customer complaints, corrective actions, SQF system, Food Safety programs, pest control, receiving/shipping, finished products, HACCP, Sanitation, food defense, traceability, training, rework, improvement projects, preventive maintenance, environmental monitoring among others. As part of the monthly updates, senior site management meets 3 times a week (remotely) on matters impacting the implementation and maintenance of the SQF System. reviewed records for 08/27/2020.

2.1.3.1 The senior site management shall be responsible for reviewing the SQF System and documenting the review procedure. Reviews shall include: i. The policy manual; ii. Internal and external audit findings; iii. Corrective actions and their investigations and resolution; iv. Customer complaints and their resolution and investigation; v. Hazard and risk management system; and vi. Follow-up action items from previous management review.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3.3 Food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be reviewed and updated as needed when any potential changes implemented have an impact on the site's ability to deliver safe food.

RESPONSE: COMPLIANT

2.1.3.4 Records of all management reviews and updates shall be maintained.

RESPONSE: COMPLIANT

2.1.4 Complaint Management (Mandatory)

The facility has a documented Customer Complaint Program SOP 2.1.4, updated 06/26/2020 which outlines how complaints will be managed. As per policy records of customer complaints are received and handled by Tessemae's Customer Happiness team. Concerns or incidents are recorded on the QCQI report. The QCQI log is updated on a daily basis. Trends of customer complaint data are investigated by category, number of complaints, and analyzed by Customer Happiness Coordinator. Upon review of customer complaint records/logs from January through September 2020 there was evidence that complaints have been resolved or closed out on a timely manner. Top issue is damage during shipping (E-commerce items)

2.1.4.1	The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities, arising from products manufactured or handled on site, shall be documented and implemented. **RESPONSE:** COMPLIANT
2.1.4.2	Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents. **RESPONSE:** COMPLIANT
2.1.4.3	Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.3. **RESPONSE:** COMPLIANT
2.1.4.4	Records of customer complaints and their investigations shall be maintained. **RESPONSE:** COMPLIANT

2.1.5 Crisis Management Planning

The Crisis Management plan SOP 2.1.5 updated 05/25/2020 contains the following: the threats such as fire, flood, extended length of power failure, storm damage, pandemic, acts of terrorism among others. senior management responsibility; evidence of nomination and training of the team; controls to ensure response does not compromise product safety; measures to isolate and identify affected products; existence and maintenance of current crisis contact list; sources of legal and expert advice; and responsibility for internal and external communications. External communication is conducted by legal department. The Crisis Management plan is reviewed, tested and verified at least annually and was last tested on 08/12/2020 with a scenario of flash flooding.

2.1.5.1	A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) 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. **RESPONSE:** COMPLIANT
2.1.5.2	The crisis management plan shall include as 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 a response does 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
2.1.5.3	The crisis management plan shall be reviewed, tested and verified at least annually. **RESPONSE:** COMPLIANT
2.1.5.4	Records of reviews of the crisis management plan shall be maintained. **RESPONSE:** COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

The food safety and quality manual is available to management and employees in hard copy and electronically in a shared drive. It outlines the methods by which the organization will use to meet the requirements of the SQF Standards. The manual is made available to relevant staff and include reference to the written procedures, scope of certification, standard operating practices, work instructions, organization chart, product safety & quality plans, and other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

2.2.1.1	A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site will use to meet the requirements of the SQF Food Safety Code for Manufacturing, 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 scope of certification; iv. A list of the products covered under the scope of certification; v. Food safety procedures, pre-requisite programs, food safety plans; and vi. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System. **RESPONSE:** COMPLIANT

2.2.1.2 All changes made to food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be validated or justified.

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

The SQF practitioner has overall responsible for maintaining and managing the Document Control and Record Program 2.2.2, dated 06/26/2020. A register of current SQF System document is in place which was last updated on 06/25/2020. Amendments to document are made as needed.

2.2.2.1 The methods and responsibility for maintaining document control and ensuring staff have access to current documents shall be documented and implemented.

RESPONSE: COMPLIANT

2.2.2.2 A register of current SQF System documents and amendments to documents shall be maintained.

RESPONSE: COMPLIANT

2.2.2.3 Documents shall be safely stored and readily accessible.

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

Any employee with HACCP training is responsible for inspecting, monitoring and recording HACCP related activities. QA is responsible for Quality related records. Production Supervisor is responsible for verification production documents. Record retention is a minimum of 5 years. Records are stored electronically and as well as in hard copy. Methods and responsibilities are well documented in the program. Records were randomly chosen dated 08/17/2020, 08/31/2020, 09/02/2020 for review during the audit. Records reviewed include the following: Pre-operation checklist; CCP; environmental monitoring program including (ATP, Salmonella, Listeria, APC, yeast/Mold) monitoring test results; equipment (scale) calibration; manufacturing orders; line clearance/start-up checklist; allergen clean-up varication; processing batch records; QA batch release records, internal audits; receiving & shipping truck inspection reports; COAs; maintenance activities; list of approved vendors; daily, monthly and less frequent cleaning schedules & checklists. All records were found to be legible, and verified by appropriate personnel.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.3.3 Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations.

RESPONSE: COMPLIANT

2.3.1 Product Development and Realization

Methods and responsibilities for product development policy 2.3.1 revised 08/08/19 is in place. Product development is initiated by customers, sales team, and internal innovation group. Tessemae's Product Development and Realization team consists of VP of R&D, the Marketing team, and the Quality team. The team collects all documentation and paperwork including: manufacturing process; nutritional information; source of raw ingredients; required capital investment; distribution and warehousing; finished product specification; shelf life study & process study (done by third party); protocol for plant trial, and final production. There are several phases of development: Phase 1- Investigation project charter; Phase 2.2- Feasibility R&D; Phase 2.2- Feasibility COGS; Phase 2.3- Manufacturing feasibility; Phase 3.1- Development hard materials; Phase 3.2- Development manufacturing; Phase 3.3- Scale up and compliance; Phase 3.4- Development label; Phase 3.1- Pilot/launch plan; Phase 4.2- Pilot launch marketing; Phase 5- Manufacturing; and Phase 6-Analytics. There have been 5 new product developed in the year 2020 (from January- September 2020).

2.3.1.1 The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.1.2	Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by site trials, shelf life trials and product testing. **RESPONSE:** COMPLIANT
2.3.1.3	Shelf life trials where necessary shall be conducted to establish and validate a product's: i. Handling and storage requirements including the establishment of "use by" or "best before dates"; ii. Microbiological criteria; and iii. Consumer preparation, storage and handling requirements. **RESPONSE:** COMPLIANT
2.3.1.4	A food safety plan shall be validated and verified for each new product and its associated process through conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food safety. **RESPONSE:** COMPLIANT
2.3.1.5	Records of all product design, process development, shelf life trials and approvals shall be maintained. **RESPONSE:** COMPLIANT

2.3.2 Raw and Packaging Materials

Ingredients are chosen by the Product Development and Realization team as per customer's need, and if they work the technical information sheet or specification of that item becomes the specification for the raw ingredient. EVP of R&D department of the company have overall responsibility for maintaining and monitoring of the specification. A register of all raw product and packaging specification that impact finished product is available in the company server. There was evidence during review of raw ingredient specifications for Garlic oil and packaging materials (pouch film) that meet regulatory standards. Letters of guarantee, or COA, or/and a letter of conformity was in place stating that all raw and packaging materials comply with relevant legislation. Bottles comply with 21 CFR 176.170 (c), and films comply with 21 CFR 1520 (c).

2.3.2.1	Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety shall be documented and kept current. **RESPONSE:** COMPLIANT
2.3.2.2	All raw and packaging materials and ingredients shall comply with the relevant legislation in the country of manufacture and country of destination, if known. **RESPONSE:** COMPLIANT
2.3.2.3	The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented. **RESPONSE:** COMPLIANT
2.3.2.4	Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, certificate of analysis, or sampling and testing. **RESPONSE:** COMPLIANT
2.3.2.5	Verification of packaging materials shall include: i. Certification that 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. ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained. **RESPONSE:** COMPLIANT
2.3.2.6	Finished product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel. **RESPONSE:** COMPLIANT
2.3.2.7	A register of raw and packaging material specifications and labels shall be maintained and kept current. **RESPONSE:** COMPLIANT

2.3.3 Contract Service Providers

Specifications for contract services that have an impact on finished product safety and quality is documented in SOP 2.3.3 updated 07/24/2020 which includes a full description of the service to be provided and detail relevant training requirements of contract personnel for all contract service providers.

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

RESPONSE: COMPLIANT

2.3.3.2 A register of all contract service specifications shall be maintained.

RESPONSE: COMPLIANT

2.3.4 Contract Manufacturers

The site has 3 contract manufacturer/co-packers. All contract manufacturer/co-packers are grandfathered as of this certification. However the contract manufacturer are required to provide as a minimum: copy of third party audits, liability of insurance; and letter of product guarantee. Upon review of records, there was evidence that: Co-packer "A" is Primus certified and valid through 09/30/2020; "B" is SQF Certified valid through/29/2020, "C" is SQF certified and valid through 02/12/2021 and "D" is BRC certified and valid till 121/7/2020. The SQF Practitioner also conducts audit of the manufacturing sites.

2.3.4.1 The methods and responsibility for ensuring all agreements relating to food safety and customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.4.2 The site shall: i. Verify compliance with the SQF Food Safety Code for Manufacturing and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the site or other third-party agency to confirm compliance to the SQF Food Safety Code for Manufacturing and agreed arrangements; and ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

RESPONSE: COMPLIANT

2.3.4.3 Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.

RESPONSE: COMPLIANT

2.3.5 Finished Product Specifications

There are in place finished product specifications documented in SOP 2.3.5, revised 06/26/2020 which include: sample labels, chemical, physical, nutritional information, shelf life, and packaging requirements. Reviewed finished product specification for Lemon Pepper dressing and Lemon Garlic dressing during the audit which contains information such as: blending; packaging material; lot number; quality parameters; nutritional labelling; and shipping criteria.

2.3.5.1 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include: i. Microbiological and chemical limits; and ii. Labeling and packaging requirements.

RESPONSE: COMPLIANT

2.3.5.2 A register of finished product specifications shall be maintained.

RESPONSE: COMPLIANT

2.4.1 Food Legislation (Mandatory)

Methods and responsibilities are in place documented in SOP 2.4.1, revised 06/03/2020 to ensure that the organization is kept informed of changes to relevant legislation, scientific and technical developments and relevant industry codes of practices. The VP of R&D, SVP Supply Chain, and SQF Practitioner are responsible for obtaining and maintaining all required updates. The site ensures that products and packaging materials comply with FDA, Organic, Kosher, Gluten Free, Health Department (last audited in October 2019), and all relevant legislative agencies. The site is in compliant with FSMA requirement.

2.4.1.1 The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of use or 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 in the event of a regulatory warning. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

The facility has in place all pre-requisite programs as required by SQF Code Edition 8.1. Pre-requisites include : personnel practices; personnel processing practices; employee training; equipment calibration; pest control; plant & equipment maintenance; cleaning and sanitation; water monitoring; control of physical contaminant; approved suppliers; and waste management & disposal among others. There was evidence, through records review, inspection, and employee interviews, that the pre-requisite programs have been implemented.

2.4.2.1 The site shall ensure the Good Manufacturing Practices described in modules 3, 4, 9, 10 or 11 (as applicable) 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 to ensure that food safety is not compromised.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

The facility has a documented food safety HACCP program reviewed on 08/03/2020. The food safety plan has been prepared in accordance with the steps identified in the Codex Alimentarius Commission HACCP guidelines, and based on a thorough analysis of the process, identifying each step in the process and completing a "hazard analysis" of hazards -Radiological; Biological (Salmonella, E.coli 0157H:7, Listeria, C. Botulinum); Chemical (allergen -soy, milk, egg, and tree nut); Physical- Foreign objects such as metal, wood, glass/brittle plastic) each step in the receiving, processing , packing, storage, and transport of the products. The HACCP team consists members from various departments. There is 1 HACCP plan. There is 1 CCP in HACCP plan which is maintaining product pH below 4.5 monitored by QA technician prior to release of each batch. Reviewed CCP monitoring records from randomly selected dates from 08/17/2020, 08/24/2020, 08/31/2020, and 09/02/2020. A raw product (incoming) risk analysis including allergen is included in the HACCP program. Corrective actions related to the HACCP plan include stopping production, isolation of affected product, and determination of the source of the foreign material. A preventive Control Plan is in place and is in compliant with FSMA. When asked/interviewed (QA technician) the employee was knowledgeable about the CCP.

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. Feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

RESPONSE: COMPLIANT

2.4.3.2 The food safety plan shall be effectively implemented, maintained and outline the means by which the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

RESPONSE: COMPLIANT

2.4.3.3 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 products and associated processes. Where the relevant expertise is not available on site, advice may be obtained from other sources to assist the food safety team.

RESPONSE: COMPLIANT

2.4.3.4	The scope of each food safety plan shall be developed and documented including the start and end-point of the processes under consideration and all relevant inputs and outputs. **RESPONSE:** COMPLIANT
2.4.3.5	Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.5.1) plus any additional information relevant to product safety, such as pH, water activity, and/or composition. **RESPONSE:** COMPLIANT
2.4.3.6	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 use of the product. **RESPONSE:** MINOR **EVIDENCE:** The HACCP program is not complete and did not identify Vulnerable group in the product information. **ROOT CAUSE:** Misinterpretation of the SQF requirements. Intended use was identified; however, vulnerable groups were not conisdered. **CORRECTIVE ACTION:** Vulnerable groups were researched. Infants and persons susceptible to allergens were identified. **VERIFICATION OF CLOSEOUT:** Reviewed the updated HACCP corrective action. Accepted and complete. Humayun Kabir **COMPLETION DATE:** 09/10/2020 **CLOSEOUT DATE:** 10/07/2020
2.4.3.7	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 material, packaging material, service inputs (e.g. water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation. **RESPONSE:** COMPLIANT
2.4.3.8	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs. **RESPONSE:** COMPLIANT
2.4.3.9	The food safety team shall conduct a hazard analysis for every identified hazard to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT
2.4.3.10	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure. **RESPONSE:** COMPLIANT
2.4.3.11	Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e. a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure. **RESPONSE:** COMPLIANT
2.4.3.12	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard (s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1). **RESPONSE:** COMPLIANT
2.4.3.13	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.15 The documented and approved food safety plan (s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs or other changes affecting product safety occur.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4 Approved Supplier Program (Mandatory)

The receipt of raw materials, ingredients, and packaging materials received from approved and non-approved supplier is documented in Incoming Goods and Services (Supplier Approval & Monitoring Program) 2.4.4 dated 06/04/2020. As per company policy, all suppliers are approved based on one or a combination of the following: a supplier questionnaire; third party audit; GFSI certification (if available). Register of approved supplier and records of inspections and audits of approved suppliers are maintained. Upon review of records during trace and mock recall exercise as described in section 2.6.2 and 2.6.3, there was evidence that suppliers comply with the required SOP as set by the site. The list of approved supplier is reviewed and updated on a weekly basis. Detail information about food defense and food fraud has been explained in section 2.7.1 and 2.7.4 of this audit.

2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification (refer to 2.3.2) and be supplied by an approved supplier.

RESPONSE: COMPLIANT

2.4.4.2 The receipt of raw materials, ingredients, and packaging materials received from non-approved suppliers shall be acceptable only in an emergency situation, and provided they are inspected or analyzed before use.

RESPONSE: COMPLIANT

2.4.4.3 The responsibility and procedure for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.4.4 The site's food defense plan (refer to 2.7.1.1) shall include measures to secure incoming materials and ingredients and protect them from deliberate act of sabotage or terrorist-like incidents.

RESPONSE: COMPLIANT

2.4.4.5 The site's food fraud vulnerability assessment (refer to 2.7.2.1) shall include the site's susceptibility to raw material or ingredient substitution, mislabeling, dilution or counterfeiting which may adversely impact food safety.

RESPONSE: COMPLIANT

2.4.4.6 The food fraud mitigation plan (refer to 2.7.2.2) shall include methods by which the identified food safety vulnerabilities from ingredients and materials shall be controlled.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4.8 The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw materials ingredients, packaging materials, and services supplied, and shall contain as a minimum: i. Agreed specifications (refer to 2.3.2); ii. Reference to the rating of the level of risk applied to a raw material, ingredients, packaging materials and services and 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

2.4.4.9 Supplier audits shall be based on risk and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

RESPONSE: COMPLIANT

2.4.4.10 A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Product or Equipment

The responsibility and methods outlining how non-conforming product, raw material, ingredients and equipment is documented in SOP 2.4.5 dated 06/03/2020. Product is placed on hold by QA, and can only be released or disposed after receiving proper instruction from QA and or the SQF practitioner. Equipment is tagged for non-use and released by the SQF Practitioner after verifying proper repair and sanitation. Reviewed hold log during the audit. Upon review of records from January 2020 through September 2020, there was evidence that disposition of the products are done as soon as possible. Every attempt is made for the disposition of the product in less than a week. Review of hold log showed there were 6 items still on hold from July 2020. The site is waiting to make a final disposition after getting an approval from the customers.

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

RESPONSE: COMPLIANT

2.4.5.2 Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.

RESPONSE: COMPLIANT

2.4.6 Product Rework

No rework is done at this site

2.4.6.1 The responsibility and methods outlining how ingredients, packaging materials, or products are reworked shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are supervised by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Each batch of reworked product is inspected or analyzed as required before release; iv. Inspections and analyses shall conform to the requirements outlined in element 2.5.4.1; and v. Release of reworked product shall conform to element 2.4.7.

RESPONSE: NOT APPLICABLE

EVIDENCE: No rework is done at this site

2.4.6.2 Records of all reworking operations shall be maintained.

RESPONSE: NOT APPLICABLE

EVIDENCE: No rework is done at this site

2.4.7 Product Release (Mandatory)

It is the responsibility of the production department and the QC department to ensure that traceability is maintained during blending, mixing, and packing with supervision and guidance offered by the SQF Practitioner. Positive release is not required for all items for the products produced at this site. Products may be released only after all production criteria and corrections have been made, the product has been inspected or analyzed to verify that legislative and food safety controls have been met, and sensory analysis and evaluations have been completed. The finished products are signed off by QA, production supervisor, and warehouse supervisor. Through review of paperwork from selected dates of 08/17/2020, 08/24/2020, 08/31/2020, and 09/04/2020. of this audit, there is evidence that product is being tested as required, and released by authorized personnel.

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: i. By authorized personnel; and ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release shall be maintained.

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

An environmental monitoring program is in place document number 2.4.8 updated 05/27/2020. The program includes corrective actions implemented where unsatisfactory trends are observed. The environmental sampling and testing schedule has been prepared, detailing the applicable pathogens or indicator organisms, to test the number of samples to be taken, and the frequency of sampling. The site has divided the plant in 4 zones. Zone 1 is product contact surfaces. Minimum of 5 sites are tested per month for APC, Yeast, Mold, and E.coli from zone 1. Zone 2 is for non product contact surfaces close to zone 1. Minimum 2 samples are tested for Salmonella and Listeria on a monthly basis from zone 2. Zone 3 is non-food contact surfaces away from production area. Minimum 1 samples is tested monthly for Salmonella and Listeria from zone 3. Zone 4 is general areas of the plant and further away from production area. Minimum 1 sample is tested for Salmonella and Listeria on a monthly basis forms this zone. Upon review of records from January 2020 through September 2020 it was noted that there was one suspect for Listeria tested on 08/27/2020 (crack on the floor in one of the packing lines). The area was vectored and cleaned and tested on 09/01/2020. One of the results came as suspect from 09.01/2020. The site re-tested on 09/2/2020 and 09/03/2020. Both tests came negative. The site has sent out the third consecutive re-test again and waiting for results. The crack on the floor has been fixed. The site is going through some renovation. There is not used at this time.

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food and pet food manufacturing processes.

RESPONSE: COMPLIANT

2.4.8.2 The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.8.3 An environmental sampling and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.

RESPONSE: COMPLIANT

2.4.8.4 Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

The methods, responsibility and criteria for ensuring the effectiveness of pre-requisite programs, and validating critical food safety limits to ensure they achieve their intended purpose are documented and implemented. Validation is provided for the CCP at the facility based on FDA Guidelines and Industry Best Practices. CCP validation for pH was done by third party (Process Authority). Validation of product is performed through review of shelf life of finished products. There have been no unsatisfactory results of shelf life tests during the last 12 months period.

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 ensure that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required result; ii. Critical food safety limits are validated, and re-validated annually; iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and iv. All applicable elements of the SQF Program are implemented and effective.

RESPONSE: COMPLIANT

2.5.1.2 Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

Frequency and methods used to validate and verify pre-requisite programs are defined in procedure 2.5.2 dated 08/08/2019. A verification and validation matrix work sheet is maintained for all prerequisite programs with the title, purpose, verification and validation points and frequencies. Verification and validation procedures are primarily based upon internal audits. Reviewed verification records from randomly selected dates from 08/31/2020, 08/24/2020, and 09/04/2020. Records shows that verifications and validations were done as follows: Crisis management (annually) done on 08/12/2020; Proficiency testing (annually) on 08/12/2020; training annually 09/03/2020; calibration of equipment verification are done daily and validation done annually (done on 08/31/2020); Pest control- weekly and monthly; Water testing annually- last done on 07/28/2020, mock recall annually among others.

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

RESPONSE: COMPLIANT

2.5.2.2 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

2.5.2.3 Records of the verification of monitoring activities shall be maintained.

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

The responsibility and methods outlining how corrections and preventive actions are investigated (CAPA), resolved, managed and controlled, including the identification of the root cause and resolution of non-compliance of critical food safety limits is documented in SOP 2.5.3 dated 06/20/2020 and implemented. QA, Production, Maintenance, Sanitation, and Customer Happiness, and the internal auditing team have overall responsibility for monitoring this program. However it is the responsibility of the SQF Practitioner to manage and initiate corrective actions, root cause analysis, and corrections. Reviewed records of CAPA from January through September 2020. A running list is maintained applicable to different areas. Upon review of records there was evidence that all deficiencies are identified, and corrected and or closed on a timely manner.

2.5.3.1 The responsibility and methods outlining how corrections and corrective 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.

RESPONSE: COMPLIANT

2.5.3.2 Records of all investigation and resolution of non-conformities including their corrections and corrective action shall be maintained.

RESPONSE: COMPLIANT

2.5.4 Product Sampling, Inspection and Analysis

The method, responsibility and criteria for sampling, inspecting and/or analysing raw material, finished product and work in progress is documented in SOP 2.5.4 dated 06/03/2020. Employees are responsible for producing high quality products. Sampling is done as follows: Incoming raw materials are visually inspected to assure acceptable condition, COA, temperature on refrigerated and frozen ingredients. Finished products: pH, viscosity, volumetric monitoring, and organoleptic analysis. Equipment used to produce allergenic products is inspected with an allergen swab to verify absence of allergen. Reviewed allergen validation records during changeover for 08/29/2020, 09/08/2020, and 09/09/2020. Environmental: Listeria, Salmonella, E.coli is tested under environmental monitoring testing program. Total Plate count and Yeast/Mold is tested for food contact surfaces by an ISO 17025 certified contracted laboratory as per program. More detail information is documented under individual programs. Reviewed records from selected dates from 08/24/2020, 08/31/2020, and 09/04/2020.

2.5.4.1 The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work-in-progress shall be documented and implemented. The methods applied shall ensure: i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements; ii. Inspections are conducted to ensure raw materials, work in process and finished products comply with the relevant specification, regulatory requirements and are true to label; and iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods.

RESPONSE: COMPLIANT

2.5.4.2 On-site personnel that conduct environmental or product testing shall participate in an applicable proficiency testing program at least annually to ensure accuracy of results.

RESPONSE: COMPLIANT

2.5.4.3 Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard and shall be included on the site's contract service specifications register (refer to 2.3.3.1).

RESPONSE: COMPLIANT

2.5.4.4 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.5.5 Internal Audits and Inspections (Mandatory)

The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System including facility and equipment inspections, pre-requisite programs, food safety plans and legislative controls are documented and implemented. Internal audits are conducted on a quarterly basis covering various elements of the SQF code as per matrix. There was evidence from training records that staff conducting on internal audit has been trained in internal audit procedures and are independent of functions being audit. Internal audits are conducted quarterly which covers various elements of the SQF code. The objective is to cove all elements at least once per year. A schedule is followed. Records showed that Internal audit for cleaning and sanitation was conducted on 05/11/2020 and pest control was conducted on 06/02/2020. There was one finding in both of those internal audit. All finding were corrected and closed out. The site also conducts internal audit of the facility (interior and exterior) once per month. A score is given. The most recent monthly audit was conducted on 08/08/2020. Records sowed that the findings have been closed out as per due date.

2.5.5.1 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 at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code for Manufacturing are audited as per the SQF audit checklist or similar tool; ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken; and iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions.

RESPONSE: COMPLIANT

2.5.5.2 Staff conducting internal audits shall be trained and competent in internal audit procedures.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.5.4	Where practical staff conducting internal audits shall be independent of the function being audited. **RESPONSE:** COMPLIANT
2.5.5.5	Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained. **RESPONSE:** COMPLIANT

2.6.1 Product Identification (Mandatory)

A program for product identification document number 2.6.1, dated 06/26/2020 is in place. All products and packaging received are kept in their original bags or boxes. The manufacturer lot number is recorded on the incoming receiving log. During batch preparation and packaging stages, employees (batching team) identify and document the product currently being produced and batch records filled out. Those records are then entered in the ERP system for traceability purpose. QA or line Lead person will also verify the batch before the final release for production. The facility identifies all finished products by assigning a Best by Date. The finished product lot code identifies product, packaging used, pack size, and expiry date. Receiving/warehouse personnel, production supervisor, and QA are responsible for managing the program. Reviewed production records, batch preparation records, and QA release records for selected dates of 08/24/2020, 08/31/2020, and 09/04/2020 as stated in section 2.2.2 of this audit.

2.6.1.1	The methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in -progress, process inputs and finished products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure: i. Raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are clearly identified during all stages of receipt, production, storage and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements. **RESPONSE:** COMPLIANT
2.6.1.2	Product identification records shall be maintained. **RESPONSE:** COMPLIANT
2.6.1.3	Product start up and changeover procedures during packing 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. **RESPONSE:** COMPLIANT

2.6.2 Product Trace (Mandatory)

The responsibility and methods used to trace product is documented in SOP 2.6.2.3 dated 06/30/2020 and implemented to ensure finished product is traceable to the customer (one up) and provides traceability through the process to the supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back). A trace exercise was conducted by the site on 07/01/2020 for ingredient Jalapeno Pepper Sauce with lot number B72222020. 336 pounds were received on 03/19/20. 53.5 pound was used on 07/01/2020. The balance was still in inventory. 99.5% recovery was achieved in less than 2 hours. A trace exercise was conducted on the first day of audit. Raw material Garlic Oil with lot number 1007840 was used during this exercise. 3 shipments of products (total 198 pounds) were received under PO number 6486, 6566, and 6567 received on 03/30/3030, 04/30/2020, and 05/19/2020. Products were used in 117 different batches. 190 pounds was used in making those 117 batches, 7 pounds of product went to R&D department and 1 pound was not accounted. 99.5% recovery was achieved in less than 2 hours. Reviewed receiving production batch records and QA monitoring records.

2.6.2.1	The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable to the customer (one up) and provides traceability through the process to the manufacturing supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back); ii. Traceability is maintained where product is reworked; and iii. The effectiveness of the product trace system shall be reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.3). **RESPONSE:** COMPLIANT
2.6.2.2	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)

A recall/withdrawal system is in place documented in SOP dated 06/30/2020. The procedure identify those responsible for initiating, managing and investigating a product withdrawal or recall; describe the management procedures to be implemented including sources of legal and expert advice; and outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner; notify SQFI and the certification body in instances of a food safety incident of a public nature or product recall for any reason. A mock recall exercise was conducted by the site on 07/01/2020. Finished product with lot PBRN was used during the exercise. 320 cases were made on 06/16/2020. 150 cases have been shipped and balance 170 cases were still in inventory. 95% recovery was achieved in less than 2 hours. Reviewed production batch records and shipping records. At the request of the auditor, a mock recall exercise was conducted on the first day of audit. Product with lot number OLG 1017 AUG 21 was selected during this exercise. 6265 units were made on August 17, 2020. 6264 units were shipped between 08/20/20 through 09/04/2020. 1 case was sent to e-commerce. 100% recovery was achieved in less than 2 hours. Reviewed inventory records, production batch records, and shipping records.

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; and iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; iv. SQFI, the certification body, and the appropriate regulatory authority shall be listed as an essential body 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 Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.

RESPONSE: COMPLIANT

2.6.3.3 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually. Testing shall include incoming materials (one back) and finished product (one up).

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

2.6.3.5 Records of all product withdrawals, recalls and mock recalls shall be maintained.

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident is documented in SOP 2.7.1 updated 07/06/2020. SVO Supply Chain, Production Supervisor, HACCP team are responsible for managing site security and food defense. Food security checks are performed as part of the monthly internal audits. A food defense protocol include: the method to control of raw and packaging material from approved vendor, the name of the senior management person responsible for food defense; the methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing and storage areas through designated access points; the methods implemented to protect sensitive processing points from intentional adulteration; the measures taken to ensure the secure storage of raw materials, packaging, equipment and hazardous chemicals; the measures implemented to ensure finished product is held under secure storage and transportation conditions; and the methods implemented to record and control access to the premises by employees, contractors, and visitors. The site is located in Essex, MD. The following observation was made during the audit: All doors were observed to be secured; the front door entry is controlled by security key; employee must enter using key fab; 24 hours monitoring and recording by security camera; and off hour security system monitored by a third party service provider. An annual food defense assessment was done by the site on 08/31/2020. The food defense plan was challenged on 08/28/2020.

2.7.1.1 The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained.

RESPONSE: COMPLIANT

2.7.1.2 A food defense plan shall include: i. The name of the senior site management person responsible for food defense; ii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing and storage areas through designated access points; iii. The methods implemented to protect sensitive processing points from intentional adulteration; iv. The measures taken to ensure the secure receipt and storage of raw materials, packaging, equipment and hazardous chemicals; v. The measures implemented to ensure raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are held under secure storage and transportation conditions; and vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.

RESPONSE: COMPLIANT

2.7.1.3 The food defense plan shall be reviewed and challenged at least annually.

RESPONSE: COMPLIANT

2.7.1.4 Records of reviews of the food defense plan shall be maintained.

RESPONSE: COMPLIANT

2.7.2 Food Fraud

A food fraud program is in place. The site divided the products into several categories such as: oil; vinegar; spices; cold ingredients; and shelf stable ingredients. The risk assessment includes historic incidents, emerging concerns, price fluctuation, trading properties, geographical origin, direct sourcing, complexity of supply chain, ease of access to raw material, price, size of market, form of ingredient, seasonal availability, special criteria, availability of adulterants, complexity, score, and likelihood of occurrence. Consequences include: characterizing ingredients, standard for consumption, micro ingredients, company of origin, regional provenance, allergen, valuable population, focused consumption, nutritional information, other special interests, price, other common concern, and consequences of severity such as -likelihood, fairly likely, significant consequences, and high potential. Mitigation include verify suppliers, train and require staff to inspect ingredients quality, train staff regarding standards and expectations of quality in processing, and train staff in upholding food fraud plan. The food fraud vulnerability assessment and mitigation plan was last reviewed on 06/30/2020.

2.7.2.1 The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.

RESPONSE: COMPLIANT

2.7.2.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.

RESPONSE: COMPLIANT

2.7.2.3 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.

RESPONSE: COMPLIANT

2.7.2.4 Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.

RESPONSE: COMPLIANT

2.8.1 Allergen Management for Food Manufacturing (Mandatory)

An allergen program SOP 2.8.2 updated 06/01/2020 is in place and include instructions on how to identify, handle, label, receive, store and segregate raw materials containing allergens. Allergens present at the site are dairy, soy, eggs, coconut, and tree nut. Allergen validation for cleaning is done by using specific allergen tests. Control measures are in place for handling ingredients to prevent cross contact. During the site audit it was observed that products containing allergen were clearly labelled and stored in designated areas. Allergen validation for cleaning is done by using specific allergen tests after each batch preparation or changeover from allergen to non-allergen products. Reviewed allergen test results during changeover for randomly selected dates of 08/29/2020, 09/08/2020, and 09/09/2020. Also reviewed label for Avocado Ranch Dressing. The label comply with regulatory guidelines. A MINOR non-conformance has been cited in section 2.8.1.2 of this audit: Allergen training has been provided to all employees how to handle products containing allergen. However, observed a damaged bottle of finished product (dressing) containing allergen in the finished product cooler. There were spills on the pallet from the damaged bottle. All products on that pallet contained like/similar allergen and were sealed. There were no other product spills or possible of contamination in or around the surrounding areas of that pallet. The finished products stored in adjacent areas were also sealed and contained inside the cases. The sanitation or cleaning team did not manage the allergen spills effectively.

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 from locker rooms, vending machines, lunch-rooms, and visitors; iii. A register of allergens which is applicable in the country of manufacture and the country (ies) of destination if known; iv. A list of allergens which is accessible by relevant staff. v. The hazards associated with allergens and their control incorporated into the food safety plan. vi. A management plan for control of identified allergens. The allergen management program shall include the identification, management, and labelling of products containing gluten, where applicable. **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 containing allergens. **RESPONSE:** MINOR **EVIDENCE:** Allergen training has been provided to all employees how to handle products containing allergen. However, observed a damaged bottle of finished product (dressing) containing allergen in the finished product cooler. There were spills on the pallet from the damaged bottle. All products on that pallet contained like/similar allergen and were sealed. There were no other product spills or possible of contamination in or around the surrounding areas of that pallet. The finished products stored in adjacent areas were also sealed and contained inside the cases. The sanitation or cleaning team did not manage the allergen spills effectively. **ROOT CAUSE:** Warehouse overcrowding caused a pallet to be damaged. **CORRECTIVE ACTION:** The damaged product should have had a Reject tag on it; however it was missed during a walkthrough. The damaged bottle/packaging was disposed of in the dumpster upon discovery. **VERIFICATION OF CLOSEOUT:** Reviewed the plan of action for handling partial and damaged bags. Accepted and complete. Humayun Kabir **COMPLETION DATE:** 09/09/2020 **CLOSEOUT DATE:** 10/07/2020
2.8.1.3	Provision 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 is 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 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 shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured. **RESPONSE:** COMPLIANT
2.8.1.8	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 is true to label with regard to allergens. Such 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
2.8.1.9	The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used. **RESPONSE:** COMPLIANT

2.8.1.10 Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable.

RESPONSE: COMPLIANT

EVIDENCE: No rework is done.

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 introducing unintended allergens through supplier, contract manufacturer, employee and visitor activities.

RESPONSE: COMPLIANT

EVIDENCE: An allergen program is in place.

2.8.2 Allergen Management for Pet Food Manufacturing

The site does not manufacture pet food and none of the products from this site is used in pet food manufacturing.

2.8.2.1 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 inputs and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A list of allergens which is accessible by relevant staff; and iv. The hazards associated with allergens and their control incorporated into the food safety plan.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture pet food and none of the products from this site is used in pet food manufacturing.

2.8.2.2 Product labeling, in accordance with regulatory requirements, shall include allergens where risks from cross-contact have been identified.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture pet food and none of the products from this site is used in pet food manufacturing.

2.8.3 Allergen Management for Manufacturers of Animal Feed

The site does not manufacture animal feed.

2.8.3.1 Sites that exclusively manufacture animal feed and do not manufacture, handle or store food or pet food products are not required to implement an allergen management plan unless required by regulation or customer requirement.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture animal feed.

2.8.3.2 Where an allergen management plan is required by regulation or customer specification, the requirements of 2.8.2 shall apply.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture animal feed.

2.9.1 Training Requirements

Appropriate training is provided is documented in company's various training modules for personnel carrying out the tasks critical to the effective implementation of the SQF Edition 8.1 and the maintenance of food safety and regulatory requirements. An employee training register/tracker is in place. The training includes: GMPs, HACCP (relevant employees), food defense, pest control, and allergen among others.

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.

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)

All employees receive training upon hire on GMP, HACCP, Food Safety, CCP (as appropriate), effective implementation of SQF System, regulatory requirements, and job related task. Reviewed site's training matrix/schedule and was observed to be current as outlines. Employees interviewed (receiving and line personnel) were knowledgeable about their specific tasks.

2.9.2.1 An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Developing and applying Good Manufacturing Practices; ii. Applying food regulatory requirements; iii. Steps identified by the hazard analysis and/or other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety; and iv. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.9.3 Instructions

There are in place specific work instructions available on all tasks critical to HACCP, product quality, meeting customer specifications, regulatory compliance, and other requirements. Work instructions are stored electronically. Hard copies are also available for all work instructions.

2.9.3.1 Instructions shall be available in the languages relevant to the staff, explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety, and process efficiency are to be performed.

RESPONSE: COMPLIANT

2.9.4 HACCP Training Requirements

There was evidence that HACCP training have been provided to all relevant staff involved in HACCP monitoring. 3 management personnel received HACCP training from outside training institutes. There was evidence that the most recent training on HACCP for employees was conducted on 08/19/2020. The are 4 management personnel who have received HACCP training from outside consultant.

2.9.4.1 HACCP training shall be provided for staff involved in developing and maintaining food safety plans.

RESPONSE: COMPLIANT

2.9.5 Language

All training and training materials are provided in English which is understood by all employees. Bi-lingual English/Spanish translators are available for individual who does not speak English.

2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.

RESPONSE: COMPLIANT

2.9.6 Refresher Training

All employees receive training on Food Safety, GMP, and work related tasks upon hire. Refresher training is provided thereafter annually. Reviewed training records/matrix from January through September 2020. All training records were current and followed as per schedule. The last refresher training on GMP was performed on 08/05/2020 and Allergen training on 09/03/2020.

2.9.6.1 The training program shall include provision for identifying and implementing the refresher training needs of the organization.

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

A training register is in place describing who has been trained in relevant skills. The register includes the participant name, skills description, description of the training provided, date training completed, the trainer or training provider, the supervisor's verification and a quiz that the training was completed, and that the trainee is competent to complete the required tasks. Upon review of training and quiz there was evidence that all training have been completed as per schedule.

2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Supervisor's verification that the training was completed, and that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

Through inspection, it was observed that the adjacent and adjoining buildings, operations and land use do not interfere with the safe and hygienic operation. Facility complex location poses no hygienic or food safety risk. Building is in compliance with the local regulatory authority. There are in place current operating permits from Maryland Department of Health and Mental Hygiene and is current. The FDA Bioterrorism registration is current and expires on 12/31/2020. The Organic Certification expires on 07/07/2020. The Kosher certificate expires on 05/25/2021.

11.1.1.1 The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations.

RESPONSE: COMPLIANT

11.1.1.2 The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

11.2.1 Materials and Surfaces

Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage and cold storage areas, and freezer are constructed of appropriate and does not pose any food safety risk.

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

RESPONSE: COMPLIANT

11.2.2 Floors, Drains, and Waste Traps

Drains are constructed and located so they can be easily cleaned and not present a hazard. Floors are constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

11.2.2.1 Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

RESPONSE: MINOR

EVIDENCE: Floors is constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned. However, observed standing water on the floor in the cooler directly under both the refrigeration units. Pallets of finished products have been stored in the standing water area. All products were contained in sealed boxes. There were no direct product contamination.

ROOT CAUSE: The cooler fan was malfunctioning due to a damaged fan blade.

CORRECTIVE ACTION: The standing water on the floor was due to the malfunctioning cooler fan. Upon discovery, the standing water was immediately cleaned up.

VERIFICATION OF CLOSEOUT: Reviewed the plan and action taken to fix cooler fan and atanding water. Accepted and complete.

COMPLETION DATE: 09/14/2020 **CLOSEOUT DATE:** 10/07/2020

11.2.2.2 Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.2.4 Waste trap system shall be located away from any food handling area or entrance to the premises.

RESPONSE: COMPLIANT

11.2.3 Walls, Partitions, Doors and Ceilings

It was observed that the walls, partitions, ceilings and doors in all preparation, processing packing and storage areas were of durable construction, and kept clean. Drop ceilings over pre-processing and packing room are constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.

11.2.3.1 Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light-colored finish and shall be kept clean (refer to 11.2.13.1).

RESPONSE: COMPLIANT

11.2.3.2 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

11.2.3.3 Ducting, conduit and pipes that convey 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.

RESPONSE: COMPLIANT

11.2.3.4 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.

RESPONSE: COMPLIANT

11.2.3.5 Doors, hatches and windows and their frames in food processing, handing or storage areas shall be of a material and construction which 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

11.2.3.6 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.

RESPONSE: COMPLIANT

11.2.3.7 Drop ceilings shall be constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.

RESPONSE: COMPLIANT

11.2.4 Stairs, Catwalks and Platforms

There are no platforms and catwalks. Stairs in food preparation and handling areas are designed and constructed appropriately and dose not present any product contamination risk.

11.2.4.1 Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1).

RESPONSE: COMPLIANT

11.2.5 Lightings and Light Fittings

It was observed during the audit that all lights in all processing, packaging, and storage areas are shatterproof. Some light bulbs in the warehouse were covered with protective sleeves/covers.

11.2.5.1 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.

RESPONSE: COMPLIANT

11.2.5.2 Light fittings 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 fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.2.5.3 Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination.

RESPONSE: COMPLIANT

11.2.6 Inspection / Quality Control Area

There is a suitable location/room for batch preparation and product weighing with sufficient lighting. The inspection have easy access to hand washing sink sufficient lighting intensity to enable as thorough inspection of the product.

11.2.6.1 A suitable area shall be provided for the inspection of the product if required.

RESPONSE: COMPLIANT

11.2.6.2 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 hand washing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

RESPONSE: COMPLIANT

11.2.7 Dust, Insect, and Pest Proofing

All external windows, ventilation openings, doors and other openings are effectively sealed when closed and proofed against dust, vermin and flies. Electric insect control devices and pheromone traps are located so as not to present a contamination risk to product, packaging, containers or processing equipment. Poison bait are not be used inside ingredient or food storage areas or processing areas.

11.2.7.1 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin and other pests.

RESPONSE: COMPLIANT

11.2.7.2 External personnel access doors shall be provided. They shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against ingress of dust, vermin and other pests.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.7.4 Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison rodenticide bait shall not be used inside ingredient or product storage areas or processing areas.

RESPONSE: COMPLIANT

11.2.8 Ventilation

There is adequate ventilation in processing and food handling areas. There is an exhaust system (through the roof) over the oven to remove fumes. There were no condensation issues.

11.2.8.1 Adequate ventilation shall be provided in enclosed processing and food handling areas.

RESPONSE: COMPLIANT

11.2.8.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.12, to prevent unsanitary conditions.

RESPONSE: COMPLIANT

11.2.8.3 Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features: i. 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); ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk; and iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: No cooking is done at this site.

11.2.9 Equipment, Utensils, and Protective Clothing

Food contact equipment's design, construction, or maintenance poses no food safety risk. All food contact equipment or utensils are properly designed. Benches, tables, conveyors, other mechanical processing equipment were observed to be properly designed and maintained. Food contact utensils were constructed of materials that are non-toxic, smooth, and can be easily cleaned. All dry and liquid waste are being discharged in a compliant manner. Protective clothing (smock) used in all processing and packaging areas was observed as compliant.

11.2.9.1 Specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.9.3 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

11.2.9.4 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 11.2.13. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

11.2.9.5 Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system, and to meet local regulatory requirements.

RESPONSE: COMPLIANT

11.2.9.6 Protective clothing shall be manufactured from material that will not contaminate food and is easily cleaned.

RESPONSE: COMPLIANT

11.2.9.7 Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.

RESPONSE: COMPLIANT

11.2.9.8 All equipment, utensils and 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

11.2.10 Premises and Equipment Maintenance

The methods and responsibility for the maintenance and repair of plant, equipment and building is documented in the Maintenance program SOP 11.2.10 updated 06/24/2020. The program includes daily, weekly, monthly and less frequently maintenance schedule. The Maintenance Manager was interviewed and reviewed the maintenance program and the daily maintenance work request process. Maintenance follow food safety and hygiene practices after conducting maintenance activities. Reviewed maintenance records for July through September 2020. Upon review of records, there was evidence that all maintenance tasks have been completed as per schedule and signed off by the Maintenance Manager.

11.2.10.1	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
11.2.10.2	Routine maintenance of plant and equipment in any food processing, handling or storage area shall be performed according to a maintenance-control schedule and recorded. The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality. **RESPONSE:** MINOR **EVIDENCE:** A program is in place for routine maintenance of plant , equipment in any food processing, and handling and storage areas (coolers and freezers). During the walkthrough it was noticed that there was dripping of water/condensate from both the overhead refrigeration units in the finished product cooler. The force of the air from the units was forcing water/condensate droplets to fall over boxes (approximately up to 10 feet) from the overhead cooler units. There was evidence that some boxes were wet. All products were contained inside the box. There was no direct product contamination. **ROOT CAUSE:** The cooler fan was malfunctioning due to a damaged fan blade. The door had been left open due to a damaged door pulley. Both have been repaired. **CORRECTIVE ACTION:** The cooler fan was malfunctioning due to a damaged blade which allowed for increased condensation. Albright's (contracted freezer/cooler repairs) came on site 9/10/20 and repaired the fan. The door pulley was also repaired so that the door remains closed at all times. **VERIFICATION OF CLOSEOUT:** Reviewed the root cause analysis and corrective action for standing water. Accepted and complete. Humayun Kabir **COMPLETION DATE:** 09/14/2020 **CLOSEOUT DATE:** 10/07/2020
11.2.10.3	Failures of plant and equipment in any food processing, handling or storage area shall be documented, reviewed and their repair incorporated into the maintenance control schedule. **RESPONSE:** COMPLIANT
11.2.10.4	Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3.1, 11.3.2, 11.3.3, 11.3.4). **RESPONSE:** COMPLIANT
11.2.10.5	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
11.2.10.6	Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling or storage area. **RESPONSE:** COMPLIANT
11.2.10.7	The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times. **RESPONSE:** COMPLIANT
11.2.10.8	Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions. **RESPONSE:** COMPLIANT
11.2.10.9	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 completed and a pre-operational inspection conducted prior to the commencement of site operations. **RESPONSE:** COMPLIANT
11.2.10.10	Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product. **RESPONSE:** COMPLIANT

11.2.10.11 Paint used in a food handling or contact zone shall be suitable for use, in good condition and shall not be used on any product contact surface.

RESPONSE: NOT APPLICABLE

EVIDENCE: Paint is not used in food contact areas.

11.2.11 Calibration

Calibration schedule and methods are documented in calibration program SOP 11.2.11, updated 06/24/2020. A procedure is in place to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration. Calibrated measuring and test equipment are stored away from unauthorized adjustment in the maintenance office or the lab, and away from processing. Upon review of records there was evidence that scales were calibrated on 08/31/2020 by an outside company, pH meter calibrated daily using standard pH solution, magnet are checked daily and pull test is done on an annual basis (last done on 08/23/2020), vacuum chamber 08/31/2020, and IR thermometer calibrated on a daily basis using ice bath.

11.2.11.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite programs and food safety plans, or to demonstrate compliance with customer specifications shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

11.2.11.2 Procedures shall be documented and implemented to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state.

RESPONSE: COMPLIANT

11.2.11.3 Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.11.6 Calibration records shall be maintained.

RESPONSE: COMPLIANT

11.2.12 Pest Prevention

Pest control program is documented in SOP 11.2.12 updated 06/01/2020, A contracted pest control company is used for pest management. Service is conducted twice per month. There are in place 54 interior traps, 18 exterior bait stations and 7 ILTs. Interior inspection is conduct twice per months. The trap map has been revised on 08/26/2020. The pest and vermin management program documented in pest control manual describes the methods and responsibility for the development, implementation and maintenance of the pest and vermin management program, identify the target pests for each pesticide application, outline the methods used to prevent pest problems, outline the pest elimination methods, outline the frequency with which pest status is to be checked, location, number and type of bait stations set, list the chemicals used, and Safety Data Sheets (SDS), outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits, and measure the effectiveness of the program to verify the elimination of applicable pests. All licenses were current. Business license for pest control company expires on 06/30/2021 and PCO's permit expires on 06/30/2021. During the audit there was no evidence of pest activities. The last service was conducted on 09/09/2021

11.2.12.1 The methods and responsibility for pest prevention shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.

RESPONSE: COMPLIANT

11.2.12.2 Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging.

RESPONSE: COMPLIANT

11.2.12.3 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 investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.

RESPONSE: COMPLIANT

11.2.12.4 The pest prevention program 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; v. Outline the frequency with which pest status is to be checked; vi. Include on a site map the identification, location, number and type of bait stations set; vii. List the chemicals used (they 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.

RESPONSE: COMPLIANT

11.2.12.5 Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present.

RESPONSE: COMPLIANT

11.2.12.6 Records of all pest control applications shall be maintained.

RESPONSE: COMPLIANT

11.2.12.7 Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.4 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces.

RESPONSE: NOT APPLICABLE

EVIDENCE: No pesticide is stored on-site.

11.2.12.8 Pest contractors shall be: i. 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 2.3.3) which will include and maintain 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; and vi. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

11.2.12.9 The site shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that: i. Empty chemical containers are not reused; ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor.

RESPONSE: NOT APPLICABLE

EVIDENCE: This is not an in-house activity and done by the PCO.

11.2.13 Cleaning and Sanitation

The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities are documented in SOP 11.2.13, updated 06/01/2020. A master sanitation schedule has been established by the site. The schedule includes daily, weekly, monthly and bi-annual activities and also includes all areas of the facility. Pre-operational inspection records from randomly selected dates were selected for review during the audit. Records reviewed (from 08/31/2020 through 09/04/2020) verify that records of pre-operational inspections and all cleaning and sanitation activities tasks have been performed as per SOP. Cleaning and sanitizing chemicals meet local regulatory requirements and have in place a current inventory of chemicals in each storage area. An inventory of cleaning chemicals is maintained by the cleaning chemical supplier. ATP tests (5 per line daily) are conducted as cleaning verification.

11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities 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. Methods used to confirm the correct concentrations of detergents and sanitizers, and vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.2.13.2	Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing. **RESPONSE:** COMPLIANT
11.2.13.3	Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils shall be provided as required. **RESPONSE:** COMPLIANT
11.2.13.4	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 modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained. **RESPONSE:** COMPLIANT
11.2.13.5	Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities and sanitary facilities and other essential areas are clean before the commencement of production. Pre-operational inspections shall be conducted by qualified personnel. **RESPONSE:** COMPLIANT
11.2.13.6	Staff amenities, sanitary facilities and other essential areas shall be inspected by qualified personnel to ensure the areas are clean, at a defined frequency. **RESPONSE:** COMPLIANT
11.2.13.7	The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared. **RESPONSE:** COMPLIANT
11.2.13.8	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 chemicals purchased and used shall be 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 handles sanitizers and detergents. **RESPONSE:** COMPLIANT
11.2.13.9	Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained. **RESPONSE:** COMPLIANT
11.2.13.10	The site shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor. **RESPONSE:** COMPLIANT
11.2.13.11	A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained. **RESPONSE:** COMPLIANT

11.3.1 Personnel

There was no evidence of any employees with exposed cuts, sores or lesions while working in food handling areas. No evidence of any employees smoking, chewing, eating, drinking or spitting in any food processing or food handling areas were observed during the audit.

11.3.1.1	Personnel who are carriers or are known to have been 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. **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 from open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury which causes spillage of bodily fluid, a properly trained employee 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 disposed of.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.1.4 Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of 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 or equipment.

RESPONSE: COMPLIANT

11.3.2 Hand Washing

Hand wash basins have been provided and made of compliant material; are located adjacent to all personnel access points; located in accessible locations throughout food handling and processing areas; and hand washing signs are posted in appropriate language. Employees were observed to comply with hand washing policy.

11.3.2.1 Hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

RESPONSE: COMPLIANT

11.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as 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

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

RESPONSE: COMPLIANT

11.3.2.4 A sign instructing people to wash their hands, and in appropriate languages, shall be provided in a prominent position.

RESPONSE: COMPLIANT

11.3.2.5 Personnel shall have clean hands and hands shall be washed by all personnel, including 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, dropped product or contaminated material.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3 Clothing

Clothing worn by staff was observed to be properly maintained and made of compliant materials. Disposable gloves are changed when they become soiled or when re-entering production. Racks are in place for aprons in designated areas. The site has undertaken a risk analysis to ensure that the clothing and hair policy protects materials, food and food contact surfaces from unintentional microbiological or physical contamination.

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 as not to present a contamination risk to products.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3.4 Excessively soiled uniforms shall be changed or replaced where 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 designated sealed containers in personnel lockers and not on packaging, ingredients, product or equipment.

RESPONSE: COMPLIANT

11.3.4 Jewelry and Personal Effects

There was no evidence of employees with exposed jewellery or loose objects while in food/product handling areas.

11.3.4.1 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and prescribed medical alert bracelets can be permitted, however the site will need to consider their customer requirements and the applicable food legislation.

RESPONSE: COMPLIANT

11.3.5 Visitors

Visitor and management were observed following proper GMP and hygiene protocol, jeweler policy which includes: hand washing; wearing smocks (production room); and appropriate protective clothing. As per policy visitors exhibiting visible signs of illness are prevented from entering areas in which product is handled or packed.

11.3.5.1 All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area.

RESPONSE: COMPLIANT

11.3.5.2 All visitors shall be required to remove jewelry and other loose objects.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.6 Staff Amenities

Staff amenities were observed with adequate lighting, ventilation, and adequate in size for all staff.

11.3.6.1 Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and processing of product.

RESPONSE: COMPLIANT

11.3.7 Change Rooms

Changing area has been provided for staff and visitors for changing into appropriate clothing as required. Lockers have been provided for all employees to store their street clothing. Showers are not required.

11.3.7.1 Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required.

RESPONSE: COMPLIANT

11.3.7.2 Change rooms shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not pack high risk products.

11.3.7.3 Provision shall be made for staff to store their street clothing and personal items separate from food contact zones and food and packaging storage areas.

RESPONSE: COMPLIANT

11.3.7.4 Where required, a sufficient number of showers shall be provided for use by staff.

RESPONSE: NOT APPLICABLE

EVIDENCE: Showers are not required.

11.3.8 Laundry

The site does not pack high risk products. Smocks are laundered by an outside company.

11.3.8.1 Provision shall be made for the laundering and storage of clothing worn by staff engaged in high risk processes and for staff engaged in processing operations in which clothing can be heavily soiled.

RESPONSE: COMPLIANT

11.3.9 Sanitary Facilities

Toilet rooms do not open directly into processing areas, are adequate in size for staff, and were observed to be easily cleanable and properly maintained. Sanitary drainage are not connected to any other drains within the premises and directed to a sewerage system. Hand wash basins are adequately placed.

11.3.9.1 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. Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and vi. Kept clean and tidy.

RESPONSE: COMPLIANT

11.3.9.2 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 in regulations.

RESPONSE: COMPLIANT

11.3.9.3 Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.2.

RESPONSE: COMPLIANT

11.3.10 Lunch Rooms

Lunch areas are separated from processing, storage and handling areas. Hand wash reminder signs in English are in place at the exit of lunch room. Employees were observed to follow hand wash policy.

11.3.10.1 Separate lunch-room facilities shall be provided away from a food contact/handling zone.

RESPONSE: COMPLIANT

11.3.10.2 Lunch-room facilities 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 them 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

11.3.10.3 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 introduction of contamination including pests to the site.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

It is the policy of the site that all personnel engaged in any food handling, preparation or processing operations ensures that products and materials are handled and stored in such a way as to prevent damage or product contamination. Sensory evaluations are performed in designated area. All wash down hoses were observed to be stored on hose racks after use and not left on the floor.

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. Packaging material, 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; v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2; vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food; and vii. Hair restraints are used where product is exposed.

RESPONSE: MINOR

EVIDENCE: Observed damaged cases (2 areas) and leaky boxes (6 areas) in the finished products storage cooler. The damaged boxes and leaky boxes have been left unattended.

ROOT CAUSE: The cooler fan was malfunctioning due to a damaged fan blade. The door had been left open due to a damaged door pulley. Both have been repaired.

CORRECTIVE ACTION: The leaking damaged cases and leaking products were missing QA Hold/Rejection tags and were not in the Hold area due to warehouse overcrowding.

VERIFICATION OF CLOSEOUT: Reviewed the action taken for the cooler fan. Accepted and complete. Humayun Kabir

COMPLETION DATE: 09/10/2020 **CLOSEOUT DATE:** 10/07/2020

11.4.1.2 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the site shall implement proper 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 separate from processing equipment.

RESPONSE: COMPLIANT

11.4.1.3 All wash down hoses shall be stored on hose racks after use and not left on the floor.

RESPONSE: COMPLIANT

11.5.1 Water Supply

Water is supplied by City of Baltimore. Adequate supplies of hot and cold water have been provided as required to enable the effective cleaning of the premises and equipment. Water potability test was done on 08/25/2020. Backflow preventers are tested annually to ensure that potable water is not contaminated within the plant. The backflow devices were last tested on 09/09/2020.

11.5.1.1	Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment. **RESPONSE:** COMPLIANT
11.5.1.2	Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment. **RESPONSE:** COMPLIANT
11.5.1.3	The delivery of water within the premises shall ensure potable water is not contaminated. **RESPONSE:** COMPLIANT
11.5.1.4	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 back flow or back siphonage. **RESPONSE:** COMPLIANT
11.5.1.5	Where water is stored on site, storage facilities shall be adequately designed, constructed and maintained to prevent contamination. **RESPONSE:** COMPLIANT

11.5.2 Water Treatment

Water is not treated at this site.

11.5.2.1	Water treatment methods, equipment and materials, if required, shall be designed, installed and operated to ensure water receives an effective treatment. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** Water is not treated at this site.
11.5.2.2	Water treatment equipment shall be monitored regularly to ensure it remains serviceable. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** Water is not treated at this site.
11.5.2.3	Treated water shall be regularly monitored to ensure it meets the indicators specified. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** Water is not treated at this site.
11.5.2.4	Water used in as an ingredient in processing, or in cleaning and sanitizing equipment, shall be tested, and if required, treated to maintain potability (refer to 11.5.2.1). **RESPONSE:** NOT APPLICABLE **EVIDENCE:** Water is not treated at this site.

11.5.3 Ice Supply

Ice is not used at this site.

11.5.3.1	Ice provided for use during processing operations or as a processing aid or an ingredient shall comply with 11.5.4.1. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** Ice is not used at this site.
11.5.3.2	Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** Ice is not used at this site.

11.5.4 Water Quality

Potable water is supplied by the city and meets all regulatory requirements. The site conducts test for water potability once per year by an outside laboratory. The last test was done on 08/25/2020. SM 9223-B04 and SM 9215-B94 methods were used. The city also publishes an annual water report. Report from city water test was available for review for 2019.

11.5.4.1 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. to convey food; iv. as 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 used to heat water that will come in contact with food.

RESPONSE: COMPLIANT

11.5.4.2 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

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

RESPONSE: COMPLIANT

11.5.5 The Quality of Air and Other Gasses

Compressed air that contacts food or food contact surfaces is tested for purity by an outside laboratory. Air filters (3 microns) are serviced as per PM program and comply with industry standards. Compressed air is also tested for purity. Samples are taken from the nozzles (point of use). The last test was conducted on 09/26/19.

11.5.5.1 Compressed air or other gases (e.g. nitrogen, carbon dioxide) that contacts 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 used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

RESPONSE: COMPLIANT

11.6.1 Storage and Handling of Goods

The site has one dry ingredient and packaging storage room. Packaging material and ingredients are stored in different sections/areas of the warehouse.

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

RESPONSE: COMPLIANT

11.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented.

RESPONSE: COMPLIANT

11.6.1.3 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

11.6.1.4 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers.

RESPONSE: COMPLIANT

11.6.1.5 Where goods described in 11.6.2 to 11.6.4 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 is no risk to the integrity of those goods or contamination or adverse effect on food safety.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have temporary storage site.

11.6.1.6 Records shall be available to validate alternate or temporary control measures for the storage of raw materials, ingredients, packaging materials, equipment, chemicals, or finished products.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have temporary storage site.

11.6.2 Cold Storage, Freezing and Chilling of Foods

There are 2 coolers and one freezer. Sufficient refrigeration capacity is available to store chilled products. A minor non-conformance has been cited in section 11.6.2.3 of this audit: MONIR non-conformance has been cited in section 11.6.2.3 of this audit: Observed discharge of frost the overhead freezer unit. Frost was noticed on the pipe of freezer units, on the floor inside the room, and on the outer cases of products that have been stored under the overhead freezer unit. All products were contained inside sealed boxes. There was no direct product contamination when this observation was made.

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

RESPONSE: MINOR

EVIDENCE: Observed discharge of frost from the overhead freezer unit. Frost was noticed on the pipe of freezer units, on the floor inside the room, and on the outer cases of products that have been stored under the overhead freezer unit. All products were contained inside sealed boxes. There was no direct product contamination when this observation was made.

ROOT CAUSE: Frost developed on the freezer pipes and floors due to the door being left open for organization

CORRECTIVE ACTION: The frost buildup was removed all surfaces wtihin the freezer.

VERIFICATION OF CLOSEOUT: Reviewed the plan of action taken for removing damaged cases and future plan to avoid damages, and frost build-up. Accepted and complete. Humayun Kabir

COMPLETION DATE: 09/09/2020 **CLOSEOUT DATE:** 10/07/2020

11.6.2.4 Freezing, chilling and cold storage rooms shall be fitted with temperature monitoring equipment and located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible.

RESPONSE: COMPLIANT

11.6.2.5 Loading and unloading docks shall be designed to protect the product during loading and unloading.

RESPONSE: COMPLIANT

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

Rooms used for the storage of product ingredients, packaging, and other dry goods are located away from wet areas and constructed to protect the product from contamination and deterioration. Racks provided for the storage of packaging are constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas are constructed adequately to prevent packaging from becoming a harborage for pests or vermin. Vehicles used in food contact, handling or processing zones or in cold storage rooms are designed and operated so as not to present a food safety hazard.

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.

RESPONSE: COMPLIANT

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Rooms used for the storage of product ingredients, packaging, and other dry goods are located away from wet areas and constructed to protect the product from contamination and deterioration. Racks provided for the storage of packaging are constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas are constructed adequately to prevent packaging from becoming a harborage for pests or vermin. Vehicles used in food contact, handling or processing zones or in cold storage rooms are designed and operated so as not to present a food safety hazard.

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to staff, product, packaging, product handling equipment or areas in which the product is handled, stored or transported.

RESPONSE: COMPLIANT

11.6.4.2 Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

RESPONSE: COMPLIANT

11.6.4.3 Daily supplies of chemicals used for continuous sanitizing of water or as a processing aid, or for emergency cleaning of food processing equipment or 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 authorized personnel.

RESPONSE: COMPLIANT

11.6.4.4 Pesticides, rodenticides, fumigants and insecticides shall be stored separate from sanitizers and detergents. All chemicals shall be stored in their original containers, or in clearly labelled and suitable secondary containers if allowed by applicable legislation.

RESPONSE: NOT APPLICABLE

EVIDENCE: Pesticides, rodenticides, fumigants and insecticides are not stored on-site.

11.6.4.5 Hazardous chemical and toxic substance storage facilities shall: i. Be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals; ii. Be adequately ventilated; iii. Be provided with appropriate signage indicating the area is a hazardous storage area; iv. Be secure and lockable to restrict access only to those personnel with formal training in the handling and use of hazardous chemicals and toxic substances; v. Have instructions on the safe handling of hazardous chemicals and toxic substances readily accessible to staff; vi. Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility; vii. Have suitable first aid equipment and protective clothing available close to the storage area; viii. In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and ix. Be equipped with spillage kits and cleaning equipment.

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

There are in place documented policy for loading, transport, and unloading of foods. This includes methods of transportation of products, for loading and unloading, to maintain appropriate storage temperature and maintain product integrity. Employees interviewed were knowledgeable about their tasks. Most products are shipped at ambient temperature where refrigeration is not required. A mall portion of finished product that require refrigeration are shipped in refrigerated truck with appropriate truck/trailer temperature control.

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

11.6.6 Loading

Truck temperatures were verified and documented prior to loading and unloading. There was evidence that all vehicles used were inspected prior to use, and were properly maintained. During the audit it was observed that loading practices and product staging areas are designed to minimize product exposure and maintain its integrity. Finished product storage areas are temperature controlled.

11.6.6.1	Vehicles (e.g. trucks/vans/containers) used for transporting food 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
11.6.6.2	Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity during loading and transport. **RESPONSE:** COMPLIANT
11.6.6.3	Vehicles (e.g. trucks/vans/containers) shall be secured from tampering using a seal or other agreed upon and acceptable device or system. **RESPONSE:** COMPLIANT

11.6.7 Transport

Through inspection and trailer inspection records, there was evidence that trailer refrigeration units are maintained below 40°F (for refrigerated product), with settings checked and temperatures monitored by the shipping co-workers using calibrated digital or infrared thermometers. Temperatures are recorded on the trailer inspection reports and documented in the BOL/invoice. Majority of the products are shipped at ambient temperature.

11.6.7.1	Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and product temperatures recorded at regular intervals during loading as appropriate. **RESPONSE:** COMPLIANT
11.6.7.2	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

11.6.8 Unloading

During receiving, it was observed that the refrigeration unit was on (for products that require refrigeration). Employee was observed to follow guidelines of checking incoming product temperature. Through record review there was evidence that receiving temperature of the refrigerated product was observed to be between 39°F - 40°F. Receiving information is documented on the receiving/unloading form.

11.6.8.1 Prior to opening the doors, the 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 commencement of unloading and at regular intervals during unloading.

RESPONSE: MINOR

EVIDENCE: A procedure is in place documented in "Transportation and Storage" updated 07/10/2020. The site's procedure states that temperature of the product during unloading should be: Fresh Products- <40 Degree F Frozen products- <26 Degree F 1. The procedure did not address that prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature to be checked and recorded which is required as per SQF code section 11.6.8.1 2. The unloading for states as follows: TEMPERATURE Ambient Y/N Refer <40F Freezer <32 F The unloading form did not match with the site's documented/established procedure. It was also noticed that the receiving person was not properly documenting if the load was ambient or not ambient.

ROOT CAUSE: The shipping and receiving team did not reiceve proper training on completing the trailer inspection sheet. The procedure didn't take into consideration all requirements.

CORRECTIVE ACTION: The procedure 11.6 Storage and Transport was revised to reflect SQF unloading requirements to state the following: 1. "Prior to opening the doors of full trailers, the seal will be checked to ensure that it's intact, if applicable. The refrigeration unit's storage temperatures and settings will be checked and recorded on the Trailer Inspection Sheet" 2. "Product will be inspected by receiving personnel or their designee during the unloading process. In the event a deficiency is identified, the QA is to be notified to determine the disposition." The Trailer Inspection Sheet was revised in order for the team to better understand the receiving and unloading requirement

VERIFICATION OF CLOSEOUT: Reviewed the action taken to train and monitor trailer inspection. Accepted and complete.

COMPLETION DATE: 09/16/2020 **CLOSEOUT DATE:** 10/07/2020

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

RESPONSE: COMPLIANT

11.7.1 Process Flow

Process flow is continuous and does not pose a risk of cross contamination. The process flow is documented in the HACCP plan. Employees were observed to follow proper GMP when moving from one section to another section of the production room.

11.7.1.1 The process flow shall be designed to prevent cross-contamination and organized so there is a continuous flow of product through the process. The flow of personnel shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

Dry ingredients and packaging are received and stored separately from chilled raw materials to ensure there is no cross contamination. Unprocessed raw materials are received and segregated to ensure there is no cross contamination.

11.7.2.1 Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross-contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross-contamination.

RESPONSE: COMPLIANT

11.7.3 Thawing of Food

Thawing procedure is documented in SOP 11.7.3, revised 06/24/2020. Thawing is done in refrigerated areas.

11.7.3.1 Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose.

RESPONSE: COMPLIANT

11.7.3.2 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.

RESPONSE: COMPLIANT

11.7.3.3 Air thawing facilities shall be designed to thaw food under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.

RESPONSE: COMPLIANT

11.7.3.4 Provision is to be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.

RESPONSE: COMPLIANT

11.7.4 High Risk Processes

The site does not manufacture high risk product.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture high risk product.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture high risk product.

11.7.4.3 Staff access points shall be located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture high risk product.

11.7.4.4 Staff engaged in high risk areas shall change into clean clothing or temporary protective outerwear when entering high risk areas.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture high risk product.

11.7.4.5 Product transfer points shall be located and designed so as not to compromise high risk segregation and to minimize the risk of cross-contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not manufacture high risk product.

11.7.5 Control of Foreign Matter Contamination

Foreign material prevention is documented in 11.7.5 revised 06/23/2020. It is the responsibility of all co-workers to prevent contamination from foreign material. Foreign material devices in place include screen. All co-workers are trained in identification of foreign material. During the audit, employees were aware to notify their supervisors if there is evidence of any foreign materials that could contaminate food products. A glass and brittle plastic log is maintained. Audit is conducted on a quarterly basis. The last audit for glass and brittle plastic was done on 08/24/2020.

11.7.5.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff.

RESPONSE: COMPLIANT

11.7.5.2 Inspections shall be performed to ensure plant and equipment remain in good condition, equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

11.7.5.3 All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location.

RESPONSE: COMPLIANT

11.7.5.4 Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing /contact zones.

RESPONSE: COMPLIANT

11.7.5.5 Regular inspections of food handling/contact zones shall be conducted 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 register.

RESPONSE: COMPLIANT

11.7.5.6 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

11.7.5.7 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.11.7.5.8 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

11.7.5.8 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

11.7.5.9 Knives and cutting instruments used in processing and packaging operations shall be controlled and kept clean and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

RESPONSE: COMPLIANT

11.7.6 Detection of Foreign Objects

The site does not have metal detector. Screens used to control possible foreign material contamination. Records of screen inspection are maintained and was reviewed during the audit.

11.7.6.1 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

11.7.6.2 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: NOT APPLICABLE

EVIDENCE: There are no metal detectors. However the site has screens. Those are monitored as per SOP.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: There are no metal detectors. However the site has screens. Those are monitored as per SOP.

11.7.7 Managing Foreign Matter Contamination Incidents

A procedure is in place 11.7.5 revised 0623/2020 and described in policy In circumstances where glass or similar material breakage occurs, the affected area is isolated, cleaned and thoroughly inspected (Including cleaning equipment) and cleared by a suitably responsible person prior to the commencement of operations.

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

RESPONSE: COMPLIANT

11.7.7.2	In circumstances where glass or similar material breakage occurs, the affected area is to be isolated, cleaned and thoroughly inspected (including cleaning equipment and footwear) and cleared by a suitably responsible person prior to the commencement of operations. **RESPONSE:** COMPLIANT

11.8.1 Location

The site does not have alternate storage policy,

11.8.1.1	On site laboratories conducting chemical and microbiological analysis 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. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** The site does not have alternate storage policy,
11.8.1.2	Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory wastewater outlet shall as a minimum be down stream of drains that service food processing and handling areas. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** The site does not have alternate storage policy,
11.8.1.3	Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** The site does not have alternate storage policy,

11.9.1 Dry and Liquid Waste Disposal

Adequate provision has been made for the disposal of all solid processing waste including trimmings, inedible waste used in packaging. Liquid waste is first collected in drums and then the empty drums are sent to the manufacturer.

11.9.1.1	The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented. **RESPONSE:** COMPLIANT
11.9.1.2	Waste shall be removed on a regular basis and not 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
11.9.1.3	Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition, cleaned and sanitized regularly so as not to attract pests and other vermin. **RESPONSE:** COMPLIANT
11.9.1.4	Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging. **RESPONSE:** COMPLIANT
11.9.1.5	Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance. **RESPONSE:** COMPLIANT
11.9.1.6	Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing. **RESPONSE:** COMPLIANT
11.9.1.7	Waste held on site prior to disposal shall be stored in a separate storage facility and suitably insect proofed and contained so as not to present a hazard. **RESPONSE:** COMPLIANT

11.9.1.8	Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard. **RESPONSE:** COMPLIANT
11.9.1.9	Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports. **RESPONSE:** COMPLIANT

11.10.1 Grounds and Roadways

Grounds and the and area surrounding the premises are maintained adequately to minimize dust and kept free of waste, accumulated debris or standing water so as not to attract pests and vermin. Paths, roadways and loading and unloading areas have been maintained so as not to present a hazard to the food safety operation of the premises.

11.10.1.1	Measures shall be established to maintain a suitable external environment, and the effectiveness of the established measures shall be monitored and periodically reviewed. **RESPONSE:** COMPLIANT
11.10.1.2	The grounds and area surrounding the premises shall be maintained to minimize dust and kept free of waste, accumulated debris or standing water so as not to attract pests and vermin. **RESPONSE:** COMPLIANT
11.10.1.3	Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises. **RESPONSE:** COMPLIANT
11.10.1.4	Paths, roadways, loading and unloading areas shall be adequately drained to prevent ponding of water. Drains shall be separate from the site drainage system and regularly cleared of debris. **RESPONSE:** COMPLIANT
11.10.1.5	Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises. **RESPONSE:** COMPLIANT
11.10.1.6	Paths from amenities leading to site entrances are required to be effectively sealed. **RESPONSE:** COMPLIANT