SQF Food Safety Audit Edition 9

N.E.W. Plastics Corp - N.E.W. Plastics Corp

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
640812 | 141570

AUDIT RATING
100
Excellent

DECISION DATE
11/03/2021

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
09/30/2022

AUDIT DATES
10/13/2021 - 10/14/2021

EXPIRATION DATE
12/14/2022

ISSUE DATE
11/08/2021

Facility & Scope

N.E.W. Plastics Corp (45522)
N.E.W. Plastics Corp
112 4th Street
Luxemburg, WI 54217
United States

Web Site: http://newplastics.com

Food Sector Categories:
27. Manufacture of Food Packaging

Products:
Plastic containers.

Scope of Certification:
Manufacturer of plastic containers.

Certification Body & Audit Team

EAGLE Food Registrations, Inc.

EAGLE Food Registrations Inc.
SERVICE • INTEGRITY • VALUE

40 N Main Street
Suite 1880
Dayton, OH 45423
United States

Phone #: 937-293-2000
Email: info@eaglecertificationgroup.com
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CB#: CB-1-Eagle
Accreditation Body: ANSI
Accreditation Number: 0894

Lead Auditor: Blazy, Warren (9603)
Technical Reviewer: Cosley, Ryan (209266)
Other Members:
Blazy, Sherry (128734)

Hours Spent on Site: 16
Hours of ICT Activities: 0
Hours Spent Writing Report: 8

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Deb Devares
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** ddevares@newplastics.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Warren Blazy: Lead Auditor, Sherry Blazy: Auditor, Timothy Burhans: Production Manager, Summer Burhans: Quality Manager, Deb Devares: SQF Practitioner, Ryan Jeffers: OPS Manager, David Goessel: Controller, Dave Goblisch: H.R. Manager, Mike Rekitzke: President, Lynie Vincent: Vice President.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** N.E.W. Plastics Corporation is located in Luxemburg, WI which is just outside of Green Bay, Wi. The site consists of 73,125 sq. ft of manufacturing space and a 100,000 sq. ft off-site warehouse nearer to Green Bay. N.E.W. Plastics employs approximately 139 employees running a continuous 8 hour shifts 24/7. Shift times 7:00 -3:00, 3:00 - 11:00 and additional hours for weekend operations. The production areas are outfitted with 31 blow molding lines producing Plastic Rigid Packaging for the food, dairy, medical, and nutraceutical industries. The facility has one line that is claimed as an exemption due to customer requirements.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Warren Blazy: Lead Auditor, Sherry Blazy: Auditor, Timothy Burhans: Production Manager, Summer Burhans: Quality Manager, Deb Devares: SQF Practitioner, Ryan Jeffers: OPS Manager, Mike Rekitzke: President.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Certification can be granted.

Section Responses

2.1.1 Management Responsibility (Mandatory)

Senior management at this location has implemented a policy statement that reflects the belief in the culture of this operation. The policy statement is posted in locations where all employees are able to see it. In interviews with top management, they talked about the food culture that they have put in place in this location. Employees are empowered to stop the operation and inform management of any concerns. The policy as well as the food culture beliefs are signed by management and are enforced by management. Everyone here speaks English and that is how the statement is written. Top management at this location has communicated to all staff members their objectives in food safety as well as the food culture and resources have been put aside that allow the practitioner of this operation the ability to make any changes needed for a safe food environment. Job descriptions for all the key employees at this operation are in place and we reviewed including that top management and the practitioner as well as the backup. Top management at this location has supported the introduction of the food safety program both verbally, financially, and with their continued support and monthly meetings. Policy is signed by the President on 3/22/2021.

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 requirements for management review are defined in Doc ID: 5734 Management Review. Senior leadership conducts a review of the food safety and quality management system at least annually. The SQF Practitioner is responsible for scheduling and leading the Management Review meeting. The Management Review includes the policy manual, internal and external findings, corrective actions, customer complaints and their investigations, hazard and risk management system, continual improvement, and follow-up items from previous management review meetings. The site meets the monthly update requirement through Daily Operations meetings and Site Leadership Team meetings. The meetings are documented by the SQFP and the topics include complaints, corrective actions, etc. Records of Management Reviews are captured using Management Review Record (5735). Records of the most recent management review, conducted on 2/12/2021 meets the requirements. A large list of goals and objectives were reviewed. Monthly meets from April, May and Aug 2021, also daily meeting are held.

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)

The requirements for complaint management are defined in Customer Complaints. The Quality Department reviews complaints, assigns a classification number (class 1 or class 2) to the complaint and responds accordingly. The complaint investigation, root cause analysis, and corrective and preventive actions are documented in IQMS. Trends are analyzed throughout the year during production meetings and on an annual basis during Management Review. Records of complaints and their investigations were reviewed and met the requirements.

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 Quality – Food Safety Manual, outlines the methods that New Plastics uses to meet the requirements of the SQF Code. The manual includes the scope of the certification, the policy statement, and food safety policies. The list of products covered under the certification is included in the Quality – Food Safety Manual. The manual is available to relevant staff in IQMS. The manual references written procedures, pre-requisite programs, and the food safety plan. Any changes made to the system are validated or justified.

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)

The facility maintains document control at all levels of the organization in accordance with the procedure, Document Control. A register of documents is maintained in IQMS. Documents were sampled against the register and met the requirements.

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)

Records are maintained in accordance with regulatory and business requirements as outlined in Document and Records Control. Records are collected on the frequency defined in the Record Control Register. Many records were sampled throughout the audit. Records reviewed during the audit were legible and readily available. Details of records sampled can be found throughout the SQF report.

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

Product development activities are defined in Product Development (5746). The procedure identifies the methods and responsibilities for designing, developing and converting concepts to commercial realization. A Product Initiation Form (PIF) is used to assess a new material or idea and includes the review of: shelf life, approved supplier, raw materials, & the HACCP Plan. Once the PIF is completed, an Engineering Change Order (ECO) steers the product development process. The food safety plan is validated any time a new product or material is used. The site does not print materials.

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)

This operation has a documented procedure in place for the approval of all raw packaging and finish product and service specifications. The written procedure addresses all raw materials, the processing aids and any packaging materials. The procedure addresses label accountability for all labels using this operation any accountability for labels at the end of the run. The raw material specifications sheet includes all Materials both bridge material and any material they would have rework or recycled materials that would be part of the product. The practitioner requires all raw suppliers to notify this operation if there are any changes in the design or food safety program they were related to any of the packaging material used here. All contract suppliers used in this operation that have anything to do with the food safety program are on a contract service provider register and are approved by this operation. All contract suppliers used in this operation that have anything to do with the food safety program are on a contract service provider register and are approved by this operation. Any of those that go directly into the production area must take GMP training. GMP records for pest control were pulled and reviewed during this audit and found to be in order.

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

This facility currently does not use any 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

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)

The requirements for incoming goods and services are defined in Supplier Selection and Approval (5290). The Purchasing and Estimation Leader is responsible for the selection and approval of suppliers and maintains an Approved Raw Material Vendors within IQMS. A Vendor Questionnaire is completed at the time of approval and is reviewed every 5 years for low risk, and every 2 years for high risk. The facility currently does not have any high risk vendors. Vendors are also reviewed by the Quality & Production Leader before they are approved. Vendors are continuously monitored. The food defense plan includes measures to prevent terrorist or sabotage events. The food fraud vulnerability assessment includes the mitigation methods to prevent substitution, mislabeling, counterfeiting, etc. Supplier audits are conducted through self-assessments. A supplier audit may be conducted for new business or if a supplier's performance doesn't meet N.E.W. standards. Supplier approval records were sampled for three suppliers and met the requirements.

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)

The requirements for food legislation are defined in Regulatory Compliance and Awareness. The Practitioner stays informed of regulatory and industry technical and scientific developments and changes by monitoring regulatory websites, reading regulatory and other educational events, and membership in industry trade organizations. The SQFP updates relevant procedural documentation to include necessary changes. SQFI & CB are noted as essential contacts within 24 hours of a regulatory warning letter.

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)

Good Manufacturing Practices are outlined in the Food Safety Manual (IQMS), and procedural documentation is in place for the elements covered in Module 13. The site has not claimed any exemptions.

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)

HACCP Plans: Rigid Plastic Bottles / Containers – blow mold and injection mold. Team: QA Mgr, SQFP, Ops Mgr, Production Operations Mgr, Estimations & CSR, Maintenance Mgr, PM Coordinator, Senior Engineered Systems Mgr. Intended Use: Direct food packing, non-food packing for consumer use. Shelf Life: typically, 2 years – labeled with lot #'s & date of production. Date annual review was approved by HACCP team on 09-27-2021. Process flow chart: Receiving (Preform/Colorants/Additives/Resin/Process aids) > Storage > Blending > Metal Detection > Injection/Blow Molding > Scrap > Rework > Package > Storage > Delivery. Raw Material and Process Hazard Analysis have risk analysis, reviewed annually. No CCPs in production of plastic containers. Resins are FDA approved. No regulatory oversite for product produced.

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

The requirements for product sampling, inspection and analysis are defined in Sampling and Analysis. Product inspection and testing follow defined procedures. All testing and inspections are completed on a pre-determined frequency and all employees interviewed were aware of this frequency. Records are maintained in IQMS. Records were sampled as part of the audit. The following sampling activities are performed: Resin (Monitored each load through COA verification) Packaging Material (Monitored each load through Visual Inspection) Colorant (Monitored each load through COA Verification) Finished Goods (1st Piece, In Process (unit check, drop test, water leak test, air test, and leak detector), End of Order through SPI recommended Procedure for measuring bottles)

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: COMPLIANT

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

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Materials and Product

The process for handling suspect or non-conforming materials including records for quarantine and disposition in Non-Conforming Product and Equipment. Non-conforming product communication is done utilizing the material review board (MRB). Non-conforming product or equipment is tagged with a HOLD label and a Non-Conformance Report (NCR) is completed and the product is moved to the hold area. Records were reviewed and met the requirements.

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

The requirements for product rework are defined in Rework. Reworked materials are documented utilizing NCR's and Rework Work Orders which can be identified and tracked according to the Product Identification and Traceability Procedure. Rework is assigned new traceability information to ensure it is properly traced. Rework Production Form is used to capture the details of the rework activity performed. Records were reviewed and met the requirements.

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)

New Plastics utilizes a passive release system. Products produced are subject to in-process inspections (Sampling and Analysis Plan) at designated points in the production process which ensure finished product complies with specified requirements without the use of positive release status. Records were reviewed during the audit to confirm the process as all records were found to be complete. Work orders were reviewed and met the requirements.

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

The requirements for environmental monitoring are defined in Environmental Microbiological Monitoring Program. Through risk assessment, the site has identified microbiological risk zones based on risk level. The program identifies the sample site by zone and organism for which the sample should be tested. The site has performed testing on product, equipment, personnel, and the facility over previous years and has determined their site to be low risk based on the low activity they have observed. Most customers clean their product prior to filling. Annual tests are performed for zones 1, 2, 3 & Environmental Monitoring. Pathogen Risks: Listeria and Salmonella swabbing is done by SQFP. Meets regulatory – not applicable. Pathogen testing frequency: Annually - 03//18/2021. Zones swabbed: 20 swabs – 10 Listeria and 10 Salmonella. Certified testing facility: Matrix certification is available on web site. Swabbing for cleaning: visual inspection per pre-op startup.

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 requirements for validation and effectiveness are defined in GMP Manual - Validation. The Plant Manager and SQFP discuss the overall effectiveness of the food safety plan and programs by meeting annually to review complaints, investigation details, internal/external audit findings, data trends, and other data relevant to the performance of the system. Validation records for all elements of the system were reviewed and met the requirements.

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

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

The verification schedule is defined in Verification and Validation Schedule. The plan states the program, activity, responsibility, frequency, and due date of each verification activity. All forms such as monitoring activities, line clearance/pre-op, cleaning/sanitation, maintenance work orders/PM's, etc. are reviewed and verified.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

The requirements for corrective and preventive action are defined in Corrective and Preventive Actions. A corrective and preventive action is required any time a non-conformity is identified against an established standard. Root cause analysis is conducted using a recognized problem-solving tool (fishbone & 5 why). A corrective action report is maintained in IQMS. An automatically generated email is sent through IQMS twice a week detailing open corrective/preventive actions. The system includes root cause, corrective action and verification. Corrective and preventive action records were sampled and met the requirements. Since the last audit this operation had 39 and of that 39, 1 is open dated 8/28/2021.

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)

The requirements for internal audits are defined in the Internal Audit Procedure (5928). The procedure outlines the required audits that must be completed throughout the year. A facility GMP and Quality audit is conducted monthly by trained staff. The SQFP & BUSQFP have completed formal internal training. Findings generated during an audit require corrective action and become part of the Corrective/Preventive action process and are stored in IQMS. Internal auditors are required to be independent of the function they are auditing. Internal Audit Schedule is maintained that defines the frequencies and responsible employees for the internal audits that need to be completed throughout the year. Records for the following internal audits were reviewed and met the requirements. Total findings show that 14% of the internal audits had some sort of finding.

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)

The requirements for product identification are defined in Product Identification and Traceability. Finished product and work in progress is clearly identified through all phases of production from receipt of raw materials, production, storage and dispatch by IQMS, work order number, or lot number and is in accordance with customer specifications and regulatory requirements. Job jackets are used to accumulate forms/documents throughout the production process. Line Verification Sheet is completed, which documents the startup and changeover methods. Regrind is traced using the Regrind and Blend Usage and Tracking Log. Startup and changeover procedures are documented using Line Verification Sheet.

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)

The requirements for product trace are defined in Production Identification and Traceability. Product and materials are clearly identified through all phases of production from receipt of raw materials, production, storage and dispatch by IQMS. Traceability Is maintained one up and one back. The most recent test of the system was performed on 5/21/2021.

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)

There is a documented recall procedure (Recall Policy 5930) maintained which identifies the personnel, methods, and communication (which includes notification of SQFI & CB), to take place in the event of a recall. Recall Checklist and Action Log (5931) is used to steer the recall system. The most recent mock took place on May 21, 2021. The mock scenario was black color needed to be recalled. 41149 was the color. P.O Number for the color was 38983-10. Lot 02213042. Total amount of the mock recall was 12 different lots for a total of 224,352 with 100% recall in 78 minutes.

2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for 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

The requirements for business continuity planning are defined in Crisis Management. A Crisis Management team is identified and reviews known threats to the safe and continual operations with responses identified for each. Methods are identified for the initiation of a crisis management event which includes communication links, sources for legal advice, and measures to ensure food safety and quality of any finished product prior to release. The plan is tested annually. Records of the most recent test, conducted was reviewed and met the requirements. The test was on bad color due to a shortage of color due to suppliers not being able to meet the demand.

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)

The requirements for food defense are defined in Food Defense (5933). The President assures proper resources are allocated to effectively carry out the Food Defense Plan. The Operations Manager/SQFP acts as the Food Defense and Food Fraud Team leader. A cross-function Food Defense/Food Fraud Team is maintained. The team conducts an annual assessment and challenge of the food defense program. Access to the facility is restricted at all times. Entrances are locked and key fobs are needed for access. Some of the entrances that are not utilized regularly and are not easily monitored by personnel are equipped with alarms. Truck drivers enter the facility through a locked caged area that is monitored by the Logistics Coordinator. Visitors are required to sign in at the reception desk and a badge is issued. Employees are trained to identify unescorted/unidentified visitors in the facility. Chemicals are stored in a restricted area and secured by a lock and key. The food defense plan is reviewed on an annual basis. The most recent assessment was completed on June 3 2021, the assessment included a challenge of the security of the plant.

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 requirements for food fraud are defined in Food Fraud Plan (Doc ID: 9738). The Food Defense/Food Fraud Team has conducted a Food Fraud Vulnerability Assessment which assesses the susceptibility to substitution, mislabeling, and counterfeiting. The site determined its risk level as low due to the production process, monitoring analytical surveillance plans for sampling, testing including reviewing COA's, the supplier approval process. A reaction strategy is defined through the non-conforming product and equipment procedure, recall procedure, and crisis management plan. The assessment and mitigation plan are reviewed on an annual basis.

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)

Allergen Control defines the methods and responsibilities for the control of allergens. Allergens are not used at this facility in any way. All labels are owned and supplied by the customer. New Plastics is not responsible for label requirements. The site identifies the big 8 US allergens. The site does not ship product outside of the US. GMP/HACCP/Allergen training is conducted annually.

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

Appropriate training is provided for personnel carrying out the tasks critical to the effective implementation of the SQF System and the maintenance of food safety. New employees undergo hands-on training which includes samples of packaging with known flaws. The employee must identify the flaw, and record the findings. Management ensures that minimum competencies for all personnel who directly or indirectly perform work affecting conformity to product/business/regulatory requirements have been identified and defined.

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)

The training program outlines training given on a monthly basis. At minimum, this training includes, GMP, Glass and Brittle. HACCP, Pest Control. The plan is signed and agreed upon by upper management. Missed training must be made up prior to the next training. Personnel interviewed from all shifts were observed up to date on their training. Detailed work instructions are given during training and were observed posted at each work area. Training is given in English and Spanish. The training matrix registers, names of participants, skill description, training provided, and date of training. Reviewed training for 2020 at 100% of all training for 2021 completed.

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 facility is located in a semi-industrial area and is maintained in such a way that neighboring facilities do not interfere with safe and hygienic operations. The facility grounds are monitored regularly and are in very good condition. Any construction-related activities are performed with proper permits in place.

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

Floors were constructed of smooth dense concrete. Floors were well maintained. Drains are not needed in the production area. Easily cleanable floors were well maintained. Operations of this facility do not require a waste trap. The contact surface poses no food safety concern. Walls, ceilings and doors were constructed of approved easily cleanable materials. All were observed clean and in good condition. Floor and wall junctions were sealed, clean and well maintained. Interior and exterior doors were constructed of metal. Windows on doors and windows adjacent to production and warehouse were made of shatterproof glass listed on the glass register.

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: COMPLIANT

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

RESPONSE: COMPLIANT

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

Sufficient lighting is provided in the packaging manufacturing and handling areas. Shatterproof lights in production and inspection areas are of appropriate intensity to enable staff to carry out their tasks efficiently and effectively. Light fittings are shatterproof to prevent contamination of product.

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 windows, ventilation openings, doors and other openings are sealed when closed and proofed against dust, vermin, and flies. Personnel access doors are provided that are self-closing. Insect control devices, bait stations, and traps are located so as not to present a contamination risk to product 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

Production areas maintain adequate ventilation.

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

RESPONSE: COMPLIANT

13.1.6 Equipment and Utensils

Equipment and tools are designed, constructed, installed, operated and maintained so as not to pose a contamination threat to product. Benches, tables, conveyors and manufacturing equipment are easily cleaned and located so as not to pose a hindrance to the cleaning of premises. Containers, tubs, and bins are constructed of materials that are non-toxic, smooth, impervious and readily cleaned. Binds are color-coded and marked for their purpose.

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 exterior grounds were well maintained. Trash was controlled. The surrounding areas of the production site and off-site warehouse are clean and well maintained. The processing plant and off-site warehouse were very clean and well maintained. Surrounding areas were did not present a hazard to hygienic or sanitary operations.

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

The methods and responsibility for the maintenance and repair of the plant, equipment and building are handled through IQMS program. The schedule and planned work are documented and carried out in a manner that minimizes the risk of product or equipment contamination. The Facilities and Equipment Maintenance Leader is responsible for the maintenance program. Routine maintenance of equipment and buildings is performed according to the maintenance control schedule housed in the IQMS system. The maintenance control schedule includes the building, equipment, and other areas of the facility critical to food safety. The schedule (in IQMS) is defined based on either calendar days or production hours. A report of PM's that are due is generated by IQMS on a daily basis. Food-grade oils and lubricants are used on all equipment located in or above a product zone. Temporary repairs follow the temporary repair policy. When an unexpected equipment failure occurs, a Work Order Request Form is completed. Work Orders are completed for all maintenance activities which includes a sign-off and verification that all tools have been collected and the area was cleaned.

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: COMPLIANT

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

All maintenance staff at this location and any outside contractors that are brought into that location must follow the same hygienic program as the employees. Anyone in maintenance or engineering or for that fact outside contractor that comes into the operation to work inside our train and a food safety rules and regulations. All tools parts are accounted for before the operation is released back to production and the cleanup takes place. A preop of any repairs is done prior to the machine being released back to operations. No concerns were noted.

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

The methods and responsibilities for the calibration and re-calibration of measuring, test, and inspection equipment used for monitoring activities outlined in the PRPs, HACCP Plan, and process controls are documented and implemented (Calibration of Measuring Devices). The procedure identifies methods for the control of measuring equipment that is out of calibration. A calibration schedule ensures equipment is calibrated to regulatory requirements and the manufacturer's recommended schedule is maintained in IQMS. Most of the facility's calibration activities are managed by a contract service provider, Precision Metrology (ISO 17025). Calibration records were sampled and met the requirements.

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

The methods and responsibility for integrated pest management are documented and implemented. The IPM procedure outlines the criteria including the identification of target pests, frequency of monitoring, site maps, approval, handling and disposal of chemicals, inspections, and records of pest control activities. A contractor, Wil-Kill Pest Control, is used to maintain the IPM. A service report is generated and is reviewed by the practitioner. All chemicals are stored off-site and are disposed of by the PCO. Service reports were reviewed and met the requirements. Service person is licensed Dec 31, 2021. Service is performed twice a month. Liability insurance Exp Jan 2022. Site Map was last updated Jan 2021.

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: COMPLIANT

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: COMPLIANT

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

The requirements for cleaning are defined in Cleaning and Sanitation (5937). Cleaning consists of blowing off equipment and wiping down with alcohol wipes between color changes. Employees are responsible for cleaning equipment and production areas which are completed at the end of shift, during changeovers and every Sunday night start-up. Cleaning is also completed during downtimes. Master Sanitation Schedule (6235) is maintained which identifies the frequency and responsibilities. Supervisors verify the cleaning. Off-line cleaning areas are not required or used. Pre-operational inspections are conducted in the form of a Line Verification and are completed at the beginning of each work order. Solvents and other compounds used for cleaning are approved and SDSs (Glass Force Professional Glass Cleaner; Ecolab Drain Duo, Soil-off II) are on file. Empty containers are disposed of properly. Records were sampled and met the requirements.

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: COMPLIANT

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

Product handling personnel who are showing signs of illness are not allowed to engage in product handling. Personnel interviewed demonstrated an understanding of this requirement. When interviewed, personnel stated that if they have cuts or small lesions they are to wear a blue band-aid. Appropriate procedures are in place for more serious injuries.

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: COMPLIANT

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

Employees enter the facility through a designated area that is key card protected and has a handwash basin located just before entering the production area. Another entry point into the production area is from the offices which also has a handwash basin near the entrance. Employees are required to wash their hands prior to entering the production area. Handwash stations are constructed of stainless steel or porcelain and include hot water, liquid soap, towels, and a waste towel receptacle. Handwash signs are posted at the entrance to production and in the restrooms. Employees indicated through interviews good overall knowledge of handwashing requirements. No issues observed.

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

All clothing worn by employees is required to comply with the N.E.W. Plastics dress code. Production employees wear street clothes that are required to be clean, freshly laundered, and comply with the dress code. The company offers optional uniform services to employees performing certain functions. Lab coats are available to be worn if need be. Depending on customer requirements, gloves must be used when handling direct food contact product. The gloves must be maintained intact, clean, and sanitary condition. When gloves are changed, hands are to be sanitized. No issues were observed. This operation has a jewelry policy and no jewelry is allowed on the floor with the exception of a smooth wedding band or a medical alert bracelet.

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 are required to follow the plant's personnel practices including if required based on what is being produced. All staff and visitors wear hairnets, beard nets, and bump caps. There is a no jewelry policy. All staff and visitors are required to wash hands. Visitors that show any sign of sickness are not allowed in the plant. No issues were observed.

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)

Storage for personal items is provided for personnel and visitors who wish to use them. Storage for personal items is located away from production areas. All tools and equipment used to clean the restrooms are separate from any of the production operation. All drains used in the restrooms were separate from those out on the production floor with no concerns were noted. Written procedures are in place or being filed and what to do if contamination of the premises or any of the raw packaging material was to take place. Handwash stations were located in the restroom with both hot and cold running water. The break room in the lunchroom was all separate from the production area and food is not permitted in the production area. No pest concerns in the eating area were noted.

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

The requirements for staff engaged in handling of food contact packaging are defined in clothing, jewelry, and hair policy. When not operating a line, employees were seen to pick up a broom and clean their area. The facility walk-through showed pride in the workplace and in the product produced. Interviews and observations confirmed employees have a good understanding of food safety system. Topics discussed with personnel included but were not limited to handwashing, cleaning/sanitation, GMP, HACCP. The process flow minimized any concern of product 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

Water is not used in the process outside with the exceptions of handwashing & quality tests. Water temperature was sampled at various areas of the facility and is adequate. Backflow devices are tested annually. The annual backflow test is scheduled annually by the local municipality. The water delivery system in the facility is a closed-loop system.

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

Water is not used in the process with the exceptions of handwashing & quality tests. Municipal water is used and the annual report is reviewed and on file. Records of the most recent water tests were reviewed from Nov 2020 by Matric Lab who has 17025 certification.

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

Filters are on the preventive maintenance schedule in IQMS and are changed every 6 months (Large Coalescing Filter .3 - .6 Micron & also a Smaller Particulate Filter 3. Last test of air was performed on 8/18/2021 and is tested by TRI-Air testing. Testing takes place 2 times a yr. at 3 different locations.

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

The facility is well-constructed and designed for its purpose. The materials used to construct the building and equipment are common to the industry and are generally impermeable, easily cleanable, and do not pose a contamination risk. All racking was clean and in good condition. Forklifts were in appropriate condition and are on regular preventive maintenance, cleaning, and inspection schedule. No issues observed.

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

Food Grade and non-food grade chemicals are segregated and appropriately marked. Processing utensils and packaging materials are stored away from any chemicals and toxic substances. Chemicals are secured in cabinets marked for Hazardous Chemicals only. SDS sheets are available for all chemicals on-site and are verified. A current register of chemicals is kept for all chemicals including cleaners and sanitizers. The supplies of chemicals used for cleaning and sanitizing are kept in a locked area assessable to authorized persons only. Pesticides are not stored at this facility. The licensed pest control operator brings supplies into the facility at the time of service and takes away any empty containers. Storage of hazardous chemicals is accomplished by Chemical Storage cabinets in each department that is locked and limited to access by authorized personnel.

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: COMPLIANT

13.6.3 Loading, Transport, and Unloading Practices

The requirements for loading and unloading are defined in Greif Receiving Trailer Inspection Sheet. Shipping personnel inspect all trailers by following inspection guidelines. Findings are recorded, when applicable. Unacceptable loads are documented. All full truckloads are sealed by ePac personnel. Records are filed by the shipping department. The requirements for loading unloading and transporting are written and checked using trailer inspection sheets and the sheets were reviewed during this audit. All tailors are inspected before loading and unloading. COA is used to trace and verify product. All dock door seals were found to be in good condition and sealed well against the trailer and the dock. No issues observed. Shipping records were reviewed as part of the audit. Shipping/receiving personnel were interviewed and demonstrated a good understanding of the requirements.

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

The requirements for control of foreign matter are defined in Foreign Material Control. Foreign material hazards in the HACCP Hazard Analysis. A documented training program is in place to ensure proper reporting of any issue that poses a potential food safety concern. The procedure identifies control methods for the following foreign materials: wood, plastic, metal, and glass. A register is maintained that has pictures of all glass or brittle plastic objects in each zone. No loose materials or temporary fixes were observed during the audit on the processing equipment.

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

The requirements for managing foreign matter contamination incidents are defined in Foreign Material Control. The affected batch or item is isolated and placed on hold pending an investigation and determination of disposition. The non-conforming product process is initiated and followed. Interviews with personnel confirmed good knowledge of foreign matter methods. Report of Glass Breakage.

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

The procedure identifies the process for collecting, handling, and removing the following forms of waste: Dry, Liquid, Hazardous Waste, Waste Containers, Trademarked and other printed materials. Bins are used to collect production waste and are color-coded and labeled to ensure dirty product does not get into the regrind process.

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