SQF Food Safety Audit Edition 9
ViskoTeepak - ViskoTeepak

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
14467 | 144799

AUDIT RATING
94
Good

DECISION DATE
12/01/2021

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
09/27/2022

AUDIT DATES
11/02/2021 - 11/04/2021

EXPIRATION DATE
12/11/2022

ISSUE DATE
12/07/2021

Facility & Scope

ViskoTeepak (45173)
ViskoTeepak
1126 88th Place
Kenosha, WI 53143
United States

Food Sector Categories:
27. Manufacture of Food Packaging

Products:
food casings, gel casings

Scope of Certification:
food casings, gel casings

Certification Body & Audit Team

Mérieux NutriSciences Certification
401 N Michigan
Suite 1400
Chicago, IL 60611
United States

Web Site: https://www.merieuxnutrisciences.com/

CB#: CB-1-Mérieux
Accreditation Body: JAS-ANZ
Accreditation Number: Z3720906AB

Lead Auditor: Jones, Patricia (9261)
Technical Reviewer: Luttrell, Sandra (132944)

Hours Spent on Site: 18
Hours of ICT Activities: 0
Hours Spent Writing Report: 8

Non-Conforming

13.1.2 Building Materials

Minor non-conformance: Large cracks on painted surfaces of the ceiling around the base of the roof drain pipe and signs of previous leaks were observed in the printing room near press #5. Floors and floor drains in the facility were observed to be adequately designed to achieve drainage and to be easily cleaned. Walls, other ceilings, wall to floor junctions, doors and structural areas were observed to be satisfactorily designed, in good condition and easily cleaned. No waste trap system was observed on the premises. Windows were of shatterproof material. Doors were observed to be of solid construction.

13.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction.

RESPONSE: MINOR

EVIDENCE: Large cracks on painted surfaces of the ceiling around the base of the roof drain pipe and signs of previous leaks were observed in the printing room near press #5.

ROOT CAUSE: After looking into the issue, it appears that there were no cracks in the pipe itself but the paint was peeling. Checking of pipes has been added to the regular auditing intervals.

CORRECTIVE ACTION: Maintenance team has sanded the area down and repainted the surface. It is added in the monthly Audit to monitor.

VERIFICATION OF CLOSEOUT: Reviewed the photograph of the corrective action and signs of previous leaks.

COMPLETION DATE: 11/19/2021 **CLOSEOUT DATE:** 11/30/2021

13.2.1 Repairs and Maintenance

Minor non-conformance: The following temporary equipment adjustments or repairs and conditions were observed: (1) Taped cardboard used as a table surface on 3 areas of press #5; (2) The heater hose was stored on the floor behind press #5; (3) Tape hanging on the hand clipper #2 and string, loose tape on hand clipper #3. A PM program was written which outlined methods and responsibilities for implementation of maintenance and repair of the building structure and equipment. Manufacturing and packaging equipment were observed to be in satisfactory operational condition. Documentation of plant or equipment deficiencies was maintained and reviewed. A work order system was used for completing scheduled and emergency equipment repairs. Food grade lubricants were used in food contact zones, where required. Maintenance staff and supervision were informed if repairs presented potential threat to food packaging from foreign objects. Maintenance repairs were conducted during production or line downtimes. Paint on structural surfaces in packaging manufacturing and product handling areas were observed to be in good condition.

13.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and 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: MINOR

EVIDENCE: The following temporary equipment adjustments or repairs and conditions were observed: (1) Taped cardboard used as a table surface on 3 areas of press #5; (2) The heater hose was stored on the floor behind press #5; (3) Tape hanging on the hand clipper #2 and string, loose tape on hand clipper #3.

ROOT CAUSE: After looking into the issue: (1) It is observed that the press operators had the cardboard in that location to hold the ink buckets and samples. There was no need to place the ink buckets on the cardboard. Instead, they can be placed on the table that is designated. (2) As there was no clamp to attach the hose, it was left on the floor (3) The tape and string was placed on the machine for the operator's convenience even though it was not needed. The machine later ran without any tape and string and produced quality product

CORRECTIVE ACTION: (1) Cardboard taped has been removed from press staging area. (2) A clamp was attached to the machine so the heater hose is placed there instead of leaving on the floor (3)Tape and string has been removed from the hand clipper machines

VERIFICATION OF CLOSEOUT: Reviewed the photographs of the temporary equipment fixes, removal of cardboard and tape as noted.

COMPLETION DATE: 11/09/2021 **CLOSEOUT DATE:** 11/30/2021

13.2.4 Pest Prevention

Minor non-conformance: All exterior rodent bait stations observed were filled with debris and cobwebs and required fresh bait. The station at the front dock was also not numbered. Written pest prevention procedures for implementation of an integrated pest management program were established. The program was administered by a certified PCO. The written program and procedures outlined methods for pest management for the premises were observed to meet the requirements of the SQF Pest Prevention Code; however, the condition of exterior devices was not compliant with the procedures. Records of site inspections were reviewed for the following dates: 9/18/2020, 1/15/2021, 4/9/2021, 6/4/2021. Pesticides were not observed or stored on the premises. Animals were not permitted in the food processing, food handling and storage areas per the internal pest prevention procedure. Other chemicals used for cleaning, sanitation and maintenance activities were observed to be properly labeled, securely stored and managed by trained personnel per 13.6.2.

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

RESPONSE: MINOR

EVIDENCE: All exterior rodent bait stations observed were filled with debris and cobwebs and required fresh bait. The station at the front dock was also not numbered.

ROOT CAUSE: After discussing with the pest control agency, It appears that the associate coming from Mccloud services was not performing his job as needed and he is no longer with their company.

CORRECTIVE ACTION: Pest Control Agency was contacted to ensure the service is being provided as needed and communicated this SQF non conformance. Pest Control Operator has cleaned all the bait stations immediately

VERIFICATION OF CLOSEOUT: Reviewed the photographs of the cleaned bait stations with fresh bait.

COMPLETION DATE: 11/12/2021 **CLOSEOUT DATE:** 11/30/2021

13.2.5 Cleaning and Sanitation

Minor non-conformance: The following conditions were observed which impacted the cleaning program: (1) Spillage of a white powdered substance and damaged broken pallet splinters around the non-soy lecithin drums in the warehouse; (2) Heavy dust accumulation on idle equipment in the receiving/shipping area, debris on the perimeter at the shrink-wrapper in this area; (3) White substance in corners and on stored items in press room #6; (4) Oil/water accumulations on the white overhead pipe above spiral #4 in the shirring room; (5) A product transfer hose was stored on the floor in the solution make-up area- (This was a potential source of product contamination if the integrity of the hose was compromised). A master cleaning schedule of all areas and processing equipment, utensils, staff amenities and structural areas within the site was established with defined frequencies for cleaning tasks. Pre-op inspections were conducted at the beginning of each production shift and at product change-overs. Equipment in the alginate gel process was cleaned and sanitized after every batch. Visual inspections were conducted after detailed equipment cleaning. ATP swabbing was conducted to verify effectiveness of cleaning within the alginate and dry processes A pre-op inspection and swabbing activity was reviewed in the alginate gel casing room during the audit; of all areas swabbed, one area failed , which was the seal under the cover of the chopper. The seal was loose and required replacement. Records of documented cleaning, ATP swabbing and pre-op checks were maintained and reviewed for the following dates: 12/15-17/2020, 3/1-3/2021, 6/9-11/2021, 10/27-29/2021.

13.2.5.1 The methods and responsibility for the effective cleaning of food sector packaging manufacturing, handling and storage areas, and staff amenities shall be documented and implemented.

RESPONSE: MINOR

EVIDENCE: The following conditions were observed which impacted the cleaning program: (1) Spillage of a white powdered substance and damaged broken pallet splinters around the non-soy lecithin drums in the warehouse; (2) Heavy dust accumulation on idle equipment in the receiving/shipping area, debris on the perimeter at the shrink-wrapper in this area; (3) White substance in corners and on stored items in press room #6; (4) Oil/water accumulations on the white overhead pipe above spiral #4 in the shirring room; (5) A product transfer hose was stored on the floor in the solution make-up area- (This was a potential source of product contamination if the integrity of the hose was compromised).

ROOT CAUSE: (1) It appears that the pallet was just moved in that location and the warehouse personnel were going to clean up the area. There as a leak from one of the bag of ingredients and QA has discarded that bag. (2) The equipment was on the sale and some of the outside contractors has been looking to buy the machine. As a part to show the machine, the plastic bag was removed which in fact caused the dust/debris (3) Press room runs with powder to eliminate bad printing. As the machine runs with powder, it is accumulated on the floor. They get cleaned up at the end of the day and on weekly basis. (4) The accumulation on the white overhead pipes were observed to be condensation due to difference in temperature of the water inside the pipe versus the outside temperature. (5) It was the understanding that the hose ends shall not touch the ground but none of the employees had knowledge on the complete hoses not touching the floor.

CORRECTIVE ACTION: (1) Spillage of a white powdered substance and damaged broken pallet splinters around the non soy lecithin drums in the warehouse has been cleaned (2) Heavy dust accumulation on idle equipment in the receiving/shipping area has been cleaned and covered with plastic (3) White substance around the corners and on stored items in the press room has been cleaned and maintained (4) Oil/water accumulations on the white overhead pipe above spiral 4 in the shirring area has been cleaned (5) The product transfer hoses in the solution make up area are taken off the floor. A stand was made to place the hoses on so they don't touch the floor

VERIFICATION OF CLOSEOUT: Reviewed the photographs of all cleaned areas noted as corrective actions.

COMPLETION DATE: 11/21/2021 **CLOSEOUT DATE:** 11/30/2021

13.3.1 Personnel Welfare

Minor non-conformance: Written medical screening procedures were not available for review for employees, visitors and contractors who handled exposed product or food packaging contact surfaces. A GMP policy was documented and implemented which required that personnel were prohibited from entering and working in food packaging manufacturing and handling areas if they were suffering from known infectious or communicable diseases. Minor cuts were to be covered with a colored metal detectable bandage. Trained staff management was responsible for ensuring adequate clean-up and disposal of any affected materials from spillages of bodily fluids in the event of injury.

13.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others on-site shall not engage in the manufacture of food sector packaging or enter areas where food sector packaging is exposed. Code Amendment #1 A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: MINOR

EVIDENCE: Written medical screening procedures were not available for review for employees, visitors and contractors who handled exposed product or food packaging contact surfaces.

ROOT CAUSE: The procedure was not in place as the amendment was recently implemented and due to the lack of understanding the amendment

CORRECTIVE ACTION: A medical screening program has been written and implemented throughout the company. It is also posted in the entrance for all visitors and contractors to implement

VERIFICATION OF CLOSEOUT: Reviewed the developed medical screening procedure dated 11/29/2021, to comply with the SQF Code Amendment, effective 10/4/2021.

COMPLETION DATE: 11/29/2021 **CLOSEOUT DATE:** 11/30/2021

13.6.2 Storage and Use of Hazardous Chemicals and Toxic Substances

Minor non-conformance: There was no spill containment in the chemical storage cage. All chemicals were observed to be in a locked well ventilated cage, properly labeled, accessible only by authorized trained personnel. Chemicals were observed to be stored in a manner to prevent cross contamination. Ventilation was satisfactory in the storage area. Disposal of waste chemicals and containers (Inks, Solvents, Waste Oils) was managed by Maintenance personnel via third party disposal contractors. All pesticides and empty pesticide containers were handled by the certified PCO only. An approved chemical list was maintained and reviewed. SDS information was maintained for the chemicals and accessible in the area for review.

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

RESPONSE: MINOR

EVIDENCE: There was no spill containment in the chemical storage cage.

ROOT CAUSE: The drums were recently received and the code was missed to follow to implement spill containment pallets

CORRECTIVE ACTION: Spill containment pallets have been orders and placed under the chemicals

VERIFICATION OF CLOSEOUT: Reviewed photographs of the spill containment pallets placed in the chemical storage area.

COMPLETION DATE: 11/18/2021 **CLOSEOUT DATE:** 11/30/2021

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Sudha Chavali
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** sudha.chavali@viskoteepak.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Sudha Chavali: QA Manager, Patricia Jones: SQF Auditor (Virtually: Shawn Devore: Plant Manager, Don Wright: Scheduling Coordinator, Nina Redd: Production Lead, Chris Papelbon: Safety Coordinator, Kelsey Aiello: HR Manager, Jason Spears: Shipping Manager, Lori Andrekus: Customer Service/Logistics Manager)
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** The site was located within the city limits of Kenosha, Kenosha County, in a mixed light industrial/residential zone, set on approximately 10 acres. The concrete and brick building consisted of 60,000 sq. ft. The site operated 3 production shifts Monday through Friday. There were 106 employees. The facility converted Collagen, Fibrous and Plastic coil roll casings into pieces and manufactured Co-Ex Gel food casings for the diary, meat, poultry and vegetarian processing industries. The facility consisted of several separate manufacturing and packaging areas, warehouse storage for some raw materials, processing aids and finished products, designated equipment storage areas, maintenance shop, chemical storage, shipping/receiving, employee amenities and administrative offices. Sanitation activities involved dry cleaning and were performed during the production shift by Operators and Sanitation staff and during line-shut-down periods. The Gel processing operation was conducted in a dedicated, locked room accessed by authorized personnel only; this room was wet cleaned using and sanitized after each production run. There were two HACCP plans developed for the food packaging processes. The site used an external company-leased distribution center located at 5718 -52nd Street, Kenosha, WI, for storage of raw materials and finished goods. The manufacturing site, all products and processes, were designated in food sector category 27 and were included within the scope of the Re-Certification Audit.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Sudha Chavali: QA Manager, Patricia Jones: SQF Auditor (Virtually: Shawn Devore: Plant Manager, Don Wright: Scheduling Coordinator, Nina Redd: Production Lead, Chris Papelbon: Safety Coordinator, Kelsey Aiello: HR Manager, Jason Spears: Shipping Manager, Lori Andrekus: Customer Service/Logistics Manager, Paul Schulz: CFO, Richard Cocora: Continuous Improvement Manager, Patricia Esparza: QA Lead)
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Maintain Certification upon completion and approval of all corrective actions.

Section Responses

2.1.1 Management Responsibility (Mandatory)

A documented food packaging safety management policy was reviewed which stated site management's commitment to establish, implement and maintain a food packaging safety and quality management system as outlined within the requirements of the SQF Code which included support of a food safety culture within the site. The management policy was posted in the employee information station; it was signed by the Director of Operations and QA Manager, dated 11/1/2021. An organizational chart was established which listed those personnel who had responsibility for food packaging safety. Job descriptions were in place. The QA Manager had been designated site SQF Practitioner. The QA Lead was designated as the alternate SQF Practitioner to provide coverage for absenteeism. Documented HACCP training was on file; the Practitioners demonstrated competence in the development and maintenance of HACCP-based food safety plans for packaging. All facility employees received training and were required to report packaging safety and quality issues to management when observed. The policy was communicated to all employees during the documented employee training. Senior management had also committed to submitting blackout dates to the Certification Body a minimum of one month prior to the 60-day re-certification window for the agreed upon unannounced audits.

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to: i. Supply safe food sector packaging; ii. Establish and maintain a food safety culture within the site; iii. Establish and continually improve the site's food safety management system; and iv. Comply with customer and regulatory requirements to supply safe food sector packaging. The policy statement shall be: v. Signed by the senior site manager and displayed in prominent positions; and vi. vi. Effectively communicated to all site personnel in language(s) understood by all site personnel.

RESPONSE: COMPLIANT

2.1.1.2 Senior site management shall lead and support a food safety culture within the site that ensures at a minimum: i. The establishment, documentation, and communication to all relevant staff of food safety objectives and performance measures; ii. Adequate resources are available to meet food safety objectives; iii. Food safety practices and all applicable requirements of the SQF System are adopted and maintained; iv. Staff are informed and held accountable for their food safety and regulatory responsibilities; v. Staff are positively encouraged and required to notify management of actual or potential food safety issues; and vi. Staff are empowered to act to resolve food safety issues within their scope of work.

RESPONSE: COMPLIANT

2.1.1.3 The reporting structure shall identify and describe site personnel with specific responsibilities for tasks within the food safety management system and identify backup for absence of key personnel. Job descriptions for the key personnel shall be documented. Site management shall ensure departments and operations are appropriately staffed and organizationally aligned to meet food safety objectives.

RESPONSE: COMPLIANT

2.1.1.4 Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review, and maintenance of the SQF System; ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.1.1.5 The primary and substitute SQF practitioner shall: i. Be employed by the site; ii. Hold a position of responsibility 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: Manufacture of Food Packaging and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

2.1.1.6 Senior site management shall ensure the training needs of the site are resourced, implemented, and meet the requirements outlined in system elements 2.9 and that site personnel meet the required competencies to carry out those functions affecting the legality and safety of food sector packaging.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.1.8 Senior site management shall inform their certification body of any defined blackout periods that prevent unannounced re-certification audits from occurring when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed-upon unannounced audit.

RESPONSE: COMPLIANT

2.1.2 Management Review (Mandatory)

The SQF System was scheduled to be reviewed in its entirety by senior management at least annually. The SQF Practitioner/QA Manager conducted monthly food safety and quality updates with senior management. Records of the updates were maintained and reviewed for the months of December 2021, May 2021 and October 2021. The food safety plans, objectives and other aspects of the SQF System per the Code were reviewed with senior management when any changes were made which impacted the site's food safety programs and implementation of the SQF System. Records of the SQF annual review in its entirety was documented 9/21/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3 Complaint Management (Mandatory)

A complaint management procedure was documented with outlined methods for managing and resolving complaints from all customers. The program, including investigating, determining root cause, corrective and preventative actions and conducting complaint data trends and analysis were managed by the SQF Practitioner. Trending was conducted monthly. Records of complaints were maintained and reviewed for the following dates: 12/21/2020, 5/12/2021, 10/5/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

The safety and quality management system for packaging was established and maintained in electronic and hard copy forms. The manual contained the procedures which outlined how the SQF Food Packaging Code would be implemented, the scope of certification, list of products, organizational chart, HACCP plans and GMP programs. The manual was made available to relevant staff. Changes made to the HACCP plans, GMPs and other aspects of the SQF System were reviewed and validated by the SQF Practitioner and food safety team.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

A document control policy was defined with methods and responsibility for maintaining document control and for ensuring that all food packaging safety and production staff had access to current documents and requirements The site SQF Practitioner was responsible for managing and maintaining SQF System documents and amendments, which were observed to be current as of 9/29/2021.

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

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

The recordkeeping policy, which outlined methods, frequency and responsibility for conducting monitoring activities, verifying and retaining food packaging safety records was reviewed. Selected records reviewed were observed to be legible and properly signed by those conducting the monitoring and inspection activities. Records were readily accessible and observed to be securely stored to prevent damage. The retention period for food packaging safety records as established by the company was 3 years.

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

RESPONSE: COMPLIANT

2.2.3.2 All records that demonstrate inspections, analyses, and other essential activities have been completed shall be legible, accurate, and reviewed for correctness and completion.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.1 Product Formulation and Realization

The site had a written product development and realization procedure which outlined methods, design, responsibility and required records and supporting documentation for new products. The process flows for new packaging as well as existing manufacturing processes were observed to be satisfactorily designed with approved specification to prevent cross-contamination and to achieve continuous flow of product through the process. Quality management was responsible for ensuring review and validation of food packaging safety plans. Reportedly, there had been no new products formulated in the past 4 years.

2.3.1.1 The methods and responsibility for the design and development of finished products from concept to commercial realization shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.1.2 Changes to raw material, design, process, and equipment to produce the finished product shall be validated by site trials and product testing as required to ensure product safety (refer to 2.3.1.5).

RESPONSE: COMPLIANT

2.3.1.3 Where applicable, finished products designed with a functional effect for food safety reasons (i.e., prevent ingress of pathogens) shall have specified criteria and be referenced in the food safety plan (refer to 2.4.3).

RESPONSE: COMPLIANT

2.3.1.4 Trials where necessary shall be conducted to establish and validate a product's: i. Handling and storage requirements; and ii. Customer specification including the intended use of the product.

RESPONSE: COMPLIANT

2.3.1.5 The site's food safety plan shall be validated and verified for each new finished product, its associated production and distribution processes, or where a change to raw material, design, manufacturing process or equipment may impact food safety.

RESPONSE: COMPLIANT

2.3.1.6 Where applicable, the site shall have a procedure for confirmation and approval of customer artwork for the finished product. The controls shall also describe how print run samples are approved by customers and changes to artwork are managed.

RESPONSE: COMPLIANT

2.3.1.7 The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured to approved product specifications to prevent cross-contamination and organized so there is a continuous flow of product through the process.

RESPONSE: COMPLIANT

2.3.1.8 Records of product design, specifications, process flows, shelf life trials (as required), and approvals for all new and existing products shall be maintained.

RESPONSE: COMPLIANT

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

Specifications for raw materials, packaging, finished products and chemicals were documented, maintained and observed to be kept current as of 2/16/2021. Letters of guarantee or certificates of conformance were required and received from approved suppliers for all packaging raw materials to verify safety of food product contact. Specifications for contract service providers were developed. QA verified accuracy of printing plates during manufacturing. The specifications included a description of services provided and required GMP training. Records of review of all specifications were maintained when changes occurred and at least annually.

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

RESPONSE: COMPLIANT

2.3.2.2 Specifications shall be documented and kept current for raw materials, additives, processing aids, and auxiliary packaging materials (those used in direct contact with finished products) for containment or unitization.

RESPONSE: COMPLIANT

2.3.2.3 Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel. Printed materials applied to or printed directly on finished product shall be accurate, legible, and comply with customer and regulatory requirements, including information regarding ingredients, allergens, identification codes, and other requirements. They shall be approved by designated company personnel and controlled to ensure relevance and accuracy.

RESPONSE: COMPLIANT

2.3.2.4 All raw materials including those made with recycled material, plant-based material, or additional additives shall be suitable for the intended use, food contact compliant where applicable, and shall comply with the relevant legislation in the country of manufacture and country of destination, if known.

RESPONSE: COMPLIANT

2.3.2.5 Site management shall require raw materials suppliers to notify of changes in product composition where they could have an impact on finished product, design, processing, or food safety.

RESPONSE: COMPLIANT

2.3.2.6 Raw and auxiliary packaging materials shall be verified to ensure food safety is not compromised and the material is fit for its intended purpose. Verification of raw and packaging materials' conformance to food safety specifications shall include a letter of guarantee and a certificate of conformance, certificate of analysis, inspection, sampling, or testing.

RESPONSE: COMPLIANT

2.3.2.7 Description of services for contract service providers that have an impact on food safety shall be documented, current, and include relevant training requirements, where applicable, for all contract personnel.

RESPONSE: COMPLIANT

2.3.2.8 Finished product specifications shall be documented, current, approved by the site and their customer, if applicable, accessible to relevant staff, and may include: i. Physical and chemical characteristics; ii. Microbiological characteristics, where applicable; iii. Artwork and unitizing requirements; iv. Confirmation that the food sector packaging is suitable for the intended use by the customer; and v. Lists of raw materials, allergens, ingredients, identification codes, etc. Specifications for direct food contact packaging shall list the functional characteristics to protect the food product (shelf life extension, barrier properties, etc.).

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.2.10 Where applicable, procedures shall also be in place for managing and verifying the specifications for correct printing plates, anilox rollers, and cylinders used during printing.

RESPONSE: COMPLIANT

2.3.3 Contract Manufacturers

The site did not use contract manufacturers.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site did not use contract manufacturers.

2.3.3.2 The site shall establish a method to determine the food safety risk level of contract manufactured product and shall document the risk. The site shall: i. Verify compliance with the SQF Food Safety Code: Manufacture of Food Packaging and that all customer requirements are being met at all times. ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

RESPONSE: NOT APPLICABLE

2.3.3.3 Records of verified compliance, contracts, and changes and approvals to contractual agreements for contract manufacturers shall be maintained.

RESPONSE: NOT APPLICABLE

2.3.4 Approved Supplier Program (Mandatory)

A written approved supplier program was established and implemented. Senior management was responsible for the selection, approval and review of all raw materials and services provided for the manufacture of food packaging. The program was observed to be effective and to meet the requirements of the SQF Code. Certificates of Conformance and letters of guarantee were received from the raw material and other packaging suppliers. An approved supplier register was maintained and included primary contact information, including alternate/emergency suppliers. The register was observed to be current as of 10/12/2021. Suppliers' third-party facility audits or GFSI Certifications were maintained and available for review.

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

RESPONSE: COMPLIANT

2.3.4.2 The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw and packaging materials and services supplied. The program shall contain at a minimum: i. Agreed specifications (refer to 2.3.2); ii. Reference to the risk rating of the supplier, materials, or services supplied; iii. An assessment of the supplier's food safety risks and or controls to ensure that supplied materials does not pose a risk to food safety; iv. Methods for granting approved supplier status; v. Methods and frequency of monitoring approved suppliers; vi. Details of the certificates of analysis or conformance if required; and vii. Methods and frequency of reviewing approved supplier performance and status.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.4.4 Raw materials and services that impact finished product food safety shall meet the agreed specification (refer to 2.3.2.2) and be supplied by an approved supplier. The receipt of raw materials, processing aids, and packaging from non-approved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.4.6 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

2.4.1 Food Legislation (Mandatory)

Operations and Quality staff ensured that all finished products had completed monitoring with documentation which verified that specifications, customer and regulatory requirements were met prior to release of product for shipment. Senior management and the SQF Practitioner ensured that site management and staff were kept informed of any regulatory changes, food packaging safety issues and relevant industry codes of practice via packaging industry resources. SQFI and the CB were listed as essential contacts to be notified in writing within 24 hours in the event of a regulatory warning.

2.4.1.1 The site shall ensure that, at the time of delivery to customers, finished products shall comply with food safety legislation applicable to the country of manufacture and sale. This includes compliance with legislative requirements applicable to food safety, packaging, product descriptions, 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)

Established GMPs as outlined in Module 13 of the Code for the manufacture of food packaging which were applicable to the scope of certification were observed to effectively describe how safety of manufacturing food packaging was controlled. The practices were observed to be satisfactorily implemented and documented.

2.4.2.1 The site shall ensure the applicable Good Manufacturing Practices described in Module 13 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)

Two food packaging safety plans were established, developed per Codex HACCP guidelines. The plans were observed to be complete with hazard analysis for all raw materials, all steps within the processes and process flow diagrams. There were no CCPs defined for either of the plans, which were defined as follows: Plan #1-Converted Casings; Plan #2- . Operators conducted in-process checks; QA conducted checks of finished products. The HACCP team was established and was responsible for development, implementation, review and validation of the plans. The plans were reviewed and re-validated annually or whenever changes were required. Records of the reviews and validation of the plans were maintained with the most recent reviews documented 8/30/2021.

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented, 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.4 Product descriptions shall be developed and documented for all food sector packaging included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.2.8) plus any additional information relevant to product safety such as water vapor transmission rate and gas permeability and the intended and potential alternative uses of each. This shall include requirements for further processing, if applicable.

RESPONSE: COMPLIANT

2.4.3.5 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 to cover all stages and hours of operation.

RESPONSE: COMPLIANT

2.4.3.6 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

2.4.3.7 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

2.4.3.8 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

2.4.3.9 Based on the results of the hazard analysis (refer to 2.4.3.7), 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

2.4.3.10 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate 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 2.5.1.1).

RESPONSE: COMPLIANT

2.4.3.11 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency.

RESPONSE: COMPLIANT

2.4.3.12 The food safety team shall develop and document deviation procedures that identify the disposition of affected food sector packaging material 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 food safety failure.

RESPONSE: COMPLIANT

2.4.3.13 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4 Product Sampling, Inspection and Analysis

There was no on-site laboratory. Visual quality checks of all raw materials were conducted upon receipt by warehouse/receiving and quality staff prior to use and for all finished products on the lines. There were no raw material samples received or maintained; finished product samples were maintained for alginate gel products only. Records of quality checks and inspections were maintained and reviewed for the following dates: 12/15-17/2020, 3/1-3/2021, 6/9-11/2021, 10/27-29/2021. Microbiological testing of the alginate gel products were conducted by an ISO 17025 certified laboratory at customer's request for Listeria sp. and soy protein; records of testing results were maintained and reviewed for the following dates and verified compliance: 4/22/2021, 6/8/2021, 9/8/2021.

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

RESPONSE: COMPLIANT

2.4.4.2 Product analyses shall be conducted to nationally recognized methods, company requirements, or alternative methods that are validated as equivalent to the nationally recognized methods. Where internal laboratories are used to conduct input, environmental, or product analysis, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025, including annual proficiency testing for staff conducting analyses. External laboratories shall be accredited to ISO/IEC 17025 or equivalent international standard and included on the site's contract service specifications list (refer to 2.3.2.7).

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: There was no on-site laboratory.

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

RESPONSE: COMPLIANT

2.4.4.5 Raw materials and finished product obtained for sampling and/or inspection shall be properly destroyed to prevent re-entry into the production process or sale to the customer.

RESPONSE: NOT APPLICABLE

EVIDENCE: There were no raw materials or finished product samples received.

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Materials and Product

The responsibility and methods outlining how non-conforming raw materials, work in progress, finished product and equipment were documented. Records were documented in the hold log. Non-conforming materials or equipment were isolated, identified, corrective action taken and managed by QA or Maintenance staff. It was documented that all personnel were to be aware of the hold and release procedures. Any product returned from a customer was to be put on hold, reviewed by authorized by QA for determination of disposition. Records of non-conforming materials were maintained and reviewed for the following dates: 12/17/2020, 12/21/2020, 3/1-3/2021, 6/7-9/2021, 10/27-28/2021.

2.4.5.1 The responsibility and methods outlining how non-conforming raw material, work-in-progress, finished product, or equipment detected during receipt, storage, manufacturing, 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; and ii. All relevant staff is aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status.

RESPONSE: COMPLIANT

2.4.5.2 Finished product returned from a customer shall be quarantined until authorized for release for use or re-shipment.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.6 Product Rework

Rework operations were managed by Operations staff and documented on work order tickets and monitored by Quality staff. Records of rework were maintained and reviewed for the following dates: 1/22/2021, 3/1/2021, 9/23/2021.

2.4.6.1 The responsibility and methods outlining how raw materials or food sector packaging product are reworked and recouped shall be documented and implemented. Rework shall be processed in a manner that does not contaminate raw materials or food sector packaging. The methods applied shall ensure: i. Reworking and recouping operations are supervised by qualified personnel; ii. Reworked and recouped product is clearly identified and traceable; iii. Each lot of reworked or recouped product is inspected or analyzed as required before release; iv. Inspections and analyses shall conform to the requirements outlined in element 2.4.4.1; v. Release of reworked and recouped product shall conform to element 2.4.7; and vi. Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

2.4.6.2 Food sector packaging that contains printed information shall be handled in a manner that prevents mixed or intermingled product.

RESPONSE: COMPLIANT

2.4.7 Product Release (Mandatory)

Operations and Quality staff verified that all finished food packaging checks were conducted and documented which confirmed that products met specifications and were acceptable for shipment. The site did not use a positive release procedure based upon product pathogen or chemical testing. Off-site warehouses were not used.

2.4.7.1 The responsibility and methods for releasing finished product shall be documented and implemented. Methods shall ensure product is released by designated personnel only after disposition activities show that product is acceptable for release and to verify legislative and food safety compliance have been met.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

A risk assessment for all processes had been conducted for concerns of Genus Listeria sp. and Salmonella. An EM program was established with defined methods, schedule and corrective actions for monthly testing for presence of both organisms for zones 2-4. Testing was conducted by an external ISO 17025 certified laboratory. Results were maintained, reviewed and observed to be compliant for the following dates: 1/7/2020, 4/12/2021, 10/10/2021. Annual air quality testing was also conducted for Yeast and Mold; results were documented 9/10/2021 and verified compliant.

2.4.8.1 A risk assessment for all processes shall be conducted against known or expected concerns to identify if an environmental monitoring program is necessary. If the program is required, all requirements of environmental monitoring shall be applied (2.4.8.2, 2.4.8.3, 2.4.8.4).

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 any applicable pathogens or indicator organisms to test for that industry (i.e., Bacillus spp. in paper or paper products), 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 SQF Practitioner and food safety team were responsible for ensuring that validations of HACCP plans and GMPs were completed at least annually or when changes to processes or procedures occurred. Records of validations were maintained and reviewed as follows: HACCP plans- 8/30/2021; GMPs-2/16/2021.

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

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

A verification and validation schedule was developed and implemented which included the frequency of verification activities, person responsible for monitoring each activity relevant to food packaging safety controls and GMPs. Records of the verifications of monitoring were maintained and reviewed as follows for the following dates: quality line checks, shirred tube length, pH, Brix for alginate gel-12/15-17/2020, 3/1-3/2021, 6/9-11/2021, 10/27-29/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

Methods and responsibilities for managing corrective and preventative actions were documented. The SQF Practitioner was responsible for ensuring methods of corrective actions, verification, identification of root cause and resolution of food packaging safety limits and deviations were implemented and documented. Records of investigation, root cause analysis and resolution of non-conformances and their corrections and preventative actions were maintained and were reviewed for the following dates: 12/4/2020, 4/7/2021, 7/16/2021, 10/20/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4 Internal Audits and Inspections (Mandatory)

An internal audit program was established and implemented to ensure the effectiveness of the SQF System. Monthly internal facility audits were performed of all interior, exterior and grounds of the premises by the SQF Practitioner and other staff trained in internal audit procedures. Results of audits and corrective actions were documented and communicated to senior management during the documented monthly food safety and quality updates. Staff conducting the audits were independent of the function being audited. Changes implemented from the internal audits that impact the site's ability to deliver safe packaging products would require a review of the SQF System. Records of audits and their corrective actions were reviewed for the following dates: 12/29/2020, 3/23/2021, 6/30/2021, 10/27/2021. SQF internal audits were documented 11/20/2020, 3/21/201, 7/12/2021, 9/28/2021.

2.5.4.1 An internal audit program shall be established to verify the implementation and effectiveness of all applicable requirements of the SQF Food Safety System. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure: i. All applicable requirements of The SQF Food Safety Code: Manufacture of Food Packaging are audited; ii. Corrective and preventative 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.1 Product Identification (Mandatory)

Methods and responsibility for ensuring identification of food packaging were defined. Raw materials were identified upon receipt and during all stages of the manufacturing processes via work order number. All finished goods were identified by work order #, lot #, computer generated label and date.

2.6.1.1 The methods and responsibility for identifying raw materials, packaging, and finished products during all stages of production and storage shall be documented and implemented. The identification system shall be implemented to ensure: i. Raw and packaging materials, work-in-progress, process inputs, recycled materials, 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, where applicable, and/or regulatory requirements.

RESPONSE: COMPLIANT

2.6.1.2 Product start-up and changeover procedures during manufacture of food sector packaging shall be documented and implemented to ensure that the correct product information is applied or labeled and that the changeover is inspected and approved by an authorized person. Product identification records shall be maintained.

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

A trace procedure was written and implemented. The effectiveness of the system was reviewed and tested at least annually. A traceability exercise (one up and one back) was conducted during this Re-Certification Audit. The finished product traced was clear Size 10 Fibrous Shirred Casing, Work Order #172055, Item # F120623, converted 10/1/2021 with finished lot # 004744284 through 0047442297. Records verified that 22,348 ft of casings were converted (15 cases); all 15 cases were shipped 10/4/2021.The facility was able to trace 100 % of the product within 50 minutes. Records of raw material inputs (fibrous roll) and primary packaging (Clear Polyethylene bags) receipt, use, declaration of conformity and letters of guarantee for the fibrous roll and primary packaging, respectively, were reviewed. Records of suppliers' GFSI certificates were available for review.

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 (minimum one step forward) and provides traceability through the process to the supplier and date of receipt of raw materials, auxiliary packaging, processing aids, and other inputs (minimum one step back); ii. Traceability is maintained where product is reworked (refer to 2.4.6); and iii. The effectiveness of the product trace system is tested and documented at least annually as part of the product recall and withdrawal review (refer to 2.6.3.1). Records of raw and auxiliary packaging material receipt and use and finished product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

Product recall procedures were established and documented in the product recall program. Senior management was responsible for initiating a product recall or withdrawal. The program was reviewed and tested at least annually via a mock recall. The most recent mock recall was conducted 2/12/2021. The product tested was Nippi Collagen Casings, processed 1/7/2021, Sales Order #2155430. The roll was received 2/9/2021. Records reviewed verified that 1,166,400 meters were received; 842,400 meters were produced. The remaining casings were in inventory. The site was able to trace 100% with completion of the exercise within 1 hour-52 minutes. There was no documentation of real finished packaging product recall or withdrawal.

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 coordinating, managing, and investigating a product withdrawal or recall with customers; ii. Describe the procedures to be implemented by site management, including sources of legal, regulatory, and expert advice; 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; and iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are 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 The withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum one step back) and finished product (minimum one step forward). Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.4 Crisis Management Planning

A crisis management plan was documented. A trained crisis management team and controls were documented to ensure safety of food packaging and verification of acceptability of product prior to release. Senior management was responsible for decision-making and external communications with authorities and the media. The plan was reviewed and tested annually. The plan contained a list of essential organizations and legal counsel. A record of the review and most recent test of the plan was dated 7/13/2021. The test involved an actual power outage event which resulted in shutdown of the site for one shift.

2.6.4.1 A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, pandemic, or other severe weather or regional events such as warfare, civil unrest, or pandemic) that can impact the site's ability to deliver safe food sector packaging shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include 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 sector packaging prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.

RESPONSE: COMPLIANT

2.6.4.2 The crisis management plan shall be reviewed, tested, and verified at least annually. Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

A food security/defense program was documented and reviewed 9/27/2021. The QA Manager/SQF Practitioner was assigned as the coordinator. A vulnerability assessment and prevention plan were established and implemented. All employees had received food security/defense training, 11/1/2021. The program was reviewed and tested at least annually or when the level of threat changed. Records of the reviews, vulnerability assessment were maintained, dated 9/18/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.2 Food Fraud (Mandatory)

The food fraud plan was established and site vulnerability assessment conducted for each step in the process and for all raw materials. The food fraud plan and mitigation plan were reviewed and verified by the food safety team, including senior site management, annually. Instruction and training had been provided to all staff regarding implementation of the food fraud mitigation plan. The most recent review of the plan, raw material risk assessment and mitigation strategies was documented 9/22/2021.

2.7.2.1 The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud shall be implemented and maintained. A food fraud vulnerability assessment shall be conducted to identify the site's susceptibility to substitution, mislabeling, and counterfeiting of raw materials and finished product that may adversely impact the food safety of the product.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.8.1 Allergen Management (Mandatory)

The site had a written policy that stated that allergen ingredients and products were not received or stored for processing and manufacture of food packaging products. An annual review of all approved suppliers was documented to ensure that no there were no changes in raw materials supplied and that all materials met FDA requirements for food packaging. Letters of guarantee and certificates of conformance were provided for all raw materials received. The policy addressed mitigation of introduction of unintended allergens through the approved supplier program, contract food vendors, employee and visitor GMP training. Allergen training for all employees was documented: 11/1/2021.

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating food sector packaging shall be documented and implemented. The allergen management program shall include: i. A detailed risk analysis and assessment of workplace-related food allergens, raw materials, printed packaging, and/or processing aids, including food grade lubricants, that may contain food allergens or food allergen statements; ii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination if known; iii. A list of allergens that is accessible by relevant staff; iv. The food safety hazards associated with allergens and their control incorporated into the food packaging safety plan; v. A management plan for control of identified allergens; vi. Cleaning and sanitation of product contact surfaces between line changeovers is effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces; and vii. Based on the risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used is effectively implemented.

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 the identification, handling, storage, and segregation of materials containing allergens.

RESPONSE: COMPLIANT

2.8.1.3 Sites that do not handle allergenic materials shall document, implement, and maintain an allergen management program that addresses at a minimum the mitigation of introduced unintended allergens through supplier, contract manufacturer, employee, and visitor activities.

RESPONSE: COMPLIANT

2.9.1 Training Requirements

Procedures were established which outlined responsibilities for ensuring conduct of the food packaging safety training requirements for site personnel. Training was provided to all employees with tasks essential to the effective implementation of the SQF System, food packaging safety and regulatory requirements. SQF training was documented 11/1/2021.

2.9.1.1 The responsibility for establishing and implementing the training needs of the site's personnel to ensure they have the required competencies to carry out functions affecting the manufacture of safe food sector packaging and regulatory compliance shall be defined and documented (refer to 2.1.1.6).

RESPONSE: COMPLIANT

2.9.1.2 Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

Training procedures were documented which outlined required competencies for specific tasks and training for those employees with responsibilities associated with GMP programs, regulatory requirements, the HACCP plan and the SQF System. Training materials and delivery of training were provided in languages understood by all employees. Records of topics of training, which included HACCP, GMPs, Allergen control, as required by the SQF Code were maintained and reviewed. The written training program included a provision for refresher training. Verification of the trainee competence was documented and reviewed each of the topics of training. Training records were reviewed as follows: SQF, GMPs, HACCP- completed 11/1/2021. Refresher training- 3/29/2021, 4/21/2021, 5/13/2021, 10/26/2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.1.1 Premises Location and Approval

The site environment and local activities were monitored and included in the monthly internal facility audits to ensure that any risks to product safety would be identified and properly controlled; documentation was maintained and reviewed. It was verified by review of application that the facility had renewed registration and was in compliance with the FDA Bio-Terrorism regulation, valid until 12/31/2022. A Kosher Certificate was maintained for the alginate gel casing, fibrous and plastic casings, valid until 6/30/2022. A Halal Certificate was on file for the alginate gel casing only, valid until 12/31/2021.

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

RESPONSE: COMPLIANT

13.1.2 Building Materials

Minor non-conformance: Large cracks on painted surfaces of the ceiling around the base of the roof drain pipe and signs of previous leaks were observed in the printing room near press #5. Floors and floor drains in the facility were observed to be adequately designed to achieve drainage and to be easily cleaned. Walls, other ceilings, wall to floor junctions, doors and structural areas were observed to be satisfactorily designed, in good condition and easily cleaned. No waste trap system was observed on the premises. Windows were of shatterproof material. Doors were observed to be of solid construction.

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

RESPONSE: COMPLIANT

13.1.2.2 Drains shall be constructed and located so they can be easily cleaned and do not present a food safety hazard.

RESPONSE: COMPLIANT

13.1.2.3 Waste trap system shall be located sufficiently far away from any food sector packaging handling area or entrance to the premises to prevent contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: No waste trap was observed on the premises.

13.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction.

RESPONSE: MINOR

EVIDENCE: Large cracks on painted surfaces of the ceiling around the base of the roof drain pipe and signs of previous leaks were observed in the printing room near press #5.

ROOT CAUSE: After looking into the issue, it appears that there were no cracks in the pipe itself but the paint was peeling. Checking of pipes has been added to the regular auditing intervals.

CORRECTIVE ACTION: Maintenance team has sanded the area down and repainted the surface. It is added in the monthly Audit to monitor.

VERIFICATION OF CLOSEOUT: Reviewed the photograph of the corrective action and signs of previous leaks.

COMPLETION DATE: 11/19/2021 **CLOSEOUT DATE:** 11/30/2021

13.1.2.5 In food sector packaging manufacturing, handling, and storage areas, wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of debris.

RESPONSE: COMPLIANT

13.1.2.6 In food sector packaging manufacturing, handling, and storage areas, doors shall be of solid construction and windows shall be of shatterproof glass or similar material.

RESPONSE: COMPLIANT

13.1.3 Lightings and Light Fittings

Lighting in food packaging manufacturing and storage areas was observed to be of adequate intensity; satisfactory for employees to perform their tasks efficiently. Lights were observed to be properly protected with covers or shattershields throughout all areas of the facility.

13.1.3.1 Lighting in food sector packaging manufacturing, handling, and storage areas shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

RESPONSE: COMPLIANT

13.1.3.2 Light fittings in food sector packaging manufacturing, handling, and storage areas shall be shatterproof, manufactured with a shatterproof covering, or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fixtures cannot be recessed, structures shall be protected from accidental breakage, manufactured from cleanable materials, and included in the cleaning and sanitation program.

RESPONSE: COMPLIANT

13.1.3.3 Light fittings in areas where the product is stored shall be designed to prevent product contamination.

RESPONSE: COMPLIANT

13.1.4 Dust, Insect, and Pest Proofing

External ventilation openings and doors were observed to be effectively sealed when closed to prevent pest entry. Dust and oil mist control systems in the manufacturing areas was effective. External doors and pedestrian doors were observed to be self-closing. Interior traps, ILTs and exterior bait stations were observed to be adequately located and did not present a contamination risk to food packaging or manufacturing equipment.

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

RESPONSE: COMPLIANT

13.1.4.2 Methods shall be in place to adequately control dust that may result from the manufacturing process.

RESPONSE: COMPLIANT

13.1.4.3 External access doors and overhead dock doors used for product, material, pedestrian, or vehicle access shall be effectively designed, maintained, and fitted with proper seals to protect against entry of dust, vermin, and other pests.

RESPONSE: COMPLIANT

13.1.4.4 Electric insect control devices, pheromone, or other traps and baits shall be located so as not to present a contamination risk to food sector packaging or manufacturing equipment. Poison rodenticide bait shall not be used inside food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.1.5 Ventilation

Ventilation in the manufacturing and packaging handling areas was satisfactory. However, excessive fumes were evident in the press rooms; ventilation in the two adjoining rooms did not appear to be adequate.

13.1.5.1 Adequate ventilation shall be provided in enclosed packaging manufacture and handling areas.

RESPONSE: COMPLIANT

13.1.6 Equipment and Utensils

Specifications for new equipment were reviewed and documented to ensure that it was acceptable for the tasks. Equipment and utensils were observed to be adequately designed for their intended purposes, installed and maintained to prevent a contamination threat to food packaging. Equipment was observed to be in good operational condition. Tools and utensils were made of acceptable materials. Forklifts used did not appear to pose a food packaging hazard. Non-conforming equipment was observed to be adequately identified and tagged or segregated for repair. Food packaging contact surfaces were observed to be constructed of materials that did not appear to contribute to a contamination risk to the manufacture of food packaging materials.

13.1.6.1 Specifications for new equipment and procedures for purchasing equipment to ensure it is appropriate for the task shall be documented and implemented.

RESPONSE: COMPLIANT

13.1.6.2 Equipment shall be designed, constructed, installed, operated, and maintained so as not to pose a contamination threat to food sector packaging and to allow for cleaning beneath and behind it. Tools, utensils, and containers used for handling raw materials or packaging, work-in-progress, and food sector packaging shall be made of foodsafe materials.

RESPONSE: COMPLIANT

13.1.6.3 Vehicles used in food sector packaging manufacturing, handling, or storage areas shall be designed and operated so as not to present a food safety hazard.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.1.6.5 In sites where food sector packaging is manufactured, product contact surfaces shall be constructed of materials that will not contribute to a food safety risk to the manufacture of packaging materials.

RESPONSE: COMPLIANT

13.1.7 Grounds and Roadways

The grounds and external areas of the site were observed to be clean and free of any debris. They were included in the monthly internal facility audits, which were documented and reviewed. The roadways, paths, loading and unloading areas were observed to have pooled water in some areas and large holes from broken asphalt surfaces. Site management had made plans to complete repairs by a contractor by the end of the year. Paths and roadways leading to the site entrances were observed to be satisfactorily sealed and in good condition.

13.1.7.1 The external grounds and areas surrounding the premises, including external storage buildings, machinery, and equipment shall be maintained to prevent accumulated debris and waste and control vegetation. These areas shall be inspected routinely to ensure they will not attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.2.1 Repairs and Maintenance

Minor non-conformance: The following temporary equipment adjustments or repairs and conditions were observed: (1) Taped cardboard used as a table surface on 3 areas of press #5; (2) The heater hose was stored on the floor behind press #5; (3) Tape hanging on the hand clipper #2 and string, loose tape on hand clipper #3. A PM program was written which outlined methods and responsibilities for implementation of maintenance and repair of the building structure and equipment. Manufacturing and packaging equipment were observed to be in satisfactory operational condition. Documentation of plant or equipment deficiencies was maintained and reviewed. A work order system was used for completing scheduled and emergency equipment repairs. Food grade lubricants were used in food contact zones, where required. Maintenance staff and supervision were informed if repairs presented potential threat to food packaging from foreign objects. Maintenance repairs were conducted during production or line downtimes. Paint on structural surfaces in packaging manufacturing and product handling areas were observed to be in good condition.

13.2.1.1 The methods and responsibility for the maintenance and repair of the facility, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of contamination of food sector packaging material or equipment.

RESPONSE: COMPLIANT

13.2.1.2 Routine maintenance of the equipment in any food sector packaging manufacturing, handling, or storage area shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall include the building, equipment, vehicles, and other areas of the premises critical to the maintenance of food safety.

RESPONSE: COMPLIANT

13.2.1.3 Equipment failures shall be documented, and repair activities shall be incorporated into the maintenance schedule.

RESPONSE: COMPLIANT

13.2.1.4 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any food sector packaging manufacturing, handling, or storage area.

RESPONSE: COMPLIANT

13.2.1.5 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to food safety from foreign objects or contaminants (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside manufacturing times.

RESPONSE: COMPLIANT

13.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and 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: MINOR

EVIDENCE: The following temporary equipment adjustments or repairs and conditions were observed: (1) Taped cardboard used as a table surface on 3 areas of press #5; (2) The heater hose was stored on the floor behind press #5; (3) Tape hanging on the hand clipper #2 and string, loose tape on hand clipper #3.

ROOT CAUSE: After looking into the issue: (1) It is observed that the press operators had the cardboard in that location to hold the ink buckets and samples. There was no need to place the ink buckets on the cardboard. Instead, they can be placed on the table that is designated. (2) As there was no clamp to attach the hose, it was left on the floor (3) The tape and string was placed on the machine for the operator's convenience even though it was not needed. The machine later ran without any tape and string and produced quality product

CORRECTIVE ACTION: (1) Cardboard taped has been removed from press staging area. (2) A clamp was attached to the machine so the heater hose is placed there instead of leaving on the floor (3)Tape and string has been removed from the hand clipper machines

VERIFICATION OF CLOSEOUT: Reviewed the photographs of the temporary equipment fixes, removal of cardboard and tape as noted.

COMPLETION DATE: 11/09/2021 **CLOSEOUT DATE:** 11/30/2021

13.2.1.7 Equipment located over raw or packaging materials, food sector packaging, or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product. Machinery lubricant controls shall be in place to prevent contamination of food sector packaging from gear box oils, bearing lubricants, hydraulics, or any other source.

RESPONSE: COMPLIANT

13.2.1.8 Paint used in food sector packaging manufacturing, handling, and storage areas and product contact zones shall be suitable for use, intact, and free of chips and shall not be used on any food contact surfaces.

RESPONSE: COMPLIANT

13.2.2 Maintenance Staff and Contractors

Maintenance staff and contractors who entered the site were required to complete training in GMP and hygiene procedures. If required, contractors were to be escorted at all times while on the premises until completion of the work. Accountability of tools and parts used during maintenance activities and cleaning/sanitizing of food processing contact zones were documented on the work order forms, which were reviewed and verified by departmental supervision. Records were maintained and reviewed. Pre-op inspections were performed by Operations and QA prior to start-up of processing activities.

13.2.2.1 Maintenance staff and contractors shall comply with the site's personnel hygiene requirements (refer to 13.3.4).

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.2.2.3 Maintenance staff and contractors shall remove all tools, parts, and debris from areas where maintenance and repairs were conducted once it has been completed. They shall inform the appropriate supervisor so that hygiene and sanitation actions and a pre-operational inspection can be conducted prior to the restarting of operations.

RESPONSE: COMPLIANT

13.2.3 Calibration

Calibration procedures and schedules were established for scales, metal detector for the gel process, refractometer and thermometers. Calibrations were performed per manufacturers' recommendations. A directory of equipment requiring calibration was maintained and records of calibrations, which were performed by QA personnel or certified third parties against national reference standards and methods. Scales were calibrated twice annually and were reviewed for the dates 1/12/2021, 9/21/2021; Metal detector- annually, 12/28/2020; Refractometer-10/28/2021.

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

RESPONSE: COMPLIANT

13.2.3.2 Procedures shall be documented and implemented to address the resolution of potentially affected food sector packaging should measuring, testing, and inspection equipment be found to be out of calibration state.

RESPONSE: COMPLIANT

13.2.3.3 Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.2.3.6 A directory of measuring, testing, and inspection equipment requiring calibration and records of calibration tests shall be maintained.

RESPONSE: COMPLIANT

13.2.4 Pest Prevention

Minor non-conformance: All exterior rodent bait stations observed were filled with debris and cobwebs and required fresh bait. The station at the front dock was also not numbered. Written pest prevention procedures for implementation of an integrated pest management program were established. The program was administered by a certified PCO. The written program and procedures outlined methods for pest management for the premises were observed to meet the requirements of the SQF Pest Prevention Code; however, the condition of exterior devices was not compliant with the procedures. Records of site inspections were reviewed for the following dates: 9/18/2020, 1/15/2021, 4/9/2021, 6/4/2021. Pesticides were not observed or stored on the premises. Animals were not permitted in the food processing, food handling and storage areas per the internal pest prevention procedure. Other chemicals used for cleaning, sanitation and maintenance activities were observed to be properly labeled, securely stored and managed by trained personnel per 13.6.2.

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

RESPONSE: COMPLIANT

13.2.4.2 Pest contractors and/or internal pest controllers shall: i. Be licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.2.7) that includes a site map indicating the location of bait stations, traps, and other applicable pest control monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; vi. Provide regular inspections for pest activity with appropriate action taken if pests are present; and vii. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: All exterior rodent bait stations observed were filled with debris and cobwebs and required fresh bait. The station at the front dock was also not numbered.

ROOT CAUSE: After discussing with the pest control agency, It appears that the associate coming from Mccloud services was not performing his job as needed and he is no longer with their company.

CORRECTIVE ACTION: Pest Control Agency was contacted to ensure the service is being provided as needed and communicated this SQF non conformance. Pest Control Operator has cleaned all the bait stations immediately

VERIFICATION OF CLOSEOUT: Reviewed the photographs of the cleaned bait stations with fresh bait.

COMPLETION DATE: 11/12/2021 **CLOSEOUT DATE:** 11/30/2021

13.2.4.4 Raw materials or packaging, processing aids, work-in-progress, or food sector packaging that is found to be contaminated by pest activity shall be effectively disposed of and the source of pest infestation investigated and resolved.

RESPONSE: COMPLIANT

13.2.4.5 Pesticides shall be clearly labeled and stored per 13.6.2 if kept on-site.

RESPONSE: NOT APPLICABLE

EVIDENCE: Pesticides were not observed or stored on the premises.

13.2.4.6 No animals shall be permitted on-site in food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.2.5 Cleaning and Sanitation

Minor non-conformance: The following conditions were observed which impacted the cleaning program: (1) Spillage of a white powdered substance and damaged broken pallet splinters around the non-soy lecithin drums in the warehouse; (2) Heavy dust accumulation on idle equipment in the receiving/shipping area, debris on the perimeter at the shrink-wrapper in this area; (3) White substance in corners and on stored items in press room #6; (4) Oil/water accumulations on the white overhead pipe above spiral #4 in the shirring room; (5) A product transfer hose was stored on the floor in the solution make-up area- (This was a potential source of product contamination if the integrity of the hose was compromised). A master cleaning schedule of all areas and processing equipment, utensils, staff amenities and structural areas within the site was established with defined frequencies for cleaning tasks. Pre-op inspections were conducted at the beginning of each production shift and at product change-overs. Equipment in the alginate gel process was cleaned and sanitized after every batch. Visual inspections were conducted after detailed equipment cleaning. ATP swabbing was conducted to verify effectiveness of cleaning within the alginate and dry processes A pre-op inspection and swabbing activity was reviewed in the alginate gel casing room during the audit; of all areas swabbed, one area failed , which was the seal under the cover of the chopper. The seal was loose and required replacement. Records of documented cleaning, ATP swabbing and pre-op checks were maintained and reviewed for the following dates: 12/15-17/2020, 3/1-3/2021, 6/9-11/2021, 10/27-29/2021.

13.2.5.1 The methods and responsibility for the effective cleaning of food sector packaging manufacturing, handling and storage areas, and staff amenities shall be documented and implemented.

RESPONSE: MINOR

EVIDENCE: The following conditions were observed which impacted the cleaning program: (1) Spillage of a white powdered substance and damaged broken pallet splinters around the non-soy lecithin drums in the warehouse; (2) Heavy dust accumulation on idle equipment in the receiving/shipping area, debris on the perimeter at the shrink-wrapper in this area; (3) White substance in corners and on stored items in press room #6; (4) Oil/water accumulations on the white overhead pipe above spiral #4 in the shirring room; (5) A product transfer hose was stored on the floor in the solution make-up area- (This was a potential source of product contamination if the integrity of the hose was compromised).

ROOT CAUSE: (1) It appears that the pallet was just moved in that location and the warehouse personnel were going to clean up the area. There as a leak from one of the bag of ingredients and QA has discarded that bag. (2) The equipment was on the sale and some of the outside contractors has been looking to buy the machine. As a part to show the machine, the plastic bag was removed which in fact caused the dust/debris (3) Press room runs with powder to eliminate bad printing. As the machine runs with powder, it is accumulated on the floor. They get cleaned up at the end of the day and on weekly basis. (4) The accumulation on the white overhead pipes were observed to be condensation due to difference in temperature of the water inside the pipe versus the outside temperature. (5) It was the understanding that the hose ends shall not touch the ground but none of the employees had knowledge on the complete hoses not touching the floor.

CORRECTIVE ACTION: (1) Spillage of a white powdered substance and damaged broken pallet splinters around the non soy lecithin drums in the warehouse has been cleaned (2) Heavy dust accumulation on idle equipment in the receiving/shipping area has been cleaned and covered with plastic (3) White substance around the corners and on stored items in the press room has been cleaned and maintained (4) Oil/water accumulations on the white overhead pipe above spiral 4 in the shirring area has been cleaned (5) The product transfer hoses in the solution make up area are taken off the floor. A stand was made to place the hoses on so they don't touch the floor

VERIFICATION OF CLOSEOUT: Reviewed the photographs of all cleaned areas noted as corrective actions.

COMPLETION DATE: 11/21/2021 **CLOSEOUT DATE:** 11/30/2021

13.2.5.2 Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of food sector packaging manufacturing, handling, and storage areas and equipment.

RESPONSE: COMPLIANT

13.2.5.3 Adjacent production equipment shall be covered or shut down and raw and packaging materials, work-in-progress, and food sector packaging shall be moved from the vicinity if using compressed air hoses to clean.

RESPONSE: COMPLIANT

13.2.5.4 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure manufacturing areas, product contact surfaces, equipment, staff amenities, and other essential areas are clean before the start of production. Inspections shall be conducted by qualified personnel to ensure the areas are cleaned at a defined frequency.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.2.5.6 Appropriate cleaning agents shall be purchased in accordance with applicable legislation and suitable for use. The site shall ensure that only trained staff handle cleaning agents and that it is according to manufacturer instructions. Documentation, storage, usage, and disposal of cleaning agents shall comply with 13.6.2.

RESPONSE: COMPLIANT

13.3.1 Personnel Welfare

Minor non-conformance: Written medical screening procedures were not available for review for employees, visitors and contractors who handled exposed product or food packaging contact surfaces. A GMP policy was documented and implemented which required that personnel were prohibited from entering and working in food packaging manufacturing and handling areas if they were suffering from known infectious or communicable diseases. Minor cuts were to be covered with a colored metal detectable bandage. Trained staff management was responsible for ensuring adequate clean-up and disposal of any affected materials from spillages of bodily fluids in the event of injury.

13.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others on-site shall not engage in the manufacture of food sector packaging or enter areas where food sector packaging is exposed. Code Amendment #1 A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: MINOR

EVIDENCE: Written medical screening procedures were not available for review for employees, visitors and contractors who handled exposed product or food packaging contact surfaces.

ROOT CAUSE: The procedure was not in place as the amendment was recently implemented and due to the lack of understanding the amendment

CORRECTIVE ACTION: A medical screening program has been written and implemented throughout the company. It is also posted in the entrance for all visitors and contractors to implement

VERIFICATION OF CLOSEOUT: Reviewed the developed medical screening procedure dated 11/29/2021, to comply with the SQF Code Amendment, effective 10/4/2021.

COMPLETION DATE: 11/29/2021 **CLOSEOUT DATE:** 11/30/2021

13.3.1.2 The site shall have measures in place to prevent contact of raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury that causes spillage of bodily fluid, a properly trained employee shall ensure that all affected areas have been adequately cleaned and that all affected materials have been quarantined and/or disposed of.

RESPONSE: COMPLIANT

13.3.1.3 Personnel with exposed cuts, sores, or lesions shall not engage in handling raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal-detectable strip or an alternative suitable waterproof and colored dressing.

RESPONSE: COMPLIANT

13.3.2 Handwashing

The written GMP policy outlined handwashing requirements. Hands-free washing station, and sinks, soap and sanitizer, potable water at acceptable temperatures and disposable paper towels were provided at entry to the food packaging manufacturing area. Hand sanitizing stations were located in designated areas throughout the manufacturing, material handling and packaging areas. Signs were posted instructing people to wash their hands before entering food packaging manufacturing and handling areas. Employees were observed to be compliant with hand washing practices and glove use.

13.3.2.1 Personnel shall have clean hands, and hands shall be washed by all personnel, including staff, contractors, and visitors: i. On entering production areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating, or drinking; and v. After handling waste or chemicals.

RESPONSE: COMPLIANT

13.3.2.2 Handwash stations shall be provided in appropriate areas that support the capability of site personnel and visitors to wash their hands as outlined in 13.3.2.3.

RESPONSE: COMPLIANT

13.3.2.3 Handwash stations shall have: i. Basins constructed of stainless steel or similar non-corrosive material; ii. A potable water supply at an appropriate temperature; iii. Liquid hand soap within a fixed dispenser; iv. Paper towels or effective hand dryer; and v. A means of containing used paper towels.

RESPONSE: COMPLIANT

13.3.2.4 Signage in appropriate languages instructing people to wash their hands before entering the food sector packaging manufacturing, handling, and storage areas shall be provided in a prominent position in break rooms, at break rooms exits, toilet rooms, and in outside eating areas if applicable.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.3.3 Clothing and Personal Effects

Procedures were established which outlined requirements for clothing and hair restraints. All employees were required to wear hair nets and beard nets for facial hair. Employees wore company-issued shirts or red aprons. Hooks were provided for temporary storage. Staff clothing and gloves used for product packaging handling were observed to be clean and acceptable at the beginning of the shift. Employees were observed to be compliant with use of jewelry. There were no documented or observed exceptions to the jewelry or clothing policy.

13.3.3.1 The site shall have a clothing and hair policy that protects raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces from unintentional contamination.

RESPONSE: COMPLIANT

13.3.3.2 Clothing worn by staff engaged in handling food sector packaging shall be maintained, stored, laundered, and worn so as not to present a contamination risk to products.

RESPONSE: COMPLIANT

13.3.3.3 Clothing worn by staff engaged in manufacturing and warehouse processes shall be made from materials that will not contaminate raw and packaging materials, workin-progress, and food sector packaging. Clothing and shoes shall be clean at the commencement of each shift, maintained in a serviceable condition, and changed where they present a product contamination risk.

RESPONSE: COMPLIANT

13.3.3.4 When protective clothing (e.g. frocks, smocks, aprons, boots, gloves, face shields, etc.) is used, hooks racks, cabinets, or other forms of off the floor storage shall be provided for temporary storage when staff leave the manufacturing area and shall be provided in close proximity or adjacent to the personnel access doors and handwashing stations. All clothing stored on-site shall be maintained and stored so as not to present a contamination risk to raw or packaging materials, work-in-progress, and food sector packaging.

RESPONSE: COMPLIANT

13.3.3.5 Gloves used when handling food sector packaging material shall be clean and replaced when needed.

RESPONSE: COMPLIANT

13.3.3.6 Jewelry and other loose objects shall not be worn or taken into any area where raw and packaging materials, work-in-progress, or food sector packaging is exposed. Wearing plain bands with no stones and medical alert bracelets that cannot be removed can be permitted; however, the site will need to consider their customer requirements and the applicable food legislation.

RESPONSE: COMPLIANT

13.3.3.7 All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.

RESPONSE: COMPLIANT

13.3.4 Visitors

All visitors were trained in the site's GMP policy and were required to comply with the hygiene requirements upon entry into the facility, prior to entering the food packaging manufacturing, product handling and storage areas. Visitors were required to be escorted at all times while within the facility. Personnel practices for all visitors included compliance with handwashing requirements. They were required to comply with use of designated entry and exit points, use of suitable clothing and footwear if entering food manufacturing or handling areas. Visitors who exhibited any signs of illness were not allowed to enter any area where food was processed or handled.

13.3.4.1 All visitors shall be trained in, and comply with, applicable food safety and hygiene procedures before entering food sector packaging manufacturing, handling, or storage areas. Visitors shall be trained in, and comply with, additional food safety policies, such as maintenance and cleaning procedures, as appropriate to the purpose of the visit. Where applicable, policies shall define exceptions for visitors when they are escorted at all times.

RESPONSE: COMPLIANT

13.3.4.2 All visitors shall wear suitable clothing and footwear when entering any food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.3.4.3 Visitors shall enter and exit food sector packaging manufacturing, handling, and storage areas through the designated entrance points.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.3.5 Staff Amenities (change rooms, toilets, break rooms)

Cleaning schedules for employee amenities were documented in the master cleaning schedule. Lighting and ventilation in employee amenities were observed to meet the requirements of the SQF Code. Employees were not required to change clothes on site. Lockers were provided for storage of personal items. Rest rooms were observed to be adequately designed and suitable for their intended purposes, separated from food packaging manufacturing and packaging handling activities. The rest rooms were accessible, sufficient in number, easily cleaned and satisfactorily maintained. Tools and equipment used for cleaning rest rooms were not used for cleaning activities within the packaging manufacturing areas. Sanitary drainage was directed to the sewerage system. There was a written procedure which outlined methods to minimize any impact of the facility, personnel, raw and packaging materials, work in progress or finished goods from contamination in the event of a sewerage backup (Sanitation Procedure-Sewer Back-Up or Roof Leak). Hand wash sinks were provided inside all rest rooms and were observed to meet Code requirements as outlined in 13.3.2.3. The employee break room was separate from food packaging processing areas. It was observed to be clean and to meet all requirements of the SQF Code. The outside eating area was observed to be clean and satisfactorily maintained.

13.3.5.1 Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for the use of all persons engaged in the handling and storage of food sector packaging.

RESPONSE: COMPLIANT

13.3.5.2 Where applicable, facilities shall be provided to enable staff to change into and out of protective clothing as required. Provision shall be made for staff to store their street clothing and personal items separate from food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.3.5.3 Toilet rooms shall be: i. Designed and constructed so that they are separate from any food sector packaging manufacturing, handling, or storage areas; ii. Accessed from operations 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. Tools/equipment used for cleaning toilet rooms shall not be used to clean food sector packaging manufacturing areas.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.3.5.5 A procedure shall document how to minimize the potential for contamination to the premises, personnel, raw and packaging materials, work-in-progress, and food sector packaging in the event of a sewage backup.

RESPONSE: COMPLIANT

13.3.5.6 Handwash stations shall be provided immediately outside or inside the toilet room and designed as outlined in 13.3.2.3.

RESPONSE: COMPLIANT

13.3.5.7 Separate break room facilities shall be provided away from food sector packaging manufacturing, handling, or storage areas. Break rooms shall be kept clean and tidy and free from waste materials and pests.

RESPONSE: COMPLIANT

13.3.5.8 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

13.4.1 Staff Engaged in Food Handling and Processing Operations

Operations personnel were observed handling food packaging materials and in a manner which prevented damage and any potential contamination of product. All employees were required to access the processing areas through designated personnel doors; doors were observed to be properly closed when not in use. Employees were observed to be compliant with GMP requirements. The manufacturing processes were observed to be adequately controlled to prevent contamination. The flow of personnel was observed to be satisfactory to minimize the prevention of potential contamination.

13.4.1.1 All personnel engaged in food sector packaging manufacture, handling, and storage operations shall comply with the following practices: i. Personnel entry to production areas shall be through designated access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Raw and packaging materials, work-in-progress, and food sector packaging shall be maintained appropriately, kept off the floor when applicable, and handled and stored in a manner to prevent damage and contamination; and iv. Waste shall be contained in the bins identified for this purpose and removed from the manufacturing area on a regular basis and not left to accumulate.

RESPONSE: COMPLIANT

13.4.1.2 Personnel working in or visiting food sector packaging manufacturing, handling, or storage operations shall ensure that: i. Eating, drinking, smoking, or spitting is not permitted in areas where food sector packaging is manufactured, handled, stored, or exposed. ii. Drinking water is permitted in food sector packaging manufacturing, handling, and storage areas in a method that will not cause a food safety risk to raw and packaging materials, workin-progress, food sector packaging, and equipment.

RESPONSE: COMPLIANT

13.4.1.3 The manufacturing process shall be controlled such that food sector packaging is safe and free from contamination. Procedures shall be in place to prevent cross-contamination of food sector packaging from contaminated materials, cleaning agents, or chemicals.

RESPONSE: COMPLIANT

13.4.1.4 The flow of personnel in food sector packaging manufacturing, storage, and handling areas shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

13.5.1 Water Supply

Supplies of potable hot and cold water were provided by the City of Kenosha. The delivery of water within the site had backflow prevention devices installed to ensure that water was not contaminated. Non-potable water in the fire sprinkler piping system was observed to be adequately identified and controlled. Backflow prevention devices were inspected every 10 years by the City of Kenosha; the most recent inspection was maintained on file and was dated 3/16/2017. On-site water storage was not observed.

13.5.1.1 Adequate supplies of hot and cold clean water shall be provided for use during manufacturing operations as needed and to enable effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

13.5.1.2 The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained.

RESPONSE: COMPLIANT

13.5.1.3 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

13.5.1.4 Where water is stored on-site, storage facilities shall be adequately designed, constructed, and maintained to prevent contamination.

RESPONSE: COMPLIANT

13.5.2 Water Quality

Review of the 2020 annual water quality report from the City of Kenosha verified that the quality of water supplied to the site met U.S. EPA drinking water standards. Microbiological analysis of water was performed quarterly for detection of Coliforms and E. coli using national reference standards and methods by an ISO 17025 certified laboratory. Results of testing reports dated 12/10/2020, 4/2/2021 and 7/2/2021 were reviewed and were observed to be compliant.

13.5.2.1 Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards as required when used for: i. Handwashing; ii. As a raw material or processing aid; iii. Cleaning of product contact surfaces and equipment; or iv. The manufacture of steam that will come into contact with food sector packaging or used to heat water that will come into contact with food sector packaging.

RESPONSE: COMPLIANT

13.5.2.2 Microbiological analysis of the water 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 on-site at sources supplying water for the process, handwashing, and/or cleaning, or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.

RESPONSE: COMPLIANT

13.5.2.3 Water shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

13.5.3 Air and Other Gases

Compressed air used on food contact surfaces was filtered and tested for purity annually. Testing for Yeast and Mold. Results of the most recent testing dated, 9/10/2021, was reviewed and verified compliance.

13.5.3.1 Dry ice, compressed air, and other gasses (e.g., nitrogen, carbon dioxide) that contact food sector packaging or product contact surfaces shall be food-grade, clean, and present no risk to food safety.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.6.1 Storage of Materials and Product

Written storage procedures were established and outlined in Storage SOP #1641 for raw materials, packaging materials, including printing plates and finished packaging products. Materials were observed to be received into and stored in clean, dry areas within the facility. FIFO principles were utilized for storage of all materials. Equipment storage areas were observed to be adequate to facilitate inspection and cleaning. External temporary storage facilities were not used; there were no temporary overflow storage facilities used by the site for any materials or products. Effective procedures were implemented for effective storage of printing plates.

13.6.1.1 The site shall document and implement a storage plan that allows for the safe, hygienic storage of raw and packaging materials, work-in-progress, food sector packaging, finished product returns, production equipment, processing aids, and chemicals that impact food safety.

RESPONSE: COMPLIANT

13.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented to ensure that all raw materials, work-in-progress, rework, and food sector packaging are utilized within their designated shelf life, where applicable.

RESPONSE: COMPLIANT

13.6.1.3 Equipment storage rooms shall be designed and constructed to allow equipment to be stored in a hygienic manner.

RESPONSE: COMPLIANT

13.6.1.4 Where raw and packaging materials, work-in-progress, and food sector packaging are held under temporary or overflow conditions that are not designed for the safe storage of those goods, a risk analysis shall be performed to ensure the integrity of those goods is maintained, they are not at risk of contamination, and there are no other food safety concerns.

RESPONSE: COMPLIANT

13.6.1.5 Rooms and equipment used for the storage of raw and packaging materials, work-in-progress, and food sector packaging shall be constructed to protect the product from contamination and deterioration.

RESPONSE: COMPLIANT

13.6.1.6 Where required, procedures shall be in place for effective storage of printing plates, cylinders, and print blankets.

RESPONSE: COMPLIANT

13.6.2 Storage and Use of Hazardous Chemicals and Toxic Substances

Minor non-conformance: There was no spill containment in the chemical storage cage. All chemicals were observed to be in a locked well ventilated cage, properly labeled, accessible only by authorized trained personnel. Chemicals were observed to be stored in a manner to prevent cross contamination. Ventilation was satisfactory in the storage area. Disposal of waste chemicals and containers (Inks, Solvents, Waste Oils) was managed by Maintenance personnel via third party disposal contractors. All pesticides and empty pesticide containers were handled by the certified PCO only. An approved chemical list was maintained and reviewed. SDS information was maintained for the chemicals and accessible in the area for review.

13.6.2.1 Hazardous chemicals and toxic substances, including solvents and agents with the potential for contamination of food sector packaging, shall be: i. Clearly labelled, identifying and matching the contents with their containers; ii. Included in a current list of all chemicals and toxic substances that are stored on-site; and iii. Supplemented with a current Safety Data Sheet (SDS) that is made available to all staff.

RESPONSE: COMPLIANT

13.6.2.2 Storage of hazardous chemicals and toxic substances shall be: i. Located in an area with appropriate signage indicating that the area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii. Adequately ventilated; iv. Stored where intended and not comingled (e.g., food versus non-food grade); v. Designed such that there is no cross-contamination between chemicals; and vi. Stored in a manner that prevents hazards to raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.6.2.4 Employees who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals, shall: i. Be properly trained on handling and usage; ii. Be provided with first aid equipment and personnel protective equipment; and iii. Ensure compliance to the proper identification, storage, usage, disposal, and clean-up requirements as defined.

RESPONSE: COMPLIANT

13.6.2.5 The site shall dispose of obsolete inventory and empty containers of chemicals, pesticides, and toxic substances in accordance with site and regulatory requirements and ensure that: i. Single-use containers are not reused; ii. Containers are segregated and securely stored prior to collection; and iii. Containers are disposed through an appropriate vendor.

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: There was no spill containment in the chemical storage cage.

ROOT CAUSE: The drums were recently received and the code was missed to follow to implement spill containment pallets

CORRECTIVE ACTION: Spill containment pallets have been orders and placed under the chemicals

VERIFICATION OF CLOSEOUT: Reviewed photographs of the spill containment pallets placed in the chemical storage area.

COMPLETION DATE: 11/18/2021 **CLOSEOUT DATE:** 11/30/2021

13.6.3 Loading, Transport, and Unloading Practices

Loading and unloading practices observed during the audit were satisfactorily implemented in a manner to maintain food packaging integrity and to prevent cross contamination. All transport vehicles were inspected prior to loading to ensure suitability. Trailers were secured with tamper-proof seals upon completion of loading. Records of inbound and outbound trailer inspections and documentation of locks and seal placement, respectively, were maintained and reviewed for the following dates: 12/17-19/2020, 3/1-3/2021, 6/9-11/2021, 10/27-29/2021, 11/2/2021.

13.6.3.1 The practices applied during transport, loading, and unloading of raw and packaging materials and food sector packaging shall be documented and implemented. Practices shall be conducted to prevent cross-contamination, maintain appropriate storage conditions, and ensure product integrity.

RESPONSE: COMPLIANT

13.6.3.2 Vehicles (e.g., semi-trucks, trailers, vans, containers) used for transporting food sector packaging 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 food sector packaging.

RESPONSE: COMPLIANT

13.6.3.3 Vehicles (e.g. semi-trucks, trailers, vans, containers) used for transporting food sector packaging from the site shall be secured from tampering using a seal or other acceptable device or system as agreed upon by the carrier and customer.

RESPONSE: COMPLIANT

13.7.1 Control of Foreign Matter Contamination

Daily operational checks at the start of each shift and product changeovers were conducted to ensure that food packaging manufacturing and handling zones were free of potential contaminants. Wooden pallets were observed to be in good condition. An inventory of glass and brittle plastic objects was maintained and reviewed. Quarterly glass and brittle plastic inspections were conducted by Maintenance; records were maintained and reviewed for the following dates: 1/13/2021, 6/21/2021, 9/28/2021. Monthly facility inspections were conducted, documented and reviewed. Knives and cutting tools were observed to be satisfactorily controlled; no snap-off blades were observed, tools were properly maintained and did not present a hazard to raw materials or packaging. Glass utensils, tools or equipment, glass dial covers and MIG thermometers were not observed in manufacturing areas.

13.7.1.1 The responsibility and methods used to prevent foreign matter contamination of raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces shall be documented, implemented, and communicated to all staff.

RESPONSE: COMPLIANT

13.7.1.2 Inspections shall be performed to ensure that the site and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

13.7.1.3 Containers, storage and transport vessels, equipment, utensils, and tools made of glass, porcelain, ceramics, and brittle plastics shall not be permitted in food sector packaging manufacturing, handling, and storage areas. Exceptions shall include product made from, or packaged in these materials, measurement instruments with glass dial covers or MIG thermometers required under regulation or part of the processing equipment, and other essential items shielded with shatterproof coverings.

RESPONSE: COMPLIANT

13.7.1.4 Glass, porcelain, ceramics, and brittle plastics that are permitted in manufacturing areas shall be listed on a glass inventory and inspected at a frequency based on risk to confirm that they have not been damaged or to monitor for further damage prior to repair or replacement. Regular inspections of product handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or similar material and to establish changes to the condition of objects listed in the glass inventory.

RESPONSE: COMPLIANT

13.7.1.5 Wooden pallets and other wooden objects used in food sector packaging manufacturing, handling, and storage areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

13.7.1.6 Wooden pallets, wooden top frames, and wooden utensils used in food sector packaging, manufacturing, handling, and storage areas shall be dedicated for that purpose, clean, maintained in good order, and subject to regular inspection.

RESPONSE: COMPLIANT

13.7.1.7 Loose, deteriorated, or damaged objects on and above structures and equipment in food sector packaging manufacturing, handling, and storage areas shall be controlled, repaired, or replaced to prevent foreign object contamination and other food safety hazards affecting raw and packaging materials, work-in-progress, and food sector packaging.

RESPONSE: COMPLIANT

13.7.1.8 Knives and cutting tools used in manufacturing operations shall be controlled, kept clean, and well maintained so as not to present a hazard to raw materials, work-in progress, or food sector packaging. Snap-off blades shall not be used in food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.7.2 Managing Foreign Matter Contamination Incidents

In situations of glass or other similar material breakage, the affected area was to be isolated, cleaned, inspected and cleared by authorized management prior to commencement of operations. All materials used for clean-up were to be disposed.

13.7.2.1 In circumstances where glass or similar brittle material breakage occurs, the affected area and equipment shall be isolated, cleaned, and thoroughly inspected prior to restarting operations. Utensils and equipment used for clean-up and footwear of those walking in the vicinity shall be inspected and cleaned if necessary.

RESPONSE: COMPLIANT

13.8.1 Waste Disposal

Procedures and responsibilities were outlined for managing all waste generated within the site. Cardboard materials, , ink, solvents and waste oil were sent to contract recyclers. Containers used for waste collection were observed to be satisfactorily maintained. Containers were identified and removed on frequent basis during the manufacturing period. The effectiveness of waste management was included in the daily cleaning activities; documentation of results was maintained. There was a written procedure which outlined methods for managing and review of disposal of trademarked packaging materials by the disposal contractor.

13.8.1.1 The responsibility and methods used to collect, handle, and store waste prior to removal from the premises shall be documented and implemented. This shall include consideration of the path of waste removal to prevent cross contamination in food sector packaging manufacturing, handling, and storage areas. Disposal of hazardous chemicals and toxic substances shall comply with 13.6.2.5.

RESPONSE: COMPLIANT

13.8.1.2 Waste shall be contained in bins identified for its purpose, located in designated areas, and removed at a routine frequency that avoids build-up in food sector packaging, manufacturing, handling, and storage areas.

RESPONSE: COMPLIANT

13.8.1.3 Waste disposal equipment, trolleys, vehicles, and collection bins shall be maintained in a serviceable condition and cleaned regularly so as not to attract pests and other vermin. Designated waste accumulation and storage areas shall be well-maintained while awaiting external collection.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

13.8.1.5 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked or printed packaging materials and finished products. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

RESPONSE: COMPLIANT