Certificate of Registration

This acknowledges that

True Citrus

11501 Pocomoke Court, Suite D
Baltimore, MD 21220

is registered as meeting the requirements for the

SQF Food Safety Code for Storage and Distribution, Edition 8.1

Registration schedule

Scope of registration [food sector categories and products]:

Food sector category: FSC 26: Food Storage and Distribution

Products: Dry Ingredients

Eurofins Food Assurance

2120 Rittenhouse Street, Suite A
Des Moines, IA 50321, USA
Ph: (515) 299-6979
www.eurofinsus.com/food-safety

DATES OF AUDIT:
10/05/2020 – 10/06/2020

DATE OF NEXT AUDIT:
10/22/2021

DATE OF DECISION:
11/04/2020

EXPIRATION DATE:
01/05/2022

CERTIFICATE NUMBER:
24060

CERTIFICATION TYPE:
Announced Recertification

Signature of issuing officer
Brian Neal
Technical Manager

Signature of authorized officer
Chuck Russo
Vice President

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SQF Institute is a division of FMI.

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eurofins | Food Assurance

Eurofins Food Assurance

2120 Rittenhouse Street, Suite A
Des Moines, IA 50321, USA
Ph: (515) 299-6979
www.eurofinsus.com/food-safety

DATES OF AUDIT:
10/7/2020 - 10/8/2020

DATE OF NEXT AUDIT:
10/24/2021

DATE OF DECISION:
11/5/2020

EXPIRATION DATE:
1/7/2022

CERTIFICATE NUMBER:
45608

CERTIFICATION TYPE:
Announced Recertification

Certificate of Registration

This acknowledges that

Pack-It, LLC- Rosedale

8989 A Yellow Brick Road
Rosedale, MD 21237

is registered as meeting the requirements for the

SQF Food Safety Code for Manufacturing, Edition 8.1

Registration schedule

Scope of registration [food sector categories and products]:

Food sector category: FSC 19: Food Ingredient

Products: Sugar, Stevia-based powdered drink mixes

Signature of issuing officer
Brian Neal
Technical Manager

Signature of authorized officer
Chuck Russo
Vice President

SQF INSTITUTE
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SQF Institute is a division of FMI.

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Z144301415UD

SQF Food Safety Audit Edition 8.1

Pack-It, LLC - Pack-It, LLC - Rosedale

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
45608 | 121689

AUDIT RATING
92
Good

DECISION DATE
11/05/2020

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
10/24/2021

AUDIT DATES
10/07/2020 - 10/08/2020

EXPIRATION DATE
01/07/2022

ISSUE DATE
11/05/2020

Facility & Scope

Pack-It, LLC (43126)
Pack-It, LLC - Rosedale
8989 Yellow Brick Road
Suite A
Rosedale, MD 21237
United States

Web Site: https://pack-it-llc.com

Food Sector Categories:
19. Food Ingredient Manufacture

Products:
Sugar, Stevia-based powdered drink mixes

Scope of Certification:
FSC 19: Food Ingredient

Certification Body & Audit Team

Eurofins

eurofins | Food Assurance

2200 Rittenhouse St. Suite 150
Des Moines, IA 50321
United States

Phone #: 515-299-6979

CB#: CB-1-Eurofins
Accreditation Body: JAS ANZ
Accreditation Number: Z14430415UD

Lead Auditor: Stephens, Terri (132598)
Technical Reviewer: Braymen, Suzie (133613)

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

Non-Conforming

2.1.5 Crisis Management Planning

Crisis Management Procedure SOP 1.6 Rev 006 is dated 10/2/20 and is approved by the Managing Partner. The team consists of the captain (Managing Partner/Director of Regulatory), Back-Up Managing Partner, QA Manager (Practitioner), Maintenance Manager, and the Administrative Assistant. The crisis contact list is developed but does not include the contact information for the legal council, the FDA, Certification Body and SQFI. The Back-up Managing Partner contacts Legal Council. The Managing Partner contacts the customers, and handles the media. The QA Manager contacts the employees, FDA, Certification Body and SQFI. The procedure stated the regulatory bodies are to be contacted within 24 hours of a public food safety issue. The Crisis policy covers the events of flood, fire, earthquake, tornado, pandemics and domestic warfare and disgruntled employee. On 7/27/20 the site conducted a mock crisis event for Covid-19.

2.1.5.3 The crisis management plan shall be reviewed, tested and verified at least annually.

RESPONSE: MINOR

EVIDENCE: The mock crisis event does not identify who would have contacted the FDA, SQF and the Certification Body. The mock event does not describe that the crisis was not a food safety issue and that the food did not need to be inspected and/or tested.

ROOT CAUSE: The Quality Manager did not fully understand what need to be included in the summary.

CORRECTIVE ACTION: The mock crisis event was redone and the summary reformatted to include items missed. Included are the investigation report and revised summary of mock crisis event. The preventative action for this is that a new skeleton was created for event summaries that provides prompting so that QA Manager does not leave items out.

VERIFICATION OF CLOSEOUT: The site conducted a second crisis event to include whom contacts the FDA, CB and SQFI. It also spells out who would contact the legal council, insurance, customers and employees. The site conducted an ivestiagational report to identify the root cause and preventative action. This meets the intent of the NC and is accepted. TLS

COMPLETION DATE: 10/29/2020 **CLOSEOUT DATE:** 10/30/2020

2.6.3 Product Withdrawal and Recall (Mandatory)

Product Recall Policy SOP 6.2 Rev 005 is dated 10/23/20 and is approved by the Managing Partner. The site policy documents a recall drill is to be conducted annually. The Director of Regulatory/Managing Partner is the captain. The Managing Partner is responsible to contact the customer and media. The QA Manager contacts regulatory (FDA, SQF and the Certification Body) and the employees. The back-up Partner contacts the Legal. The site policy documents an investigation to root cause is required. Notification to regulatory is to be within 24 hours. A mock recall drill conducted on 10/5/20 and SQF and the CB were not mock contacted.

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

RESPONSE: MINOR

EVIDENCE: The site conducted the mock recall 10/5/20. It is observed that the SQFI and the CB were not mock contacted during the mock crisis drill.

ROOT CAUSE: The Quality Manager did not fully understand what need to be documented.

CORRECTIVE ACTION: The mock recall event was redone and the summary reformatted to include items missed. Included are the investigation report, email thread from new recall, new contact list created for team members, and revised summary of mock recall event. The preventative action for this is that a new skeleton was created for event summaries that provides prompting so that the QA MAnager does not leave things out.

VERIFICATION OF CLOSEOUT: The site updated the recall SOP to include the internal folks that will contact the external required parties. The mock event was redone and clearly identifies the communications which covers the required parties. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

2.7.1 Food Defense Plan (Mandatory)

Food Defense SOP 7.1 Rev 003 is dated 6/28/19 and is approved by the Managing Partner. The site defends itself through: Facility Entry (door key locks, fobs, cameras and proper lighting and doors kept in closed positions) and Pre-Hire Employee Screening. The site conducts monthly inspections for food defense during the site internal audit and then again during an annual food defense plan assessment. The last plan assessment was conducted on 9/27/19 and approved by the Managing Partner. The Managing Partner is the site food defense coordinator and has a food defense coordinator on-line certificate from AIB on 8-11-19.

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

RESPONSE: MINOR

EVIDENCE: The site has not challenged the plan this year.

ROOT CAUSE: When SQF Practitioner set up the annual systems review schedule food defense was scheduled for December so the Practitioner forgot to have the challenge done before the 2020 SQF audit.

CORRECTIVE ACTION: The Food Defense Challenge was completed. Included are the investigation report and the event summary. The preventative action for this is that the 2021 system review schedule will be changed so that the Food Defense review happens earlier in the year so that the practitioner has the challange done before the audit.

VERIFICATION OF CLOSEOUT: The site conducted an investigation to determine why the challenge had not occurred and has now completed a FD challenge. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 11/02/2020 **CLOSEOUT DATE:** 11/04/2020

11.2.7 Dust, Insect, and Pest Proofing

The site does not have any windows or fans within the production rooms or warehouse. The warehouse skylights are observed to be well sealed with no evidence of leaking. The man doors are observed to be maintained in closed position and most are observed to be tightly sealed. Two doors, Door 9 and the Ramp door have visible daylight around them. The dock doors have insect light traps installed which were observed functioning and clean. The internal pest control devices do not contain bait. Only bait used on site is in the exterior bait boxes which is serviced by the PCO only.

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

RESPONSE: MINOR

EVIDENCE: Door 9 and the Ramp door do not have a secure gasket. Light can be seen around the perimeter of the doors.

ROOT CAUSE: This was not a part of the monthly site audit and no one recognized that we should be checking them.

CORRECTIVE ACTION: New Gaskets obtained and installed on doors. Included are the investigation report, pictures of both doors from multiple angles, and revised monthly site inspection form. The preventative action for this is that checking egress doors to make sure gaskets are secure has been added to the monthly site audit form.

VERIFICATION OF CLOSEOUT: The site has installed gaskets to both identified doors. The monthly GMP inspection form has been modified. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

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

RESPONSE: MINOR

EVIDENCE: Within the Pre-Weigh room the plume/vent stack up through the roof to the exterior sky does not have a screen installed to prevent pest entry.

ROOT CAUSE: Management did not realize that the vent design did not include anything preventing entrance through the top.

CORRECTIVE ACTION: Filter obtained and installed in the vent. Included are the investigation report, and picture of the installed filter. The preventative action for this is that management is now cognazant of the need to make sure all openings are designed to prevent entrance when plans are made for new construction.

VERIFICATION OF CLOSEOUT: The site conducted and investigational report to find the roort cause and preventative action. They have installed a new filter within the plume. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

11.2.10 Premises and Equipment Maintenance

Maintenance and PM Policy SOP 10.1 Rev 001 is dated 9/9/19 and approved by the Managing Partner. The PM system is a manual program managed by the Maintenance Supervisor. Records of PMs for January, February and March 2020 were reviewed and found to be acceptable. The work order for changing Teflon on the line 1 for 10/14/20 and the work order completed on 10/16/20 for the cutting wheel on lines 1 and 2 were reviewed and found to be acceptable. A temporary repair of red tape on the control panel leg/bustle to the Stik Pac Filler was observed. The site does not have the item listed on the temporary equipment/repair plan to manage the items sited. The tool boxes observed within the shop were each found to be very clean. The hazardous chemicals within the locked storage cabinets were organized and had the company stop-light green, red stickers on each chemical container per the company program.

11.2.10.8 Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: MINOR

EVIDENCE: Red tape is observed on the Control Panel leg/bustle to the Stik Pac Filler. It is not listed on the temporary repair log.

ROOT CAUSE: Tape applied by former employee and not documented

CORRECTIVE ACTION: 1. An incident report was written to learn the root cause and preventative action 2. The item was added to the temporary repair log. 3. A work order was written for the repair to be made. 4. Permenent cover made for the top of arm and red tape replaced. Picture of the permenant repair was taken and forwarded to auditor.

VERIFICATION OF CLOSEOUT: The site placed the item onto the temporary log, wrote a work order and made a permanent correction. Picture of the correction was received and reviewed. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

The Chemical Control Program SOP 13.4 Rev 003 is dated 6/24/19. The room in which the sanitation chemicals are stored is the maintenance shop. The shop is gated and locked. The cage fence is posted with a authorized personnel only sign and a hazardous chemical sign. The chemicals are observed labeled. The area is well ventilated and lighted. The area has a first aid station nearby. The chemicals are inventoried by the QA Manager. A second chemical storage area has been implemented this audit year inside a closet. The closed is observed locked however it does not have proper signage and the chemicals inside are not stored within containment pans.

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

RESPONSE: MINOR

EVIDENCE: 1. The chemical storage closet is not labeled as a restricted chemical storage and as an authorized personnel only room. 2. The chemicals are not stored over a containment pan.

ROOT CAUSE: Management assumed that because the closet was locked at all times and only accessed by sanitation employees we could keep the unopened cases of sanitation chemicals in that closet and did not think about signage or containment pans not being present.

CORRECTIVE ACTION: A larger chemical cabinet purchased and placed in maintenance cage, all chemicals removed from storage closet and placed in new cabinet. Included are: investigation report, and pictures of the new cabinet with the chemicals in it. Preventative action for this is that a larger cabinet was purchased so that there is enough space for all chemicals.

VERIFICATION OF CLOSEOUT: The site has purchased and implemented a new larger chemcial storage cabinet and placed it within the maintenance cage wihin a spill containment pan. The closet is no longer being used to store chemicals. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

11.7.5 Control of Foreign Matter Contamination

Foreign Matter SOP 14.19 Rev 004 is dated 9/17/20 and is approved by the Managing Partner. The program covers foreign material, glass, brittle plastic, and breakage events. The glass register inspection was last completed on 9/8/20 by the Maintenance Supervisor. Knives are inspected and the blades are replaced each batch and documented on the batch mix record. Records from 10/1 through 10/6/20 were reviewed and found to be acceptable. Four potential Foreign Material concerns were observed. 1. a loose pen with cap was on the desk on the dumping platform on line 8. 2. trash was observed stuck on a stand on the dumping platform on line 8. 3. A worker's apron was observed torn in several places. 4. The evacuation map in the line 8 room was observed pulling from the wall.

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

RESPONSE: MINOR

EVIDENCE: Potential Foreign Material are observed. 1. A loose pen with cap was on the desk on the dumping platform on line 8. 2. Trash was observed stuck on a stand on the dumping platform on line 8. 3. A worker's apron was observed torn in several places. 4. The evacuation map in the line 8 room was observed pulling from the wall.

ROOT CAUSE: Lack of understanding and training by all.

CORRECTIVE ACTION: 1. All pens used in warehouse changed to click pens (no Caps) and employees trained to keep in pockets within 3ft of open product. 2. Employees trained that trash is a foreign material and must be disposed of properly. 3. Employees trained that any damaged PPE's could result in foreign matter contamination and must be changed immediately. 4. All evacuation maps in the facility were put into frames (no glass) and hung on the walls. 5. The GMP Policy was updated to include the above.

VERIFICATION OF CLOSEOUT: The site has updated the GMP Policy to describe the conditon of PPE must remain in good condition. A picture of the modified evacuation maps throughout the site was submitted. Training was conducted with the entire plant on the changes made which reflect the findings of this NC. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/29/2020 **CLOSEOUT DATE:** 10/30/2020

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Holly Mattson: QA Manager/SQF Practitioner
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** hmattson@pack-it-llc.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Holly Mattson: QA Manager/SQF Practitioner, Pat O'Conner: Managing Partner, Rich Soper: QA Director; True Citrus, and Terri Stephens: SQF Lead Auditor.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** The company is a privately held LLC which has been in business since 2006. The site is solely a co-manufacturer for one customer. The customer purchases and provides all raw materials and packaging components for the site. The site is located within a leased 30,000 sq. ft. section of an industrial park in a suburb of Baltimore, Maryland. It is operated through two shifts, Monday through Friday, 6:00 AM to 11:00 PM with 35 full-time and 28 part-time employees. The site operates 2 blending and 4 packaging lines under one Food Safety Plan. The site has identified 3 CCPs, 2 different sized screens (4 and 14 mesh) and metal detection. The site does not use any allergens, has no exemptions from the SQF Code 8.1 and has never been involved in a Recall. The site ships the product to Maryland, USA. The site's only customer ships product throughout the USA and Canada. The non-conformities of the Facility audit have been reviewed and found to have effective corrective actions. The pandemic has resulted in higher product demand. The site has written and implemented a Health Related Pandemic Policy which requires each person entering the building to complete a health screening questionnaire and has their temperature taken by an infrared thermometer by the Staffing Coordinator. The site has not had any people at the site found positive however three people have had to quarantine due to ride-sharing. They were tested and each found to be negative.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Holly Mattson: QA Manager/SQF Practitioner, Brian Lavelle: Director of Regulatory/Managing Partner, Pat O'Conner: Managing Partner, Rich Soper: QA Director; True Citrus, Terri Stephens: SQF Lead Auditor.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Once any non-conformities found are corrected and approved it is recommended a re-certification be issued.

Section Responses

2.1.1 Food Safety Policy (Mandatory)

Management Commitment SOP 1.1 Rev 005 is dated 7/16/20 and is approved by the Managing Partner/Regulatory Director. The site documents the program is a continuous improvement program to meet customer, FDA and the international auditing scheme requirements of food safety and quality. Each employee is trained in food safety and quality and as a member of the team is required to communicate to the QA department any food safety, quality or food defense issues they notice. The commitment policy is written in both English and Spanish. It is posted in the front lobby where all folks pass when entering the building .

2.1.1.1	Senior site management shall prepare and implement a policy statement that outlines as a minimum the: i. The site's commitment to supply safe food; ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; and iii. The site's commitment to establish and review food safety objectives. **RESPONSE:** COMPLIANT
2.1.1.2	The policy statement shall be: i. Signed by senior site management; ii. Made available in language understood by all staff; iii. Displayed in a prominent position; and iv. Effectively communicated to all staff. **RESPONSE:** COMPLIANT

2.1.2 Management Responsibility (Mandatory)

The organizational chart is dated 9/1/20 and is approved by the Managing Partner. All positions on the chart are currently filled. The chart indicates the members of the food safety team. The Senior SQF Practitioner role is the QA Manager. The QA Manager is a full time employee certified in Implementing SQF Systems: Manufacturing as of August 10, 2019, certified in HARPC Online January 16, 2018, and certified in Internal Auditing on September 9, 2019. The Managing Partner is certified as a Food Defense Coordinator as of August 11, 2019, PCQI for Human Foods 6/22/2017 and the Implementing SQF for Manufacturers August 1, 2019. Within each job description the back-up designee is determined. The job descriptions for the Managing Partner/Director of Regulatory, QA Manager, Blending Leader and the QA Supervisor, and Blending Technician were reviewed and found to be acceptable. The continuous improvements the site has completed this year are: Resurfaced the sanitation room, installed a grinder, the ceiling area above the line 4 blender was re-engineered and additional air conditioning was installed within the line 8 blender and stick pack rooms. The site has purchased several new pieces of equipment including a line vacuum and a forklift. The site understand the requirements around the unannounced audit year and the black-out date communications.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2.5 The SQF practitioner shall: i. Be employed by the site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code for Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3 Management Review (Mandatory)

The site Food Safety team meets monthly. The site Practitioner and senior manager are also meeting monthly. The records of the one on one meeting from 10/3/19 was reviewed and found to be acceptable. The food safety team is comprised of the team leader: Managing Partner/Director of Regulatory, QA Manager, QA Supervisor, Maintenance Supervisor, Blending Leader and the Stick Pack Leader. The meeting minutes for 3/24/20, 6/25/20 and 8/27/20 were reviewed and found to be fully documented. The agendas have each of the major areas of the code discussed along with follow-up/open items from the past month. After the food safety meeting the Practitioner and the Managing Partner meet for the one to one meeting. The one to one meeting discussion points are documented at the end of the food safety meeting minutes.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.4 Complaint Management (Mandatory)

Consumer Complaints SOP 1.5 Rev 005 is dated 6/14/19 and approved by the Managing Partner. Per the program each complaint is to be investigated and trended. A Complaint investigation from 9/18/20 for mislabeled product and on 2/27/20 the lot number was not the correct line it actually was run on. The corrective actions, root causes and preventative actions are documented on the investigation reports. The site has developed trend charts for the customer complaints to number of complaints month over month and to type of complaint.

2.1.4.1 The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities, arising from products manufactured or handled on site, shall be documented and implemented.

RESPONSE: COMPLIANT

2.1.4.2 Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents.

RESPONSE: COMPLIANT

2.1.4.3 Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.3.

RESPONSE: COMPLIANT

2.1.4.4 Records of customer complaints and their investigations shall be maintained.

RESPONSE: COMPLIANT

2.1.5 Crisis Management Planning

Crisis Management Procedure SOP 1.6 Rev 006 is dated 10/2/20 and is approved by the Managing Partner. The team consists of the captain (Managing Partner/Director of Regulatory), Back-Up Managing Partner, QA Manager (Practitioner), Maintenance Manager, and the Administrative Assistant. The crisis contact list is developed but does not include the contact information for the legal council, the FDA, Certification Body and SQFI. The Back-up Managing Partner contacts Legal Council. The Managing Partner contacts the customers, and handles the media. The QA Manager contacts the employees, FDA, Certification Body and SQFI. The procedure stated the regulatory bodies are to be contacted within 24 hours of a public food safety issue. The Crisis policy covers the events of flood, fire, earthquake, tornado, pandemics and domestic warfare and disgruntled employee. On 7/27/20 the site conducted a mock crisis event for Covid-19.

2.1.5.1 A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis.

RESPONSE: COMPLIANT

2.1.5.2 The crisis management plan shall include as a minimum: i. A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure a response does not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations and media.

RESPONSE: COMPLIANT

2.1.5.3 The crisis management plan shall be reviewed, tested and verified at least annually.

RESPONSE: MINOR

EVIDENCE: The mock crisis event does not identify who would have contacted the FDA, SQF and the Certification Body. The mock event does not describe that the crisis was not a food safety issue and that the food did not need to be inspected and/or tested.

ROOT CAUSE: The Quality Manager did not fully understand what need to be included in the summary.

CORRECTIVE ACTION: The mock crisis event was redone and the summary reformatted to include items missed. Included are the investigation report and revised summary of mock crisis event. The preventative action for this is that a new skeleton was created for event summaries that provides prompting so that QA Manager does not leave items out.

VERIFICATION OF CLOSEOUT: The site conducted a second crisis event to include whom contacts the FDA, CB and SQFI. It also spells out who would contact the legal council, insurance, customers and employees. The site conducted an ivestiagational report to identify the root cause and preventative action. This meets the intent of the NC and is accepted. TLS

COMPLETION DATE: 10/29/2020 **CLOSEOUT DATE:** 10/30/2020

2.1.5.4 Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

The system is maintained both in hard binders located in the QA Managers office and as a back-up on a flash drive with the Managing Partner. The SQF system includes the requirements of this element and code section. Only the QA Manager and managing Partner are able to change a document. The master document register and change log is maintained by the QA Manager. Both were reviewed and found to be acceptable.

2.2.1.1 A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site will use to meet the requirements of the SQF Food Safety Code for Manufacturing, be made available to relevant staff and include: i. A summary of the organization’s food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The scope of certification; iv. A list of the products covered under the scope of certification; v. Food safety procedures, pre-requisite programs, food safety plans; and vi. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

The Managing Partner and the QA Manager are the only employees able to change a document. The staff have access to the program through the hard binders located in the QA Managers office. The master document register is developed and is fully populated. The site documents are stored in the office and then boxed and moved onto a pallet in the warehouse for continued storage for 2.5 years at which point the documents are planned to be shredded by a third party provider. The system document binders are available in the QA Managers office.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2.3 Documents shall be safely stored and readily accessible.

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

Document Creation, Management Change Control Practices , Retention and Destruction SOP 2.1 Rev 008is dated 6/2/20 and approved by the Managing Partner. The document describes that no white out can be used. If an error occurs a strike through shall be used followed with an initial and date of correction. Records are held for 2.5 years.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.1 Product Development and Realization

The site does not develop new products for themselves. As a Co-Manufacturer: blender and packager of the customers formula a Product Research and Development SOP-029-4 dated 7/27/20 is approved by the customers QA Director. The procedure includes the process of idealization through to commercialization. The new products are tested for microbial contamination, water activity, pH levels, granulation and moisture to determined schedules. The shelf life is determined to be 1 or 2 years depending on the product type.

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

RESPONSE: COMPLIANT

2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by site trials, shelf life trials and product testing.

RESPONSE: COMPLIANT

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

2.3.2 Raw and Packaging Materials

The site has a Raw material Register SOP 3.2b Rev 002 dated 10/6/20, a Packaging Register SOP 3.2a Rev 002 dated 10/6/20 and a Label Register SOP 3.2e Rev 002 developed. The registers covers the type of raw material, supplier, specification, certificate of compliance and or conformance. Records of specifications for Bitter Blocker, Mango 130-B and Layn Stevia were reviewed and found to be acceptable. The label register was reviewed for Lime Shaker. The specification and continuing guarantee were reviewed and was found to be acceptable. In the warehouse the items 158061- 50Lb. shipper and 135503-Orange Durarome where observed to be on the registers.

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

2.3.3 Contract Service Providers

The site contract register is fully developed, describes the service provided and identifies the relevant training for each.

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

2.3.3.2	A register of all contract service specifications shall be maintained. **RESPONSE:** COMPLIANT

2.3.4 Contract Manufacturers

The site does not use co-manufacturers. They are solely a co-manufacturer for one customer/supplier.

2.3.4.1	The methods and responsibility for ensuring all agreements relating to food safety and customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented. **RESPONSE:** NOT APPLICABLE
2.3.4.2	The site shall: i. Verify compliance with the SQF Food Safety Code for Manufacturing and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the site or other third-party agency to confirm compliance to the SQF Food Safety Code for Manufacturing and agreed arrangements; and ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel. **RESPONSE:** NOT APPLICABLE
2.3.4.3	Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained. **RESPONSE:** NOT APPLICABLE

2.3.5 Finished Product Specifications

The finished product specifications register is 025-003-1 is dated 9/28/20 for each of the approximate 310 SKUs are developed. Specifications for Peach Lemonade 1970, True Lime 3014 and White Wine Powder 6824 were reviewed and found to be acceptable. The Lemon 650 Ct 00-7958 was observed in the warehouse and is verified to be on the finished goods register.

2.3.5.1	Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include: i. Microbiological and chemical limits; and ii. Labeling and packaging requirements. **RESPONSE:** COMPLIANT
2.3.5.2	A register of finished product specifications shall be maintained. **RESPONSE:** COMPLIANT

2.4.1 Food Legislation (Mandatory)

The site has documented that the SQFI and Certification Body is to be contacted within 24 hours of an food safety event. The site delivers product to one location in Maryland, USA. The product does not contain allergens. All products are manufactured Kosher OU. Net weights are controlled through verifications every thirty minutes.

2.4.1.1	The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of use or sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice. **RESPONSE:** COMPLIANT
2.4.1.2	The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented. **RESPONSE:** COMPLIANT
2.4.1.3	SQFI and the certification body shall be notified in writing within twenty-four (24) hours in the event of a regulatory warning. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com. **RESPONSE:** COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

Personnel and Visitor GMPs SOP 11.1 Rev 007 is dated 9/14/20 and is approved by the managing Partner. Included in the policy are: Escort and Supervision, Entry/Exit, Cleanliness, Hands, Hair and Facial Hair, Clothing, Safety, Jewelry, Personnel Items, Locker Policy, Food/Beverage/Medication/Tobacco usage, Injury or Communicable Disease, Health Related Pandemic, Ingredient/Product Protection, Ingredient/Product Security, Chemicals, Containers and Utensils, Allergens, and Reporting Food Safety Concerns. The last locker inspections and clean-out was conducted on 6/4/19. During the audit the employees were observed to be following the GMP policy. The employees interviewed during the audit were each aware of how the affect food safety and were observed in the proper PPE. The lockers opened and inspected were found to be clean.

2.4.2.1 The site shall ensure the Good Manufacturing Practices described in modules 3, 4, 9, 10 or 11 (as applicable) of this Food Safety Code are applied, or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

The site has a food safety plan developed following the HACCP guidelines with the FSMA requirements of the preventative controls included. The plan is dated 9/30/20 and approved by the QA Manager/SQF Practitioner and the Managing Partner/Director of Regulatory. The Food Safety team is the same members as the Food Safety Plan team captained by the Managing Partner, with the team members of the QA Manager, QA Supervisor, Maintenance Supervisor, Blend Leader, Stick Pack Leader. The Product Description Section includes the intended use, storage and distribution, shelf life, technical information including the pH level <4.0, packaging requirements, intended use customers (all population) and food safety information. The site has the process developed through 6 flow diagrams. Compressed air, CCPs and the waste flow are identified within the flow diagrams. The six flow diagrams are: Cloud Line 1 and 2, Shaker Line 3, Blending line 4, Manual Line 5, Stick Pack Line 7, and Blending Line 8. The pre-requisite programs are included within the plan addressing how they contribute in reducing and or eliminating hazards. CCP1 is identified as a 4 mesh/.18 inch screen at he blender verified at start and end of each batch within the production run. CCP2 a 14 mesh/1.4 mm screen which is verified at the start, change-overs and end of each production run. CCP3 is metal detection after the magnet during the product release from the blender, verified at the beginning of shift, after each blend/lot and at the end of the shift. The CCP monitoring step is developed. The site has developed a risk assessment for each of the raw materials. Since the program started the site has not had a CCP deviation and or failure.

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. Feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.4 The scope of each food safety plan shall be developed and documented including the start and end-point of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

2.4.3.5 Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.5.1) plus any additional information relevant to product safety, such as pH, water activity, and/or composition.

RESPONSE: COMPLIANT

2.4.3.6	The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative use of the product. **RESPONSE:** COMPLIANT
2.4.3.7	The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw material, packaging material, service inputs (e.g. water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation. **RESPONSE:** COMPLIANT
2.4.3.8	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs. **RESPONSE:** COMPLIANT
2.4.3.9	The food safety team shall conduct a hazard analysis for every identified hazard to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT
2.4.3.10	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure. **RESPONSE:** COMPLIANT
2.4.3.11	Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e. a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure. **RESPONSE:** COMPLIANT
2.4.3.12	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard (s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1). **RESPONSE:** COMPLIANT
2.4.3.13	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT
2.4.3.14	The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure. **RESPONSE:** COMPLIANT
2.4.3.15	The documented and approved food safety plan (s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs or other changes affecting product safety occur. **RESPONSE:** COMPLIANT
2.4.3.16	Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5). **RESPONSE:** COMPLIANT
2.4.3.17	Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements. **RESPONSE:** COMPLIANT

2.4.4 Approved Supplier Program (Mandatory)

Supplier Approval Program SOP 4.1 Rev 004 is dated 6/11/19 and approved by the Managing Partner. The process requires each supplier to provide the documentation for: HACCP plan, GMP program, finished product specifications, ingredient specifications, food defense program, employee training program, third party audit, letter of continuing guarantee, liability insurance, letter of compliance and food fraud. As the site is solely a co-manufacturer for one customer the customer supplies all materials used by the site. The approved supplier register is maintained and managed by the said supplier. The supplier documentation was reviewed during the audit and found to be acceptable.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.5 Non-conforming Product or Equipment

Hold/Rejection Procedure SOP 4.6 Rev 003 is dated 6/20/19 and is approved by the Managing Partner. The procedure has both a hold tag and the hold log as reference documents. The four items observed within the hold cage were also observed properly documented into the hold log. The tags were observed fully complete.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.6 Product Rework

The site does not use rework.

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

RESPONSE: NOT APPLICABLE

2.4.6.2 Records of all reworking operations shall be maintained.

RESPONSE: NOT APPLICABLE

2.4.7 Product Release (Mandatory)

Quality Release Procedures SOP 4.8 Rev 003 is dated 6/20/19 and is approved by the Managing Partner. The procedure includes raw material testing, packaging testing, blending approvals, and finished product approval. The finished product inspection sheets (packet) is completed and verified daily prior to shipment. Daily the finished goods are shipped to the customer. Release paperwork from 10/6/20 was reviewed and found to be acceptable. The records included within the packet are: work order/BOM, Quality check sheet for (seal, weight, count, humidity and temperature and moisture), label quality and information, case label and information, line clearance and scale verification. The packet is signed off by the Quality Supervisor.

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released: i. By authorized personnel; and ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release shall be maintained.

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

Environmental Monitoring Program SOP 4.11 Rev 002 is dated 6/25/19 and is approved by the Managing Partner. The site program is broken into 4 zones. The site's monitoring schedule is testing zones 2, 3 and 4 for Salmonella, and Listeria. The site is swabbing randomly in zone 2, 3 and 4 for both the pathogens. Year to date 45 swabs have been taken. Yeast and Mold is tested through air plates. The site external laboratory is certified in environmental testing through November 30, 2020. The environmental program started in September 2019. The site swab reference list is developed and used to choose the monthly swab sites. Since the program began no positive results have returned from the third party laboratory. The program documents triple cleaning should it be needed. E. Coli was tested for the sanitation water and laboratory water on 1/28/20 and tested negative.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

The Verification and Validation Program SOP 5.1 Rev 002 is dated 9/18/19 and approved by the Managing Partner. The verification and validations are completed to the predetermined schedule based on the SQF module sections and per this element code 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 ensure that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required result; ii. Critical food safety limits are validated, and re-validated annually; iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and iv. All applicable elements of the SQF Program are implemented and effective.

RESPONSE: COMPLIANT

2.5.1.2 Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

The Verification and Validation Program SOP 5.1 Rev 002 is dated 9/18/19 and approved by the Managing Partner. The verification and validations are completed to the predetermined schedule. The verification activities and schedule are built within the master document register. Each food safety record has a verification line to confirm the data within the record is within acceptability.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

Reportable Quality Incidents SOP 4.5 Rev 004 is dated 6/24/19 and is approved by the Managing Partner. The program identifies corrections in two concerns. The first is internal Corrective actions and the second are customer driven incidents. The site has an investigational report with the issue topic, corrective action, root cause and preventative action documented. On 10/1/20 an internal incident was documented as the second shift put an in-house label on an external shipper. The error was found during the QA finished goods verification. The product was put on hold and recouped the next day with proper shipper labels. The investigation report is documented with the CA, root cause and the preventative actions taken.

2.5.3.1 The responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4 Product Sampling, Inspection and Analysis

Collection and Storage of Finished Good Sample Retains SOP 5.2 Rev 003 is dated 6/18/19 and is approved by the Managing Partner. Samples of each production run B,M,E are pulled and held in the retain library for 2.5 years which is 6 months past the longest shelf life. An electronical retain log is maintained and was found to be active and complete. Testing of the product is done for organoleptic (appearance, aroma, dispersion and taste), granulation, and moisture. The technicians responsible for testing have demonstrated their proficiency for each test they perform. The proficiency testing was conducted on 9/30/20. The external laboratory testing for water and pathogens are conducted by the same laboratory company. The accreditation certificates are observed to be current through November 30, 2020.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4.4 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.5.5 Internal Audits and Inspections (Mandatory)

Site Improvement Policy SOP 5.6 Rev 005 is dated 5/19/20 and is approved by the Managing Partner. The site is inspected monthly both internally and externally by a team of the QA Manager (captain), Blend Lead, QA Supervisor, Maintenance Manager and the Managing Partner. Each month two of the team members conduct the audit. The audit is inspected using a pre-developed form called the Food Safety and Quality Site Improvement Audit Form 5.6a Rev 004 dated 11/5/19 and approved by the Managing Partner. The inspection information is developed into a tracking spreadsheet and the needed corrective actions are tracked until they are corrected and closed by the QA Manager.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.5.4 Where practical staff conducting internal audits shall be independent of the function being audited.

RESPONSE: COMPLIANT

2.5.5.5 Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained.

RESPONSE: COMPLIANT

2.6.1 Product Identification (Mandatory)

Product Identification SOP 6.1 Rev 002 is dated 3/11/20 and approved by the Managing Partner. The methods and responsibility for identifying raw materials, WIP and finished goods is documented. The site finished goods lot number as example is: 1011217886 would mean Oct, 11, 2021 line 7 batch number sequentially year to date 886. The production line changeover process and the record documents required at blending are described within the procedure. Records from 10/6/20 were reviewed and found to be acceptable.

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

RESPONSE: COMPLIANT

2.6.1.2 Product identification records shall be maintained.

RESPONSE: COMPLIANT

2.6.1.3 Product start up and changeover procedures during packing shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label, and that the changeover is inspected and approved by an authorized person.

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

Traceability Policy 6.3 Rev 001 is dated 3/11/20 is approved by the Managing Partner. The site is conducting trace exercises annually, one up and one down. The last trace exercise was conducted on 8/18/20 for the raw material Cherry Red Flavor 13-1320 and finished good Black Cherry 13-7008 with a 100.0% recovery on the raw material and a 97.7% recovery on the finished good. The exercise took 2 hours and 35 minutes. During the this audit the product Orange Durarome 1355032 was traced. On 3/26/20 6,559,28 lbs. of lot number 1004991587 was received. 4,512,17 remain in stock. 2,048.13 have been consumed during 19 different production days. The site is able to pull the data to support the use. This is a 100.01% recovery which took the team 1 hour to complete.

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

RESPONSE: COMPLIANT

2.6.2.2 Records of raw and packaging material receipt and use, and finished product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

Product Recall Policy SOP 6.2 Rev 005 is dated 10/23/20 and is approved by the Managing Partner. The site policy documents a recall drill is to be conducted annually. The Director of Regulatory/Managing Partner is the captain. The Managing Partner is responsible to contact the customer and media. The QA Manager contacts regulatory (FDA, SQF and the Certification Body) and the employees. The back-up Partner contacts the Legal. The site policy documents an investigation to root cause is required. Notification to regulatory is to be within 24 hours. A mock recall drill conducted on 10/5/20 and SQF and the CB were not mock contacted.

2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall; ii. Describe the management procedures to be implemented including sources of legal, regulatory and expert advice and essential traceability information; and iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; iv. SQFI, the certification body, and the appropriate regulatory authority shall be listed as an essential body and notified in instances of a food safety incident of a public nature, or product recall for any reason.

RESPONSE: COMPLIANT

2.6.3.2 Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: The site conducted the mock recall 10/5/20. It is observed that the SQFI and the CB were not mock contacted during the mock crisis drill.

ROOT CAUSE: The Quality Manager did not fully understand what need to be documented.

CORRECTIVE ACTION: The mock recall event was redone and the summary reformatted to include items missed. Included are the investigation report, email thread from new recall, new contact list created for team members, and revised summary of mock recall event. The preventative action for this is that a new skeleton was created for event summaries that provides prompting so that the QA MAnager does not leave things out.

VERIFICATION OF CLOSEOUT: The site updated the recall SOP to include the internal folks that will contact the external required parties. The mock event was redone and clearly identifies the communications which covers the required parties. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

2.7.1 Food Defense Plan (Mandatory)

Food Defense SOP 7.1 Rev 003 is dated 6/28/19 and is approved by the Managing Partner. The site defends itself through: Facility Entry (door key locks, fobs, cameras and proper lighting and doors kept in closed positions) and Pre-Hire Employee Screening. The site conducts monthly inspections for food defense during the site internal audit and then again during an annual food defense plan assessment. The last plan assessment was conducted on 9/27/19 and approved by the Managing Partner. The Managing Partner is the site food defense coordinator and has a food defense coordinator on-line certificate from AIB on 8-11-19.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: The site has not challenged the plan this year.

ROOT CAUSE: When SQF Practitioner set up the annual systems review schedule food defense was scheduled for December so the Practitioner forgot to have the challenge done before the 2020 SQF audit.

CORRECTIVE ACTION: The Food Defense Challenge was completed. Included are the investigation report and the event summary. The preventative action for this is that the 2021 system review schedule will be changed so that the Food Defense review happens earlier in the year so that the practitioner has the challange done before the audit.

VERIFICATION OF CLOSEOUT: The site conducted an investigation to determine why the challenge had not occurred and has now completed a FD challenge. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 11/02/2020 **CLOSEOUT DATE:** 11/04/2020

2.7.1.4	Records of reviews of the food defense plan shall be maintained. **RESPONSE:** COMPLIANT

2.7.2 Food Fraud

The site is a co-manufacturer for one supplier/customer. The supplier is managing the food fraud program. The plan, plan assessment and the mitigation plan is developed, was reviewed and found to be acceptable. The food fraud assessment 030-001-2 is dated 3/5/20 and the mitigation plan 030-002 dated 7/10/19 was reviewed and found to be acceptable. The supplier/customer running the food fraud program is contracted with a third party search company, Horizon Scan which assists in the program evaluation.

2.7.2.1	The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety. **RESPONSE:** COMPLIANT
2.7.2.2	A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled. **RESPONSE:** COMPLIANT
2.7.2.3	The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually. **RESPONSE:** COMPLIANT
2.7.2.4	Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained. **RESPONSE:** COMPLIANT

2.8.1 Allergen Management for Food Manufacturing (Mandatory)

Allergen Program SOP 8.1 Rev 004 is dated 3/24/20 and is approved by the Managing Partner. The site does not use any of the USA or Canadian allergens which are the two countries the site's one customer ships to. Allergen control is one of the topics trained to all employees annually. The date of the last allergen training was conducted on 9/2/20.

2.8.1.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A register of allergens which is applicable in the country of manufacture and the country (ies) of destination if known; iv. A list of allergens which is accessible by relevant staff. v. The hazards associated with allergens and their control incorporated into the food safety plan. vi. A management plan for control of identified allergens. The allergen management program shall include the identification, management, and labelling of products containing gluten, where applicable. **RESPONSE:** COMPLIANT
2.8.1.2	Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in progress, rework or finished product on how to identify, handle, store and segregate raw materials containing allergens. **RESPONSE:** COMPLIANT
2.8.1.3	Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored. **RESPONSE:** COMPLIANT
2.8.1.4	Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided where satisfactory line hygiene and clean-up or segregation is not possible. **RESPONSE:** COMPLIANT
2.8.1.5	Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented. **RESPONSE:** COMPLIANT

2.8.1.6	Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact. **RESPONSE:** COMPLIANT
2.8.1.7	The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured. **RESPONSE:** COMPLIANT
2.8.1.8	The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in-progress and finished product is true to label with regard to allergens. Such measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures. **RESPONSE:** COMPLIANT
2.8.1.9	The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used. **RESPONSE:** COMPLIANT
2.8.1.10	Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable. **RESPONSE:** COMPLIANT
2.8.1.11	Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introducing unintended allergens through supplier, contract manufacturer, employee and visitor activities. **RESPONSE:** COMPLIANT
2.8.2	**Allergen Management for Pet Food Manufacturing** The site is not a pet food manufacturer.
2.8.2.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those inputs and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A list of allergens which is accessible by relevant staff; and iv. The hazards associated with allergens and their control incorporated into the food safety plan. **RESPONSE:** COMPLIANT
2.8.2.2	Product labeling, in accordance with regulatory requirements, shall include allergens where risks from cross-contact have been identified. **RESPONSE:** COMPLIANT
2.8.3	**Allergen Management for Manufacturers of Animal Feed** The site does not manufacture animal feed.
2.8.3.1	Sites that exclusively manufacture animal feed and do not manufacture, handle or store food or pet food products are not required to implement an allergen management plan unless required by regulation or customer requirement. **RESPONSE:** NOT APPLICABLE
2.8.3.2	Where an allergen management plan is required by regulation or customer specification, the requirements of 2.8.2 shall apply. **RESPONSE:** NOT APPLICABLE
2.9.1	**Training Requirements** The Training SOP 9.1 Rev 005 is dated 1/15/20 and is approved by the Managing Partner. The QA Manager is responsible for the program. The site requires an 85% comprehension of each topic trained. The site documents the trainings will be achieved at a 96% completion.

2.9.1.1 The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

The site trains 9 topics to all company employees: Allergen Awareness, Bodily Fluid Contamination, Metal Detection or Screen Use/Inspection, Foreign Matter, Personnel GMPs, Food Grade and Non-Food Grade Chemicals, Waste Management, Food Defense, and Food Safety. Thirteen job specific trainings are also given annually as applicable.

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

RESPONSE: COMPLIANT

2.9.3 Instructions

The individual topic training is completed in small groups and the training roster is signed by the trainer and trainee. The site trains in English, the language understood by all.

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

RESPONSE: COMPLIANT

2.9.4 HACCP Training Requirements

The QA Manager has increased the HACCP team members to the team described in the Food Safety section of this report. On 1/30/20 the new team met and discussed the 7 steps and 12 principal of HACCP.

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

RESPONSE: COMPLIANT

2.9.5 Language

All training and communications throughout the site are in English the language understood by all.

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

RESPONSE: COMPLIANT

2.9.6 Refresher Training

Each of the identified trainings an individual is to have are refreshed on an annual basis.

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

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

The training matrix/register was last reviewed on 10/5/20 was reviewed and found to be complete. The site maintains each employee on the register even if they leave the company until the next calendar year.

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

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

The Maryland Department of Health has issued a license for Food Processing Plant current through 9/30/2020 for Title 21. The site has evidence of the renewal application form as of 9/21/20. The site has an email from the State saying they have approved the application however has not sent the new certificate to the site. The site is located in a small industrial mall. The businesses around the site are individual companies which do not pose a food safety concern.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.1 Materials and Surfaces

The food contact equipment is observed to be stainless steel. The materials of the equipment and food handling areas do not pose a food safety concern.

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

RESPONSE: COMPLIANT

11.2.2 Floors, Drains, and Waste Traps

The site is concrete flooring and polished concrete in the manufacturing rooms. The floor to wall junctures are observed to be well sealed. The site has one floor drain located in the sanitation room which is cleaned weekly. The site does not have a waste trap.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.3 Walls, Partitions, Doors and Ceilings

The walls, doors and ceilings are observed clean and good condition. The overheads are cleaned on an annual basis and were last cleaned 9/23/20. The walls and doors are of light color. The sanitary drains are not plumbed across production rooms. The pest operator is able to service the drop ceiling above the offices which was last completed on 9/29/20.

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

RESPONSE: COMPLIANT

11.2.3.2	Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris. **RESPONSE:** COMPLIANT
11.2.3.3	Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed to prevent the contamination of food, ingredients and food contact surfaces and allow ease of cleaning. **RESPONSE:** COMPLIANT
11.2.3.4	Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients and food contact surfaces, and shall allow ease of cleaning. **RESPONSE:** COMPLIANT
11.2.3.5	Doors, hatches and windows and their frames in food processing, handing or storage areas shall be of a material and construction which meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction and windows shall be made of shatterproof glass or similar material. **RESPONSE:** COMPLIANT
11.2.3.6	Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. **RESPONSE:** COMPLIANT
11.2.3.7	Drop ceilings shall be constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities. **RESPONSE:** COMPLIANT
11.2.4	**Stairs, Catwalks and Platforms** The only stairway on site is the one to reach the mixing platform. The steps are solid construction and the risers are open to the back. The steps were observed clean. They are on the sanitation schedule to be cleaned daily.
11.2.4.1	Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1). **RESPONSE:** COMPLIANT
11.2.5	**Lightings and Light Fittings** The internal site lighting is florescent and the bulbs are shatter-shield covered and under guards. The site has a glass breakage policy SOP 14.20 Rev 002 dated 6/24/19 and approved by the Managing Partner. The site has not had a glass breakage incident this year.
11.2.5.1	Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively. **RESPONSE:** COMPLIANT
11.2.5.2	Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program. **RESPONSE:** COMPLIANT
11.2.5.3	Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination. **RESPONSE:** COMPLIANT
11.2.6	**Inspection / Quality Control Area** Within the production room an area is set up for product review and testing. The area is observed to be food safe, clean, on a stainless steel table and has a trash can next to the evaluation station. Hand washing is near-by. Product is further evaluated in the internal laboratory away from the production rooms.

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

RESPONSE: COMPLIANT

11.2.6.2 The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to hand washing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

RESPONSE: COMPLIANT

11.2.7 Dust, Insect, and Pest Proofing

The site does not have any windows or fans within the production rooms or warehouse. The warehouse skylights are observed to be well sealed with no evidence of leaking. The man doors are observed to be maintained in closed position and most are observed to be tightly sealed. Two doors, Door 9 and the Ramp door have visible daylight around them. The dock doors have insect light traps installed which were observed functioning and clean. The internal pest control devices do not contain bait. Only bait used on site is in the exterior bait boxes which is serviced by the PCO only.

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: Door 9 and the Ramp door do not have a secure gasket. Light can be seen around the perimeter of the doors.

ROOT CAUSE: This was not a part of the monthly site audit and no one recognized that we should be checking them.

CORRECTIVE ACTION: New Gaskets obtained and installed on doors. Included are the investigation report, pictures of both doors from multiple angles, and revised monthly site inspection form. The preventative action for this is that checking egress doors to make sure gaskets are secure has been added to the monthly site audit form.

VERIFICATION OF CLOSEOUT: The site has installed gaskets to both identified doors. The monthly GMP inspection form has been modified. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

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

RESPONSE: MINOR

EVIDENCE: Within the Pre-Weigh room the plume/vent stack up through the roof to the exterior sky does not have a screen installed to prevent pest entry.

ROOT CAUSE: Management did not realize that the vent design did not include anything preventing entrance through the top.

CORRECTIVE ACTION: Filter obtained and installed in the vent. Included are the investigation report, and picture of the installed filter. The preventative action for this is that management is now cognazant of the need to make sure all openings are designed to prevent entrance when plans are made for new construction.

VERIFICATION OF CLOSEOUT: The site conducted and investigational report to find the roort cause and preventative action. They have installed a new filter within the plume. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

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

RESPONSE: COMPLIANT

11.2.8 Ventilation

The production rooms are air conditioned through the roof top HVAC units. The HVAC roof filters are Merv 8 and the room filters are Merv 4. The room filters are cleaned daily and the roof filters are replaced quarterly by a third party provider. The site does not have an extractor fan.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.8.3 Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features: i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over the cooker(s); ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk; and iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.

RESPONSE: COMPLIANT

11.2.9 Equipment, Utensils, and Protective Clothing

The warehouse racking is steel and is observed to be clean and in solid condition. The site does have a specifications register 3.2j dated 10/6/20 for the utensils, brooms, buckets, etc. to show they are approved for use in food plants. The mixer operators are observed to be wearing their personal clothing with plastic aprons over their clothing. The aprons are one time use only. The site does have a risk assessment to show the clothes as low risk in that it does not contribute as a food safety concern.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.9.3 Benches, tables, conveyors, mixers, mincers, graders and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious and free from cracks or crevices.

RESPONSE: COMPLIANT

11.2.9.4 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned as per 11.2.13. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

EVIDENCE: See 11.3.3.1

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

RESPONSE: COMPLIANT

11.2.9.8 All equipment, utensils and protective clothing shall be cleaned after use or at a frequency to control contamination and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

11.2.10 Premises and Equipment Maintenance

Maintenance and PM Policy SOP 10.1 Rev 001 is dated 9/9/19 and approved by the Managing Partner. The PM system is a manual program managed by the Maintenance Supervisor. Records of PMs for January, February and March 2020 were reviewed and found to be acceptable. The work order for changing Teflon on the line 1 for 10/14/20 and the work order completed on 10/16/20 for the cutting wheel on lines 1 and 2 were reviewed and found to be acceptable. A temporary repair of red tape on the control panel leg/bustle to the Stik Pac Filler was observed. The site does not have the item listed on the temporary equipment/repair plan to manage the items sited. The tool boxes observed within the shop were each found to be very clean. The hazardous chemicals within the locked storage cabinets were organized and had the company stop-light green, red stickers on each chemical container per the company program.

11.2.10.1 The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and implemented in a manner that minimizes the risk of product, packaging or equipment contamination.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.10.3 Failures of plant and equipment in any food processing, handling or storage area shall be documented, reviewed and their repair incorporated into the maintenance control schedule.

RESPONSE: COMPLIANT

11.2.10.4 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3.1, 11.3.2, 11.3.3, 11.3.4).

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.10.6 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling or storage area.

RESPONSE: COMPLIANT

11.2.10.7 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times.

RESPONSE: COMPLIANT

11.2.10.8 Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: MINOR

EVIDENCE: Red tape is observed on the Control Panel leg/bustle to the Stik Pac Filler. It is not listed on the temporary repair log.

ROOT CAUSE: Tape applied by former employee and not documented

CORRECTIVE ACTION: 1. An incident report was written to learn the root cause and preventative action 2. The item was added to the temporary repair log. 3. A work order was written for the repair to be made. 4. Permenent cover made for the top of arm and red tape replaced. Picture of the permenant repair was taken and forwarded to auditor.

VERIFICATION OF CLOSEOUT: The site placed the item onto the temporary log, wrote a work order and made a permanent correction. Picture of the correction was received and reviewed. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

11.2.10.9 Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed and a pre-operational inspection conducted prior to the commencement of site operations.

RESPONSE: COMPLIANT

11.2.10.10 Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.11 Calibration

Calibration Program SOP 10.3 Rev 002 is dated 9/15/20 and is approved by the Managing Partner. The site has calibration measurements completed annually for the scales and the metal detector. The scales were last completed on 9/22/20. The metal detector was last completed on 5/29/20. The magnets were last pull tested on 9/17/20. The site certified weights were last purchased on 9/9/19. The moisture machine was serviced on 9/22/20.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.11.6 Calibration records shall be maintained.

RESPONSE: COMPLIANT

11.2.12 Pest Prevention

The Pest Control Program is dated November 12, 2019 and approved by the QA Manager. The pest company services the site monthly both on the interior and exterior of the facility. The liability certificate is current through 10/1/21. The Pest Control Company license is current through June 30, 2021. The PCO license is current through 6/30/2021. The PCO training records were included in the pest binder, were reviewed and found to be acceptable. The chemical SDS sheets are available on a CD and individually inserted in the binder. The approved chemical list is dated 7/20/20. The site map is dated 7/21/20 and includes the ILTs, and the interior and exterior rodent stations. The service reports are reviewed at end of service with the QA Manager. They are observed to be signed each visit. The last annual inspection is dated 7/15/20 conducted by the area Pest Company Operations Manager. The chemical usage log is observed to be maintained. The trending reports were reviewed and observed to be acceptable.

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

RESPONSE: COMPLIANT

11.2.12.2	Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging. **RESPONSE:** COMPLIANT
11.2.12.3	Food products, raw materials or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation investigated and resolved. Records shall be kept of the disposal, investigation, and resolution. **RESPONSE:** COMPLIANT
11.2.12.4	The pest prevention program shall: i. Describe the methods and responsibility for the development, implementation and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods; v. Outline the frequency with which pest status is to be checked; vi. Include on a site map the identification, location, number and type of bait stations set; vii. List the chemicals used (they are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available); viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests. **RESPONSE:** COMPLIANT
11.2.12.5	Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present. **RESPONSE:** COMPLIANT
11.2.12.6	Records of all pest control applications shall be maintained. **RESPONSE:** COMPLIANT
11.2.12.7	Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.4 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces. **RESPONSE:** COMPLIANT
11.2.12.8	Pest contractors shall be: i. Licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.3) which will include and maintain a site map indicating the location of bait stations traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and vi. Provide a written report of their findings and the inspections and treatments applied. **RESPONSE:** COMPLIANT
11.2.12.9	The site shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that: i. Empty chemical containers are not reused; ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor. **RESPONSE:** COMPLIANT

11.2.13 Cleaning and Sanitation

Cleaning and Sanitation Program SOP 10.5 Rev 004 is dated 9/15/20 and approved by the Managing Partner. The QA Manager is managing the Sanitation program. The program schedule is broken into daily, weekly, monthly, and quarterly tasks. Restrooms are cleaned at the end of shift by the dedicated Sanitor team. Records for 1/4 through 10/9/20 were reviewed and found to be complete. The production team is responsible to clean the equipment daily at end of shift and or at product change-over. Visual inspections are conducted during pre-op and or after change-over to confirm cleaning effectiveness. It is observed that inspections for glass and brittle plastic conditions on the lines are inspected each pre-op inspection. Cleaning records for 9/18 to 10/7/20 was reviewed and found to be acceptable. Chemical Control Program SOP 13.4 Rev 003 is dated 6/24/19 and is approved by the Managing Partner. The chemicals are documented to be stored within the locked and signed chemical cage. The chemical register 13.4a appears to be complete. The chemicals WD 40, Oasis 146, a multi-sanitizer and the glue, G25A77-002 observed in the glue guns were both observed on the chemical register and SDS sheets were available for both. The sanitizer used is diluted through an equipment diluter. Dilution records and the diluter calibration records for 9/10/20 were reviewed and found to be acceptable. The Pre-operational records for 9/18 through 10/7/20 were reviewed and found to be acceptable.

11.2.13.1	The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Methods used to confirm the correct concentrations of detergents and sanitizers, and vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program. **RESPONSE:** COMPLIANT
11.2.13.2	Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing. **RESPONSE:** COMPLIANT
11.2.13.3	Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils shall be provided as required. **RESPONSE:** COMPLIANT
11.2.13.4	Cleaning in place (CIP) systems where used shall not pose a chemical contamination risk to raw materials, ingredients or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored and recorded (e.g., chemical and concentration used, contact time and temperature). CIP equipment including spray balls shall be maintained and modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained. **RESPONSE:** COMPLIANT
11.2.13.5	Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities and sanitary facilities and other essential areas are clean before the commencement of production. Pre-operational inspections shall be conducted by qualified personnel. **RESPONSE:** COMPLIANT
11.2.13.6	Staff amenities, sanitary facilities and other essential areas shall be inspected by qualified personnel to ensure the areas are clean, at a defined frequency. **RESPONSE:** COMPLIANT
11.2.13.7	The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared. **RESPONSE:** COMPLIANT
11.2.13.8	Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use; ii. An inventory of all chemicals purchased and used shall be maintained; iii. Detergents and sanitizers are stored as outlined in element 11.6.4; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v. Only trained staff handles sanitizers and detergents. **RESPONSE:** COMPLIANT
11.2.13.9	Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained. **RESPONSE:** COMPLIANT
11.2.13.10	The site shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor. **RESPONSE:** COMPLIANT
11.2.13.11	A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained. **RESPONSE:** COMPLIANT

11.3.1 Personnel

Personnel and Visitor GMPs SOP 11.1 Rev 007 is dated 9/14/20 and is approved by the managing Partner. Included in the policy are: Escort and Supervision, Entry/Exit, Cleanliness, Hands, Hair and Facial Hair, Clothing, Safety, Jewelry, Personnel Items, Locker Policy, Food/Beverage/Medication/Tobacco usage, Injury or Communicable Disease, Ingredient/Product Protection, Ingredient/Product Security, Chemicals, Containers and Utensils, Allergens, and Reporting Food Safety Concerns. During the audit the employees were observed to be following the GMP policy. The employees interviewed during the audit were each aware of how they affect food safety and were observed in the proper PPE.

11.3.1.1 Personnel who are carriers or are known to have been carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed.

RESPONSE: COMPLIANT

11.3.1.2 The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids from open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury which causes spillage of bodily fluid, a properly trained employee shall ensure that all affected areas including handling and processing areas have been adequately cleaned and that all materials and products have been quarantined and disposed of.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.1.4 Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging or equipment.

RESPONSE: COMPLIANT

11.3.2 Hand Washing

Within the GMP Policy handwashing practices is documented. The sinks in the restrooms are each porcelain. The sinks in the plant are made of polyester resin and the material specification documenting NSF/ANSI 372 meeting the Lead-Free content requirement was reviewed and found to be acceptable. The sinks each had liquid soap, hot and cold water and paper towels and trash cans available. The employees interviewed explained that gloves are to be thrown away and that hands are to be rewashed when picking up something from the floor.

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

RESPONSE: COMPLIANT

11.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as a minimum supplied with: i. A potable water supply at an appropriate temperature; ii. Liquid soap contained within a fixed dispenser; iii. Paper towels in a hands-free cleanable dispenser; and iv. A means of containing used paper towels.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.2.5 Personnel shall have clean hands and hands shall be washed by all personnel, including staff, contractors and visitors: i. On entering food handling or processing areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating or drinking; and v. After handling wash down hoses, dropped product or contaminated material.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3 Clothing

The site has conducted a risk assessment to determine the personal clothing the site is allowing the employees to wear is not a risk to unintentional microbiological contamination. The risk assessment was reviewed and found to be acceptable.

11.3.3.1 The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food and food contact surfaces from unintentional microbiological or physical contamination.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3.4 Excessively soiled uniforms shall be changed or replaced where they present a product contamination risk.

RESPONSE: COMPLIANT

11.3.3.5 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or designated sealed containers in personnel lockers and not on packaging, ingredients, product or equipment.

RESPONSE: COMPLIANT

11.3.4 Jewelry and Personal Effects

Jewelry is not allowed in the warehouse or production rooms. The site allows plain wedding bands only and medical alert bracelets and or necklaces as directed by a doctor.

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

RESPONSE: COMPLIANT

11.3.5 Visitors

The visitor program is documented within the site's GMP policy. All visitors are to check in at the front lobby and sign the log book. Visitors are to read and sign the GMP policy. Visitors are to be escorted when in the plant. Contractors after training are able to be without an escort as applicable. Visitors are required to follow the site GMP policy. The log book was observed to be well utilized.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.6 Staff Amenities

Staff amenities are observed to be well lighted and ventilated.

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

RESPONSE: COMPLIANT

11.3.7 Change Rooms

The site does not have change rooms provided. Should a person want to change their clothing single person restrooms are available.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.8 Laundry

The site does not contract with a laundry provider or do laundry themselves.

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

RESPONSE: COMPLIANT

11.3.9 Sanitary Facilities

The toilet rooms were adequate in number, each were found to be clean, provided toilet paper, sinks with hot and cold water, liquid soap, paper towels and trash cans. Each toilet room are individual person restrooms. The drainage goes directly to the public sewer system. Cleaning restroom records were reviewed and found to be current.

11.3.9.1 Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and vi. Kept clean and tidy.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.10 Lunch Rooms

The lunch room is observed clean, well lighted and ventilated, has a refrigerator, microwave, vending machines, hand washing signage, ample seating and tables. An out door eating area is provided was found clean of trash and or food debris. The site has a program for how the area is to be maintained.

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

RESPONSE: COMPLIANT

11.3.10.2 Lunch-room facilities shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities enabling them to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

The GMP policy does not allow for false fingernails and or polish. Sensory evaluation is conducted in the laboratory only. The wash down hose was observed coiled on the wall rack off the floor. Waste is not observed to build up during production and is removed routinely throughout the process.

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

RESPONSE: COMPLIANT

11.4.1.2 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the site shall implement proper controls and procedures to ensure: i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel only; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; and v. Equipment used for sensory evaluations is sanitized, maintained and stored separate from processing equipment.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.1 Water Supply

The site water is received by the Baltimore City Department of Public Works 2019. The report has test results for Total Coliforms and the radiological contaminants of Beta Photon Emitters and Alpha Emitters. The site has both hot and cold water at each restroom, hand wash station the lunch room and in the sanitation room. The site has two back flow devices which were tested and passed on 9/28/20.

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment.

RESPONSE: COMPLIANT

11.5.1.2 Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

11.5.1.3 The delivery of water within the premises shall ensure potable water is not contaminated.

RESPONSE: COMPLIANT

11.5.1.4 The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent back flow or back siphonage.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.2 Water Treatment

The site does not treat the water.

11.5.2.1 Water treatment methods, equipment and materials, if required, shall be designed, installed and operated to ensure water receives an effective treatment.

RESPONSE: NOT APPLICABLE

11.5.2.2 Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

RESPONSE: NOT APPLICABLE

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the indicators specified.

RESPONSE: NOT APPLICABLE

11.5.2.4 Water used in as an ingredient in processing, or in cleaning and sanitizing equipment, shall be tested, and if required, treated to maintain potability (refer to 11.5.2.1).

RESPONSE: NOT APPLICABLE

11.5.3 Ice Supply

The site does not use ice.

11.5.3.1 Ice provided for use during processing operations or as a processing aid or an ingredient shall comply with 11.5.4.1.

RESPONSE: COMPLIANT

11.5.3.2 Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution.

RESPONSE: COMPLIANT

11.5.4 Water Quality

The site pulls water from two sites annually and sends it to the accredited lab. The lab tests for E. Coli and Total coliform. Results of the testing from 1/22/20 were reviewed and found to be acceptable.

11.5.4.1 Water shall comply with local, national or internationally recognized potable water microbiological and quality standards as required when used for: i. washing, thawing and treating food; ii. handwashing iii. to convey food; iv. as an ingredient or food processing aid; v. cleaning food contact surfaces and equipment; vi. the manufacture of ice; or vii. the manufacture of steam that will come into contact with food or used to heat water that will come in contact with food.

RESPONSE: COMPLIANT

11.5.4.2 Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning, or from within the site. The frequency of analysis shall be risk-based, and at a minimum annually.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.5 The Quality of Air and Other Gasses

The site has compressed air which hits food contact packaging on lines 1 and 2. Compressed air is also used to blow out the bottles on line 3 prior to filling. The air is tested annually by a third party laboratory. The Aerobic Plate test results from 9/16/20 for yeast and mold were reviewed and found to be acceptable. The air filters are replaced quarterly. The last date the filters were replaced were on 10/2/20. The packaging contract air filters are .01 micron filters. The compressed air system is filtered at 3.0 microns. The compressed air is listed within the Food Safety plan and has a risk assessment completed within the plan.

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

RESPONSE: COMPLIANT

11.5.5.2 Compressed air systems, and systems used to store or dispense other gases used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

RESPONSE: COMPLIANT

11.6.1 Storage and Handling of Goods

Receiving Storage and Shipping Procedures SOP 13.2 Rev 002 is dated 5/19/20 and is approved by the Managing Partner. The site is rotating the stock through first expired first out. During the audit the product was observed to be following the procedure. The site's MRP program is able to track the date of inventory received, the shelf life assigned to the product and where used.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.1.5 Where goods described in 11.6.2 to 11.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.2 Cold Storage, Freezing and Chilling of Foods

The site does not use refrigeration.

11.6.2.1 The site shall provide confirmation of the effective operational performance of freezing, chilling and cold storage facilities. Chillers, blast freezers and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of food and easily accessible for inspection and cleaning.

RESPONSE: COMPLIANT

11.6.2.2 Sufficient refrigeration capacity shall be available to chill, freeze, store chilled or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

Receiving Storage and Shipping Procedures SOP 13.2 Rev 002 is dated 5/19/20 and is approved by the Managing Partner. The racking is made of steel and was observed to be good condition and clean. The fork lifts and pallet jacks are observed clean and are on the sanitation program as being cleaned on a quarterly cycle. The floor scrubber is cleaned weekly.

11.6.3.1 Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

The Chemical Control Program SOP 13.4 Rev 003 is dated 6/24/19. The room in which the sanitation chemicals are stored is the maintenance shop. The shop is gated and locked. The cage fence is posted with a authorized personnel only sign and a hazardous chemical sign. The chemicals are observed labeled. The area is well ventilated and lighted. The area has a first aid station nearby. The chemicals are inventoried by the QA Manager. A second chemical storage area has been implemented this audit year inside a closet. The closed is observed locked however it does not have proper signage and the chemicals inside are not stored within containment pans.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4.3 Daily supplies of chemicals used for continuous sanitizing of water or as a processing aid, or for emergency cleaning of food processing equipment or surfaces in food contact zones, may be stored within or in close proximity to a processing area provided that access to the chemical storage facility is restricted to authorized personnel.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: 1. The chemical storage closet is not labeled as a restricted chemical storage and as an authorized personnel only room. 2. The chemicals are not stored over a containment pan.

ROOT CAUSE: Management assumed that because the closet was locked at all times and only accessed by sanitation employees we could keep the unopened cases of sanitation chemicals in that closet and did not think about signage or containment pans not being present.

CORRECTIVE ACTION: A larger chemical cabinet purchased and placed in maintenance cage, all chemicals removed from storage closet and placed in new cabinet. Included are: investigation report, and pictures of the new cabinet with the chemicals in it. Preventative action for this is that a larger cabinet was purchased so that there is enough space for all chemicals.

VERIFICATION OF CLOSEOUT: The site has purchased and implemented a new larger chemcial storage cabinet and placed it within the maintenance cage wihin a spill containment pan. The closet is no longer being used to store chemicals. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/30/2020 **CLOSEOUT DATE:** 10/30/2020

11.6.5 Loading, Transport, and Unloading Practices

Receiving Storage and Shipping Procedures SOP 13.2 Rev 002 is dated 5/19/20 and is approved by the Managing Partner. The procedure includes the trailer and product inspection protocols. The procedure inspects both inbound and outbound trailers for leaks, water damage, infestation, and chemical residue. The product (inbound and outbound) is inspected for open containers, infestation, and that the correct product is on the BOL. The trailer is to have a seal and or a lock. Shipping and Receiving records from 9/3 through 9/25 were reviewed and found to be acceptable.

11.6.5.1 The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported and unloaded under conditions suitable to prevent cross-contamination.

RESPONSE: COMPLIANT

11.6.6 Loading

The dock doors open to the warehouse. They product is not exposed to weather. The dock bumpers were observed in good condition. Receiving Storage and Shipping Procedures SOP 13.2 Rev 002 is dated 5/19/20 and is approved by the Managing Partner. The procedure includes the trailer and product inspection. The procedure inspects both inbound and outbound trailers for leaks, water damage, infestation, and chemical residue. The product (inbound and outbound) is inspected for open containers, infestation, and that the correct product is on the BOL. The trailer is to have a seal and or a lock. Shipping and Receiving records from 9/3 through 9/25/20 were reviewed and found to be acceptable.

11.6.6.1 Vehicles (e.g. trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product.

RESPONSE: COMPLIANT

11.6.6.2 Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity during loading and transport.

RESPONSE: COMPLIANT

11.6.6.3 Vehicles (e.g. trucks/vans/containers) shall be secured from tampering using a seal or other agreed upon and acceptable device or system.

RESPONSE: COMPLIANT

11.6.7 Transport

The site does not transport under refrigeration.

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

RESPONSE: COMPLIANT

11.6.7.2 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature at regular intervals during transit.

RESPONSE: COMPLIANT

11.6.8 Unloading

The product is not received refrigerated and the product is not exposed to weather. See 11.6.5.

11.6.8.1 Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.1 Process Flow

The process flow is designed to prevent cross contamination. The process is straight line and does not cross during the process.

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

RESPONSE: COMPLIANT

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

The packaging components are received in the same manner as an ingredient. They are stored in the warehouse separately from the raw materials. Cross contamination is not likely.

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

RESPONSE: COMPLIANT

11.7.3 Thawing of Food

The site does not undergo a thaw process.

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

RESPONSE: NOT APPLICABLE

11.7.3.2 Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature do not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor.

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.7.4 High Risk Processes

The site is not a high risk process.

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.7.5 Control of Foreign Matter Contamination

Foreign Matter SOP 14.19 Rev 004 is dated 9/17/20 and is approved by the Managing Partner. The program covers foreign material, glass, brittle plastic, and breakage events. The glass register inspection was last completed on 9/8/20 by the Maintenance Supervisor. Knives are inspected and the blades are replaced each batch and documented on the batch mix record. Records from 10/1 through 10/6/20 were reviewed and found to be acceptable. Four potential Foreign Material concerns were observed. 1. a loose pen with cap was on the desk on the dumping platform on line 8. 2. trash was observed stuck on a stand on the dumping platform on line 8. 3. A worker's apron was observed torn in several places. 4. The evacuation map in the line 8 room was observed pulling from the wall.

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: Potential Foreign Material are observed. 1. A loose pen with cap was on the desk on the dumping platform on line 8. 2. Trash was observed stuck on a stand on the dumping platform on line 8. 3. A worker's apron was observed torn in several places. 4. The evacuation map in the line 8 room was observed pulling from the wall.

ROOT CAUSE: Lack of understanding and training by all.

CORRECTIVE ACTION: 1. All pens used in warehouse changed to click pens (no Caps) and employees trained to keep in pockets within 3ft of open product. 2. Employees trained that trash is a foreign material and must be disposed of properly. 3. Employees trained that any damaged PPE's could result in foreign matter contamination and must be changed immediately. 4. All evacuation maps in the facility were put into frames (no glass) and hung on the walls. 5. The GMP Policy was updated to include the above.

VERIFICATION OF CLOSEOUT: The site has updated the GMP Policy to describe the conditon of PPE must remain in good condition. A picture of the modified evacuation maps throughout the site was submitted. Training was conducted with the entire plant on the changes made which reflect the findings of this NC. This meets the intent of the NC and is approved. TLS

COMPLETION DATE: 10/29/2020 **CLOSEOUT DATE:** 10/30/2020

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.5.5 Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register.

RESPONSE: COMPLIANT

11.7.5.6 Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

RESPONSE: COMPLIANT

11.7.5.7 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.11.7.5.8 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

11.7.5.8 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.6 Detection of Foreign Objects

The metal detector is verified with 1.0 mm stainless steel, 0.8 non-ferrous and 0.6 mm ferrous test pieces. The metal detector is verified before every batch and at the end of the shift. The metal detector was observed verified during the audit and the operator was interviewed during the process. The magnet is inspected between batches and the process of the operator reviewing the tailings was observed and found to be acceptable. The screens are reviewed for findings and condition of the screen at the beginning and the end of product run. The records from 10/6/20 throughout the run were reviewed and found to be acceptable. The site maintains a Foreign Matter Log 14.16a Rev 002 dated 6/27/19. The site has not one foreign material incident for metal shavings which is on hold with in the On Hold cage.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.7 Managing Foreign Matter Contamination Incidents

The site has a glass breakage policy within the Glass Brittle Plastic and Ceramic 14.20 Rev 00.2 dated 6/24/19. To date no glass breakage has occurred.

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

RESPONSE: COMPLIANT

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

11.8.1 Location

The site laboratory is observed to have a restricted personal only sign on the door. The room has a sink with hot and cold water, soap and a trash can. The technician was observed to demonstrate the moisture test, granulation, color and taste testing and the product paperwork release process. The QC Supervisor was able to answer how food safety is affected in her job. The technicians are each calibrated annually, last completed on 9/30/20.

11.8.1.1	On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel. **RESPONSE:** COMPLIANT
11.8.1.2	Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory wastewater outlet shall as a minimum be down stream of drains that service food processing and handling areas. **RESPONSE:** COMPLIANT
11.8.1.3	Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel. **RESPONSE:** COMPLIANT

11.9.1 Dry and Liquid Waste Disposal

Waste Management SOP 15.1 Rev 001 is dated 11/15/17 and is approved by the Managing Partner. The waste is removed from within the site daily and or as needed throughout the shift. The recycled corrugate waste is separated into its own waste receptacle. The landfill is stored within its own receptacle. Both are lidded, observed clean and on a cleanable surface. The site does not have liquid waste and does not have a grease trap. During the audit waste was not observed to accumulate. Site waste is removed from the site multiple times each week. The corrugate is removed three times each week. The site was observed to be very clean.

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

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

11.10.1 Grounds and Roadways

The site grounds are maintained by the landlord. Bushes are not observed against the building. Each outlet is observed to be screened. The roof drains and steam line is well drained. Debris is not observed. The loading dock is asphalt and the pathway to the doors are cement. Standing water is not observed.

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

SQF Food Safety Audit Edition 8.1
TRUE CITRUS COMPANY - TRUE CITRUS COMPANY

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
24060 | 116868

AUDIT RATING
99
Excellent

DECISION DATE
11/04/2020

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
10/22/2021

AUDIT DATES
10/05/2020 - 10/06/2020

EXPIRATION DATE
01/05/2022

ISSUE DATE
11/04/2020

Facility & Scope

TRUE CITRUS COMPANY (50647)
TRUE CITRUS COMPANY
11501 Pocomoke Ct
Suite D
Middle River, MD 21220
United States

Food Sector Categories:
26. Food Storage and Distribution

Products:
Dry Ingredients

Scope of Certification:
FSC 26: Food Storage and Distribution

Certification Body & Audit Team

Eurofins

eurofins | Food Assurance

2200 Rittenhouse St. Suite 150
Des Moines, IA 50321
United States

Phone #: 515-299-6979

CB#: CB-1-Eurofins
Accreditation Body: JAS ANZ
Accreditation Number: Z14430415UD

Lead Auditor: Stephens, Terri (132598)
Technical Reviewer: Braymen, Suzie (133613)

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

Non-Conforming

2.7.1 Food Defense Plan (Mandatory)

The Food Defense Program SOP 007-1 is dated 7/23/20 and is approved by the EVPOP. The Food Safety/HACCP team members are the members of the food defense team. The areas of door security, site lighting, key fobs, receiving dock doors being in place and secure, approved supplier register being current and that only approved suppliers are used, and that the visitor program is effective are the food defense attributes inspected during the monthly internal audits. An annual vulnerability assessment was conducted on 8/31/20 by the QA Director. The VP of R&D is the current site food defense coordinator, certified in 2011. Program results are discussed at the monthly food safety meetings. The site conducted their annual food defense challenge on 9/30/20 by having a fired person's key fob activation challenged. The lessons learned were that the physical testing worked and that the fob was quickly deactivated however it was noted that key fobs are not written into the food defense plan. This is being written into the program at the time of this audit. It is observed that the food defense program does not address the security of the transportation vehicles both inbound and outbound from the site. The truck inspection form does ask for the truck lock or seal to be documented on the form however many truck inspection forms during September to 10/2/20 were reviewed and the seal and lock data entry is marked as "no" not applied. See 12.6.7.5.

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

RESPONSE: MINOR

EVIDENCE: The site Food Defense program does not address transportation vehicles be sealed and or locked. The truck inspection forms do ask the warehouse person to inspect for the lock or seal and to identify which is used on the inspection form. However the records for September through October 2, 2020 were observed incomplete without having the seal and seal number or lock documented on the forms. See 12.6.7.5

ROOT CAUSE: While looking for a lock/seal was already part of our trailer inspection program, the need for a lock was not relayed to the trucking companies. Nor was this enforced by our warehouse team.

CORRECTIVE ACTION: We immediately contacted our shuttle service as well as our third party logistics company and explained locks must be used. ACTION EVIDENCE- I have included the updated Food Defense Plan, calling out the need for a lock/seal on each truck, incoming and outgoing. I have included current truck reports showing the lock present, and also a photo of a truck backing in showing a lock present. --PREVENTIVE ACTION--Re-training of all employees has occurred 10/26/20 explaining the changes to the Food Defense Plan to include locks, and explaining the importance of a lock or seal on each and every truck.

VERIFICATION OF CLOSEOUT: As stated the site has sent in receiving PO's and Bill of ladings showing the lock is on the trailers both inbound and outbound. A picture of a trailer with lock was sent. The Food Defense SOP was updated to include the lock requirement for both inbound and outbound and the completed training exercise was sent. Each have been reviewed and found to be acceptable. This meets the intent of the NC and is approved by this auditor.

COMPLETION DATE: 10/26/2020 **CLOSEOUT DATE:** 10/26/2020

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Rich Soper: QA Director
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** rich.soper@truecitrus.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Rich Soper: QA Director, Terri Stephens: SQF Auditor
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** The site is a product formulator and a storage and distribution company that relies solely on cooperation with various Co-Manufacturers for weighing, blending and packaging the product. The site stores and distributes dry powdered citrus beverage and ingredient mixes. Located within a commercial strip mall within a leased 30,000 sq. ft., 3 suite space it is surrounded by woods, a trampoline jumping center and another company's distribution center. The company was started in 2003 and is privately held by two investment companies. The site operates one shift, Monday through Friday with 20 office personnel and a crew of 8 in the warehouse. Part-time and or seasonal employees are not used. Products are shipped throughout the USA and Canada and does not use or handle any of the USA or Canadian allergens. During the audit process the findings of the first Facility audit are observed to be effectively corrected. The site has written and implemented a Contingency Plan for Covid-19 which requires everyone upon office and or plant entry to have a temperature check and all surface materials are wiped with sanitizer wipes twice daily. At the time of the audit, now 7 months into the pandemic the site has not had any employees or their family members test positive for Covid-19. The pandemic has resulted in increased business for the site.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Rich Soper: QA Director, Gary Kratochvil: Executive Vice President of Operations, Terri Stephens: SQF Auditor
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Recommend certification once any sited non-conformances are corrected and approved.

Section Responses

2.1.1 Food Safety Policy (Mandatory)

The Management Commitment Policy 001-2 is dated 3/5/20, is signed by the QA Director and is approved and signed by the Chief Executive Officer. The commitment statement OO1-OO1-2 is posted in the main office foyer, the door all employees and visitors enter through when entering the building. The policy documents a commitment to providing resources to implement, maintain and continually improve their food safety program. The employees are involved and are to voice any observed issues in food safety and or quality. Through training, internal standards, auditing body codes and government regulations the company states they shall provide safe foods.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2 Management Responsibility (Mandatory)

The organizational chart is dated 8/22/19 and is signed by the Executive Vice President of Operations. The organizational chart documents that all employees are responsible for food safety and quality. All positions on the chart are filled positions. It is observed that senior staff has provided enough resources, equipment and secondary supplies to run a food safe environment. Continuous improvements over the past year are noted as: 1. The site has purchased a granulator to improve blend consistency 2. The QA Director completed two co-manufacturers internal audits. 3. A Co-Mans blend verification sheet was developed and implemented to reduce the number of batching and product run errors. The Practitioner is a full time employee and responsible for implementation, maintenance and communications of the SQF System to all staff. The QA Director has taken the courses of Implementing SQF, HACCP and Internal Auditing. The QA Director is the SQF Practitioner, and received Implementing SQF Code for Manufacturing Edition 8 on 2-12-19, HACCP in Spring 2019, FSPCA Preventative Controls in Human Food on 5/17/18 and Internal Auditing Training on June 13, 2019. The job descriptions each have identified the back-up designee. The job descriptions for the VP of R&D, the Operations Manager, Warehouse Associate, and the QA Director were reviewed and found to be acceptable. Within the commitment policy the employees are instructed to communicate any food safety and or quality concerns to their supervisor. Through customer complaint, internal and external audits, and the pre-requisite programs running effectively the site shows validations the SQF System is effective. The site understands the code requirements for unannounced audit years and the needed blackout period communications.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2.5 The SQF practitioner shall: i. Be employed by the distribution or storage site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation to the management of the distribution or storage site SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code for Storage and Distribution and the requirements to implement and maintain SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3 Management Review (Mandatory)

A Monthly Management Review 001-003-2 is dated 1/22/20 and includes the topics of R&D, customer complaints, review of policy manual and safety plan, follow up actions from previous meeting, and results of internal or external audits are discussed. The one on one meetings of September 19 and August 25, 2020 were reviewed and found to be acceptable. The system annual review and sign-off by the senior member, CEO was completed on 9/29/20.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3.3 Food Safety Plans, Good Storage and Distribution Practices and other aspects of the SQF system shall be reviewed and updated as needed when any potential changes implemented have an impact on the site's ability to deliver safe food.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.4 Complaint Management (Mandatory)

Consumer Complaints Program SOP 015-2 dated 7/24/20 and approved by the EVPOP (Executive Vice President of Operations). The program documents a complaint is received through customer service who inputs it into the customer complaint log. The QA Director is responsible for the investigations. Complaint trending by product type, lot number, and type of issue for both food safety and quality are trended (empty packets, flavor issues, hard or clumpy product, missing packets and packaging complaints. Complaints at present are being tracked month over month. The site has an investigation report form 012-001 dated 7/10/19 which is used in tracking complaints. An investigation from a complaint on 4/30/20 for the shaker jars being light weight and the seals not being intact. The corrective action, root cause and preventative actions are documented. A complaint for 13/30/20 for the Strawberry Lemonade 12/10 Ct for empty sticks. The complaint reviewed has complete documentation. The process of investigations is found to be acceptable.

2.1.4.1 The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities, arising from products handled on site, shall be documented and implemented.

RESPONSE: COMPLIANT

2.1.4.2 Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents.

RESPONSE: COMPLIANT

2.1.4.3 Corrective action shall be implemented commensurate with the seriousness of the incident and as outlined in 2.5.3.

RESPONSE: COMPLIANT

2.1.4.4 Records of customer complaints and their investigations shall be maintained.

RESPONSE: COMPLIANT

2.1.5 Crisis Management Planning

The Crisis Management Plan SOP 010-4 is dated 10/5/20 and is approved by the EVPOP. The plan documents the crisis events of: fire, flood, chemical spill, explosion, hurricane, workplace violence, product recall and pandemics. The Crisis team members are: The EVPOP as the team captain, the QA Director and the EVP of Marketing. The EVOP is responsible for contacting the legal council, insurance and landlord. The EVP of Marketing is responsible to contact employees, customers, general public and media. The regulatory agencies (FDA, SQFI and the Certification Body) are to be contacted by the QA Director. This year a mock crisis event was conducted on 9/29/20 for a mock Covid-19 incident of an employee testing positive. The event information is documented and found to be acceptable.

2.1.5.1 A crisis management plan that is based on the understanding of known food safety potential threats (e.g. flood, drought, fire, tsunami, or other severe weather events) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility that the site shall implement to cope with such a business crisis.

RESPONSE: COMPLIANT

2.1.5.2 The crisis management plan shall include as a minimum: i. A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure a response does not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations and media.

RESPONSE: COMPLIANT

2.1.5.3 The crisis management plan shall be reviewed, tested and verified at least annually.

RESPONSE: COMPLIANT

2.1.5.4 Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

The SQF system is maintained both electronically and in hard copy form. The hard copies are stored within binders in the QA Directors office. The documents are available for use by the employees as job requires. Items required within 2.2.1.1i. through vi. are within individual documents and or within the Food Safety plan. Revisions to plans, policies, and procedures are captured within a Revision Log 023-001 dated 6/28/19. The log is observed to be a rolling active log and is found acceptable.

2.2.1.1 A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the organization will use to meet the requirements of the SQF Food Safety Code, be made available to relevant staff and include: i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The scope of the certification; iv. A list of the products covered under the scope of certification; v. Food safety procedures, pre-requisite programs, food safety plans; and vi. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

RESPONSE: COMPLIANT

2.2.1.2 All changes made to Food Safety Plans, Good Distribution Practices and other aspects of the SQF System shall be validated or justified.

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

The Document Creation, Management, Change Control, and Practices SOP 023-3 is dated 7/23/20 and is approved by the EVPOP. The SOP covers each policy, procedure and form for all food safety and system tasks. Each document (policy, SOP and form) are numbered and reviewed annually. The master document register MDR-001 3/5/20 includes all said documents, the department responsible for them as well as the individual of the department, where the documents are stored electronically and the frequency of verification. The documents are held in both electronic and or hard copy versions. The documents are secured and can be altered by only the QA team (the Practitioner, EVPOP and the VP of R&D). Documentation is available as needed for all employees. Within the Document Retention and Destruction SOP 027-2 dated 7/27/20 and approved by the EVPOP the records are held for 2.5 years. The paper records are then destroyed through shredding through a third party provider. The electronica records are backed-up twice daily on the company server both on site and at an off-site location. The hard binders are stored in the QA Director's office.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2.3 Documents shall be safely stored and readily accessible.

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

How to write a record is covered within the Document Creation, Management, Change Control, and Practices SOP 023-3. It is dated 7/23/20 and is approved by the EVPOP. During the audit the records of BOL's and PO's inbound and outbound and the restroom services were reviewed and are observed to be documented in accordance to the procedure.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.1 Product for Storage and Distribution

The Storage and Distribution Warehouse Plan: Materials Receiving, Storage, Release, Picking and Shipping SOP-005-4 is dated 7/23/20 and is approved by the EVPOP. The procedure covers the processes to properly receive, store, rotate, release, pick and ship all materials of True Citrus. Inspection of in-bound and out-bound trailers and materials coming in and going out. All materials inbound and finished goods outbound are maintained at ambient temperatures.

2.3.1.1 Product handling and storage requirements for all products received, stored and intended for distribution, shall be documented, current, approved by the distributor and their customer (if applicable), accessible to relevant staff and include temperature requirements, storage conditions, and handling and transportation conditions.

RESPONSE: COMPLIANT

2.3.2 Incoming Supplies

The site has the incoming supplies controlled through the Specifications Procedure SOP-025-02 dated 8/24/20 and is approved by the EVPOP. The register of supplier is 025-005-2 and is dated 9/25/20. The register addresses the SDS, allergen statement, specification sheet, food grade, etc. The procedure describes the methods and responsibility for developing and approving incoming supplies, required documentation as well as the product descriptions. The site does have a chemical compounds list 031-002-2 dated 10/17/19 for all the chemicals used by the site. The site does not use or purchase ice. The Zep Foaming Wall Cleaner chemical was requested for the SDS sheet and specification which was made available and found to be acceptable.

2.3.2.1 Product descriptions for all incoming supplies used by the site but not intended for distribution, including, but not limited to hazardous chemicals, ice, food packaging materials or janitorial supplies that are used on site and impact on product safety shall be documented and kept current.

RESPONSE: COMPLIANT

2.3.2.2 All incoming materials and ingredients shall comply with the relevant legislation.

RESPONSE: COMPLIANT

2.3.2.3 The methods and responsibility for developing and approving product descriptions shall be documented.

RESPONSE: COMPLIANT

2.3.2.4 Incoming materials shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Validation of incoming materials shall include a review of the product description to determine conformance.

RESPONSE: COMPLIANT

2.3.3 Contract Service Providers

The site has a contract service register 025-004-2 dated 8/24/20. The register includes the name of the service provider, description of service, how often the service is provided, trainings requested, and who they report to when onsite. The register is found to be current.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.4 Contract Third Party Storage or Distributor

The site has three Co-manufacturers. The agreements were reviewed and found to be acceptable. The QA Director has completed site visits and inspections of two of the three Co-mans and plans are in place to visit the third site when the Covid-19 pandemic is over. The VP of R&D has been to all three sites when they were being approved as Co-mans. The contracts have not changed since they were originated.

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

RESPONSE: COMPLIANT

2.3.4.2 The site shall: i. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel; ii. Verify compliance with the SQF Code and that all customer requirements are being met at all times.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.1 Food Legislation (Mandatory)

The site is following the FSMA regulations. The SQFI and the Certification Body are documented to be contacted at the correct email addresses within 24 hours of a food safety event requiring public notification. The site management stays current in industry changes and recalls through the FDA warning letter communications, Food Chain ID (the owners of horizon scan) for food fraud ingredient information, industry webinars and plans to attend the SQFI communications.

2.4.1.1 The site ensures that the food delivered to the customer is handled in a manner that complies with the relevant legislation in the country of its origin and destination.

RESPONSE: COMPLIANT

2.4.1.2 The methods and responsibility for ensuring the organization is kept informed of changes to relevant legislation, scientific and technical developments and relevant industry codes of practice shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.1.3 The 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 (e.g. receipt of a regulatory warning letter). Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

2.4.2 Good Storage and Distribution Practices (Mandatory)

Personnel and Visitor cGMP Requirements SOP 019-2 is dated 4/16/20 and is approved by the EVPOP. The policy covers visitors, employees, contractors and or any other persons entering the site. The topics of visitors, disease control including Covid-19, hygienic practices (hand washing, outer garments, jewelry, gloves, hair restraints, skin preparations, personal affects, and food drink and tobacco) are all described within the procedure. The site has written and implemented a Contingency Plan for Covid-19 Confirmed Cases 010-006-1 dated 4/23/20 and approved by the EVPOP.

2.4.2.1 The site shall ensure the Good Distribution Practices described in Module 12 of this Code are applied, or exempted according to a risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

The site has one Food Safety Plan following the 7 Principles of HACCP in compliance with FSMA HARPC guidelines. The plans scope is described as a product formulator, storage and distribution company that relies solely on cooperation with various co-manufacturers for weighing, blending and packaging the products. The products are dry powdered citrus beverage and ingredient mixes. The Food Safety/HACCP team is made up of the QA Director (leader), VP of R&D, EVPOP and the Operations Manager. Product description and the intended use which identifies no restricted populations is documented. The products are stored at ambient temperatures and has a shelf life of 2 years. Technical information is provided with the product pH at <4.0. The product general information including best by date identification and packaging sizes are documented. The flow diagram includes each step in the process from receiving through to shipment. The process does not use gas, water or steam. Rework is identified within the plan. A risk assessment is complete for each process step. The site has not identified a CCP within the process. The Food Safety plan was last approved on 9/3/19 and is signed by both the QA Director and the EVPOP.

2.4.3.1 A food safety plan or HACCP based plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.4 The scope of each food safety plan shall be developed and documented including the start and end-point of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

2.4.3.5 Product requirements shall be developed and documented for all products (or groups of products) included in the scope of the food safety plans. This shall reference the product descriptions (refer to 2.3.2.1) plus any additional information relevant to product safety, such as temperature for storage, how the product is packaged, allergen requirements, raw or cooked, etc.

RESPONSE: COMPLIANT

2.4.3.6 The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative use of the product.

RESPONSE: COMPLIANT

2.4.3.7	The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw material, packaging material, and service inputs (e.g. water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework and rework/recoup. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation. **RESPONSE:** COMPLIANT
2.4.3.8	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including food products received and stored. **RESPONSE:** COMPLIANT
2.4.3.9	The food safety team shall conduct a hazard analysis for every identified hazard, to identify which hazards are significant. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT
2.4.3.10	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure. **RESPONSE:** COMPLIANT
2.4.3.11	Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure. **RESPONSE:** COMPLIANT
2.4.3.12	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard(s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1). **RESPONSE:** COMPLIANT
2.4.3.13	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT
2.4.3.14	The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure. **RESPONSE:** COMPLIANT
2.4.3.15	The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs or other changes affecting product safety occur. **RESPONSE:** COMPLIANT
2.4.3.16	Implemented food safety plans shall be verified as part of SQF system verification (refer to 2.5). **RESPONSE:** COMPLIANT
2.4.3.17	Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements. **RESPONSE:** COMPLIANT

2.4.4 Approved Suppliers (Mandatory)

Approved Supplier, Raw Material, Packaging Material, and Label Program SOP 011-2 is dated 7/27/20 and approved by the EVPOP. The required supplier documentation is their third party audit report, NC report and copy of the certification. If the supplier does not send or have the third party audit then the requested documents for each vendor are as follows: 3rd party audit results, HACCP flow plan, food defense program, food fraud program, ingredient specification, nutritional analysis, kosher certificate, allergen statement, SDS, GMO statement, lot code explanation, country of origin, COA, letter of guarantee, Prop. 65, Gluten Free statement, emergency contact information, FDA registration statement, FSMA statement, recall plan, sanitation validation methods, lab accreditation, continuing letter of guarantee and a pest control program. Records of the required information from the vendors shall be reviewed annually. The approved supplier information is populated into a master approved supplier spreadsheet 10/13/19 which was reviewed on 9/19/20 for this years annual review. The spreadsheet documents the date of when documentation is due. Each suppliers rating of low, medium or high has been assessed. The site has determined 1 supplier as high 2 as medium and the rest are determined to be low. The high risk supplier is visited each year. The program has procedures in place to cover emergent situations of accepting material from non-approved suppliers. To date the site has not had to use the emergent process.

2.4.4.1 Incoming goods (identified in 2.3.1 and 2.3.2) that may have an impact on product safety shall be supplied by an approved supplier.

RESPONSE: COMPLIANT

2.4.4.2 Incoming goods received from non-approved supplier shall be acceptable in an emergency situation provided they are inspected or analyzed before use.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4.5 Incoming goods and packaging materials received from other sites under the same corporate ownership, shall be subject to the same product requirements and approved supplier requirements as all other material providers.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Product or Equipment

Non-Conforming Product/Equipment and Correct & Preventive Action Program SOP 012 is dated 7/10/19 and is approved by the EVPOP. Within this program an investigation report, On-Hold Log and a Product Destruction Form are included. The warehouse and quality teams were last trained in the quarantine and release processes on 9/23/20. The On-Hold log was reviewed and the rejection item from 1/24/20 was reviewed and traced back to the destruction log which is observed to be acceptable.

2.4.5.1 The responsibility and methods outlining how non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment detected during receipt, storage, processing, handling or delivery is handled shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or delivery, or risk to the integrity of finished product; ii. Non-conforming equipment is effectively repaired or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and iii. All relevant staff 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 Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.

RESPONSE: COMPLIANT

2.4.6 Product Recoup

The handling of recouped product is described within the Storage and Distribution Warehouse Plan: Materials Receiving , Storage, Release, Picking and Shipping dated 7/23/20 and approved by EVPOP. It is observed that recouped product is listed as a component of the traceability exercise summary sheet. The site has not had the need to conduct recouping of product this audit year.

2.4.6.1 The responsibility and methods outlining how the product is recouped shall be documented and implemented. The methods applied shall ensure: i. Recouping operations are conducted by qualified personnel; ii. Recouped product is traceable.

RESPONSE: COMPLIANT

2.4.7 Product Release (Mandatory)

Within the Storage and Distribution Plan the QA department or designee are documented as able to release product for shipment once all quality and food safety measures are completed. The process of product release is conducted through the computer system. The work order is placed into the system by the supply chain manager. The order is seen at the co-manufacturer's site and filled. The product is then transferred back to the site as "on hold" within the system. It is then received, inspected, and the count confirmed to the work order by the warehouse team. The work order is then moved to "A" for available. The product is then available for the Customer Service team to set the shipment order. Product transfer and release records for 10/5/20 were reviewed and found to be acceptable.

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release shall be maintained.

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

Verification and Validation Program SOP 006 is dated 9/3/19 and is approved by the EVPOP. A verification and validation schedule is developed, dated 9/28/20 and also approved by the EVPOP. Records of validations of the pre-requisite programs and calibrations and customer complaints were reviewed and found to be acceptable. The site is current to their predetermined validation schedule.

2.5.1.1 The methods, responsibility and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall ensure that: i. Good Distribution Practices are confirmed to ensure they achieve the required result; ii. Critical food safety limits are validated, and re-validated annually; iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and iv. All applicable elements of the SQF Program are implemented and effective

RESPONSE: COMPLIANT

2.5.1.2 Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

Verification and Validation Program SOP 006 is dated 9/3/19 and is approved by the EVPOP. A verification and validation schedule is developed, dated 9/28/20 and also approved by the EVPOP. The method for verifying the GDP, internal audits and the pre-requisite programs are documented. Records of verifications for inbound and outbound truck inspections as well as the restroom and lunch room cleanings were reviewed and found to be acceptable. The verification schedule is fully developed and found to be acceptable.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

The Corrective and Preventative Actions Program is within the SOP 012 dated 7/10/19 and approved by the EVPOP. The corrective action, root cause and preventative actions are within the investigation report form. A record of a corrective action dated 9/28/20 for damaged product within a third party contracted carrier shipment was reviewed. The immediate corrective action taken, the investigation to the root cause and the preventative control are well documented within the investigation report and found to be acceptable. The records of all investigations are maintained within a binder.

2.5.3.1 The responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits, and deviations from food safety requirements, shall be documented and implemented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.5 Internal Audits and Inspections (Mandatory)

The site breaks internal audits and inspections into two programs. The first is the Written Procedure Audits SOP 008 dated 9/3/19 which is approved by the EVPOP. The procedure documents that all policies, procedures, programs and forms are to be reviewed annually. The second program is the Food Safety Internal Inspection SOP 013 dated 9/3/19 and also approved by the EVPOP. This program identifies the IA team leader as the QA Director and the EVPOP, the VP of R&D and the Operations Manager as team members. The team conducts audits monthly. The site has a prepared inspection audit form to be completed during the internal audits. A corrective action form is also in place. The audit conducted on September 11, 2020 was reviewed. The audit shows the template items are inspected, two findings were identified and both are corrected. The site is in the process of taking the program results into trend charts for future continuous improvements. The team leader is certified in Internal Auditing and has trained the other team members in auditing techniques. The site maintains records for 2.5 years.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.5.4 Where practical staff conducting internal audits shall be independent of the function being audited.

RESPONSE: COMPLIANT

2.5.5.5 Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained.

RESPONSE: COMPLIANT

2.6.1 Product Identification (Mandatory)

Within the Storage and Distribution Warehouse Plan SOP 005-4, dated 7/23/20, the site uses first in first out stock rotation principles. The site has a process for incoming materials and storage location determination. Through a company MRP software system the product inventory and rack location is tracked. Picking is done from the floor level and restocked as it is emptied.

2.6.1.1 The methods and responsibility for identifying products during all stages of storage shall be documented and implemented. The product identification system shall be implemented to ensure: i. proper stock rotation; ii. accurate location of product.

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

The Traceability Program SOP 017 is dated 6/26/19 and is approved by the EVPOP. The program documents a traceability exercise one up, one back is to be conducted annually. The site documents the traceability is to be conducted to a 98-102% recovery within 4 hours. The Traceability Form 017-001-2 is dated 4/23/20 and approved by the EVPOP. The trace exercise conducted on 9/29/20 for a packaging component, carton 10 Ct was found at 95.84%. The site documents the lessons learned within an investigation report. A raw material, Cherry Red color was traced on 9/2/20 and 100% was recovered. The finished goods black Cherry Stick was traced on 9/14/20 at 100.09% however it took the site 3 days to find it all. The lessons learned were that the two of the three Co-Man's re-identify the raw materials upon receiving at the Co-Man's. These are then not traceable by the site. The trace summary reports shows date of receipt, use, rework, recoup, amount on hand and the amount shipped, dates of shipment and where the product was sent. During this recertification audit the Finished goods Lemon 500 was traced. The lot number is 1001222067. 645 cases were made at the Co-man on 10/1/20. 645 cases were received at the site on 10/2/20. All 645 remain on site. The Co-Man report shows a .60% production loss. This is a 100% recovery.

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

RESPONSE: COMPLIANT

2.6.2.2 Records of product receipt and use, and product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

The Recall and Withdrawal Program SOP 014-3 is dated 7/24/20 and is approved by the EVPOP. The recall team consists of the Recall Coordinator (EVPOP), CEO, VP of R&D, QA Director, EVP of Marketing, Co-Man Blender Regulatory Manager, and the Co-Man Blender QC Manager. The program states that the site shall contact the SQFI, Certification Body and the FDA within 24 hours of a food safety incident involving public safety. Investigations shall be conducted to root cause and preventative actions. The persons responsible to contact the legal council, customers, employees and the media are stated. The program states a mock recall shall be conducted annually. The mock recall drill was conducted on 9/10/20 by the QA Director. Each team member was instructed to email back their responsibilities within the recall process which took place within one day. The QA Director is responsible for reviewing the recalled product and setting disposition.

2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall; ii. Describe the 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; iv. SQFI, the certification body, and the appropriate regulatory authority shall be listed as an essential body and notified in instances of a food safety incident of a public nature, or product recall for any reason.

RESPONSE: COMPLIANT

2.6.3.2 Investigation shall be undertaken to determine the root cause of a withdrawal or recall and details of investigations and any action taken shall be documented.

RESPONSE: COMPLIANT

2.6.3.3 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

The Food Defense Program SOP 007-1 is dated 7/23/20 and is approved by the EVPOP. The Food Safety/HACCP team members are the members of the food defense team. The areas of door security, site lighting, key fobs, receiving dock doors being in place and secure, approved supplier register being current and that only approved suppliers are used, and that the visitor program is effective are the food defense attributes inspected during the monthly internal audits. An annual vulnerability assessment was conducted on 8/31/20 by the QA Director. The VP of R&D is the current site food defense coordinator, certified in 2011. Program results are discussed at the monthly food safety meetings. The site conducted their annual food defense challenge on 9/30/20 by having a fired person's key fob activation challenged. The lessons learned were that the physical testing worked and that the fob was quickly deactivated however it was noted that key fobs are not written into the food defense plan. This is being written into the program at the time of this audit. It is observed that the food defense program does not address the security of the transportation vehicles both inbound and outbound from the site. The truck inspection form does ask for the truck lock or seal to be documented on the form however many truck inspection forms during September to 10/2/20 were reviewed and the seal and lock data entry is marked as "no" not applied. See 12.6.7.5.

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: The site Food Defense program does not address transportation vehicles be sealed and or locked. The truck inspection forms do ask the warehouse person to inspect for the lock or seal and to identify which is used on the inspection form. However the records for September through October 2, 2020 were observed incomplete without having the seal and seal number or lock documented on the forms. See 12.6.7.5

ROOT CAUSE: While looking for a lock/seal was already part of our trailer inspection program, the need for a lock was not relayed to the trucking companies. Nor was this enforced by our warehouse team.

CORRECTIVE ACTION: We immediately contacted our shuttle service as well as our third party logistics company and explained locks must be used. ACTION EVIDENCE- I have included the updated Food Defense Plan, calling out the need for a lock/seal on each truck, incoming and outgoing. I have included current truck reports showing the lock present, and also a photo of a truck backing in showing a lock present. --PREVENTIVE ACTION--Re-training of all employees has occurred 10/26/20 explaining the changes to the Food Defense Plan to include locks, and explaining the importance of a lock or seal on each and every truck.

VERIFICATION OF CLOSEOUT: As stated the site has sent in receiving PO's and Bill of ladings showing the lock is on the trailers both inbound and outbound. A picture of a trailer with lock was sent. The Food Defense SOP was updated to include the lock requirement for both inbound and outbound and the completed training exercise was sent. Each have been reviewed and found to be acceptable. This meets the intent of the NC and is approved by this auditor.

COMPLETION DATE: 10/26/2020 **CLOSEOUT DATE:** 10/26/2020

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.2 Food Fraud

Food Fraud Vulnerability SOP 030-2 is dated 3/5/20 and is approved by the EVPOP. The program lists within the register each raw material, if the material is from an approved supplier, country of origin, search findings from the internet, and the likelihood of substitution, mislabeling, dilution and counterfeiting fraud. Each raw material is assigned a risk level of low, medium or high. A mitigation strategy is written for the high risk items to have annual 3rd party testing for validations. Site visits may be needed per the QA Directors discretion. The site has contracted with a food fraud search company, Horizon Scan, which enables the site to stay current in their raw material published information.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.8.1 Allergen Management (Mandatory)

Allergen Control Program SOP 032-2 is dated 7/23/20 and approved by the EVPOP. The site does not handle allergens for the USA or Canada which are the countries the product is shipped into. The site does train all site employees annually in allergen control. The training occurred on 9/23/20.

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management controls shall include the identification and handling of compromised product to prevent inadvertent cross contact.

RESPONSE: COMPLIANT

2.9.1 Training Requirements

Training Program SOP 033-1 is dated 9/10/19 and is approved by the EVPOP. It is the responsibility of the QA Director to ensure training is delivered to all employees. The site requires all employees to pass the topic training at an 80% or greater comprehension. The trainings given to all site employees are: cGMPs, food defense, crisis management, documentation practices and control, allergen control, SQF and Food Safety overview. As appropriate job task specific training is completed.

2.9.1.1 The responsibility for establishing and implementing the training needs of the organization’s personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

The new employees are to be trained in cGMPs, visitor expectations, food defense and any other procedure associated with their position. They include: crisis plan, complaints, receiving procedures, documentation practices, shipping and receiving, sanitation and or pest control. A new person started in the company early July and was given the new hire trainings on 7/13/20.

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

RESPONSE: COMPLIANT

2.9.3 Instructions

The site has SOPs for each task undertaken.

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

RESPONSE: COMPLIANT

2.9.4 HACCP Training Requirements

The 5 member HACCP team have 3 team members individually certified in HACCP.

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

RESPONSE: COMPLIANT

2.9.5 Language

English is the language spoken and understood by all at the site. All communications are conducted in English.

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

RESPONSE: COMPLIANT

2.9.6 Refresher Training

Refresher training is conducted annually for the topics of: cGMPs, crisis management, visitor expectations, food defense program, allergen control, document control and overview of SQF and the Food Safety Plan. The cGMP refresher trainings for the contractors for fire extinguishers and back flow, pest control, and the HVAC were each reviewed and found to be current.

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

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

The site has a prepared training skills register with 16 topics and all 27 employees. The dates of training of each employee and the training topic completed are listed on the register. The QA Director is the trainer for each training event. Should an employee not pass at 80% retraining is conducted privately by the Director.

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

RESPONSE: COMPLIANT

12.1.1 Premises Location and Approval

The Baltimore County, Maryland department of permits, approvals and inspections has issued a right to occupy on 1/18/17. The Maryland Department of Health has issued a Food Processing Plant License to operate a food warehouse current through 1/31/21.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.1 Materials and Surfaces

The product is not ever in an open condition. Even when the product is recouped it remains in sealed containers and or packets. The warehouse racking is steel and observed to be in good condition and clean. The sorting tables are made of stainless steel. The conveyors are metal and are also observed to be clean.

12.2.1.1 In warehouses where food products are recouped or exposed, product contact surfaces shall be constructed of materials that will not contribute a food safety risk.

RESPONSE: COMPLIANT

12.2.2 Floors, Drains and Waste Traps

The site does not have waste traps. The site does not have floor drains. The Mop bucket and the floor scrubber are emptied into the utility sink. The utility sink is cleaned weekly using bleach as the sanitizer.

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

RESPONSE: COMPLIANT

12.2.2.2 Drains shall be constructed and located so they can be easily cleaned and not present a hazard. Drains if located in storage and handling areas, shall be maintained in a clean manner.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.3 Walls, Partitions, Doors and Ceilings

The walls, wall to floor junctions, partitions, doors and ceiling are all observed to be very clean and in great condition. The drop ceiling over the office space is open to the pest provider for services.

12.2.3.1 Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious, and shall be kept clean (refer to 12.2.11.1).

RESPONSE: COMPLIANT

12.2.3.2 Wall to wall and wall to floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: COMPLIANT

12.2.3.3 Doors shall be of solid construction; and windows shall be made of shatterproof glass or similar material.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.4 Lighting and Light Fittings

The lighting throughout the site is bright. All lighting is shatter shield protected and under cover. A glass breakage policy is written within the Foreign Material Program SOP 035-02 dated 7/24/20. The warehouse staff are all trained in glass breakage as of 9/26/20. The site has not had a glass breakage event in multiple years.

12.2.4.1 Lighting in warehouses where food product is recouped or exposed shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

RESPONSE: COMPLIANT

12.2.4.2 Light fittings in areas where food product is recouped or exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.5 Dust, Insect and Pest Proofing

The site does not have external windows. The roof vent is screened at the top and louvered at the bottom. The lovers were observed clean and are cleaned annually. The dock doors and man doors are observed to be well sealed. The insect light traps are observed to be next to dock doors and are observed to be working and clean.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.6 Ventilation

The site does not have ceiling fans however adequate ventilation throughout the warehouse is observed. Heating is plumbed into the warehouse. Two floor fans are used to move the air at the floor level. The floor fans were observed clean and on the sanitation cleaning schedule at twice annually.

12.2.6.1 Adequate ventilation shall be provided in enclosed storage and food handling areas.

RESPONSE: COMPLIANT

12.2.6.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 12.2.11.

RESPONSE: COMPLIANT

12.2.7 Equipment, Utensils and Protective Clothing

The site utensils are purchased through a national supply company. The specifications for each utensil: brooms, dust pans, trash cans, buckets, bins etc. are available and determined to be FDA approved for use in a food plant. The specifications for each utensil are stored in a company maintained electronica folder. The company provides each warehouse employee with shirts manufactured by a national clothing company. The material is 100% cotton. The employees are observed to be wearing clean shirts which are in good condition.

12.2.7.1 Equipment and utensils shall be designed, constructed, installed, operated and maintained so as not to pose a contamination threat to products.

RESPONSE: COMPLIANT

12.2.7.2 Protective clothing in areas where food product is recouped or exposed shall be manufactured from material that is not liable to contaminate food and easily cleaned.

RESPONSE: COMPLIANT

12.2.7.3 In areas where food product is recouped or exposed, racks shall be provided for the temporary storage of protective clothing when staff leaves the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.

RESPONSE: COMPLIANT

12.2.8 Premises and Equipment Maintenance

Preventive Maintenance and Calibrations SOP 003-3 is dated 8/24/20 and is approved by the EVPOP. The site is unique as it does not have an assigned maintenance person or team. When repairs are needed an appropriate contractor or service provider is brought in. The site is on a leased contract with the building owner. As such when building repairs are needed a request for work is made to the building owner. PM's for the service providers of the forklifts and the HVAC system are in place. Records for the maintenance service for the forklifts, HVAC, lab scales, backflow prevention device and the fire extinguishers were reviewed and found to be adequate. The temporary repair log 003-002 dated 10/21/19 is current in its annual review. At the time of this audit no issues are entered on the temporary log. Temporary repair controls are documented within the Maintenance SOP.

12.2.8.1 The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and implemented in a manner that minimizes the risk of product, packaging or equipment contamination.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.8.3 Failures of site and equipment in any storage area shall be documented, reviewed and their repair incorporated into the maintenance control schedule.

RESPONSE: COMPLIANT

12.2.8.4 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 12.3.1, 12.3.2, 12.3.3, 12.3.4).

RESPONSE: COMPLIANT

12.2.8.5 All maintenance and other engineering contractors required to work on site shall be trained in the site's food safety and hygiene procedures and shall be assessed in their understanding before entering into any food storage areas.

RESPONSE: COMPLIANT

12.2.8.6 Facility supervisors shall be notified when maintenance or repairs are to be undertaken in any food processing, handling or storage area.

RESPONSE: COMPLIANT

12.2.8.7 The maintenance supervisor and the facility supervisor shall be informed if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside operating times.

RESPONSE: COMPLIANT

12.2.8.8 Temporary repairs, where required shall not pose a food safety risk. They shall exclude the use of fasteners such are wire or tape, are clearly identified and dated and included on cleaning programs. There shall be a plan in place to address final completion of temporary repairs in order to ensure temporary repairs do not become permanent solutions.

RESPONSE: COMPLIANT

12.2.8.9 Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed prior to the commencement of site operations.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.9 Calibration

Calibrations is covered within the Preventive Maintenance and Calibrations SOP 003-3 dated 8/24/20 and is approved by the EVPOP. The HVAC roof system is maintained twice annually, the forklifts are serviced twice annually, the warehouse and laboratory scales are calibrated annually, backflow and fire extinguishers are inspected annually and the temperature/humidity chamber is calibrated annually. Each of these are listed on calibration log with the date last completed. The log was reviewed and found each were current in their cycle of calibration.

12.2.9.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite program, 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.9.6 Calibration records shall be maintained.

RESPONSE: COMPLIANT

12.2.10 Pest Prevention

The Pest Management Program SOP 009 is dated 6/3/19 and approved by the EVPOP. The contract is reviewed and approved annually last signed on 2/18/20. The liability certificate is current through 10/1/21. The service company license is current through 6/30/21 and the two pest control operator's licenses are current though 6/30/21. The service is conducted monthly both internally and externally. The PCO training is provided within the pest company binder. The site map is dated 9/29/20 and the devices challenged were in the actual place the map indicated. The pest sighting log is being utilized. The SDS information is within a CD disk. The annual assessment is dated 7/15/20. The site does not store any pest control devices and or chemicals on site.

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

RESPONSE: COMPLIANT

12.2.10.2 Any identified pest activity shall not present a risk of contamination to food products or packaging.

RESPONSE: COMPLIANT

12.2.10.3 Food products or 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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.10.6 Records of all pest control applications shall be maintained.

RESPONSE: COMPLIANT

12.2.10.7 Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 12.6.5 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces.

RESPONSE: COMPLIANT

12.2.10.8 Pest control contractors shall be: i. Licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest control management plan (refer to 2.3.3) which will include and maintain a site map indicating the location of bait stations and traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and vi. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.2.11 Cleaning and Sanitation

Facility Sanitation SOP 031-3 is dated 7/27/20 and is approved by the EVPOP. The site has a master sanitation schedule 031-001-3 dated 3/10/20 and it is observed to be fully built and on task with daily, weekly, monthly quarterly. The site has a third party janitorial service which cleans the restrooms and kitchen Monday through Friday. Records of the cleaning tasks were reviewed and found to be acceptable. The site does not use restricted chemicals for cleaning purposes. The SDS sheets for Sani-Master 6 and Zep wall cleaner were requested and found to be current. The site does not mix chemicals and therefore does not have records to indicate the ppm of the cleaning aids. The emptied containers are rinsed and placed into the waste bin.

12.2.11.1 The methods and responsibility for the cleaning of the food handling and storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; and v. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

12.2.11.2 Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing.

RESPONSE: COMPLIANT

12.2.11.3 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.

RESPONSE: COMPLIANT

12.2.11.4 Detergents and sanitizers that are used to clean, sanitize and maintain the facility shall be purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use within the site; ii. An inventory of all chemicals purchased and used for cleaning and sanitation purposes shall be maintained; iii. Detergents and chemicals are stored as outlined in 12.6.5; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; v. Only trained staff handles sanitizers and detergents;

RESPONSE: COMPLIANT

12.2.11.5 Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.

RESPONSE: COMPLIANT

12.2.11.6 The site; shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor.

RESPONSE: COMPLIANT

12.2.11.7 A record of hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

RESPONSE: COMPLIANT

12.3.1 Personnel

Personnel and Visitor cGMP Requirements SOP 019-1 is dated 10/13/19 and is approved by the EVPOP. The policy covers visitors, employees, contractors and or any other persons entering the site. The topics of visitors, disease control, hygienic practices (hand washing, outer garments, jewelry, gloves, hair restraints, skin preparations, personal affects, and food drink and tobacco) are all described within the procedure. The site does not allow smoking, chewing, eating or spitting within the warehouse. Exposed cuts and sores are to be covered. Personal are required to inform management if they have a contagious disease. Persons with obvious illness are not allowed to work in the warehouse. Since the outbreak of the pandemic the site has written and implemented a Contingency Plan for Covid-19 Confirmed Cases 010-006-1 dated 4/23/20 and approved by the EVPOP. This plan is now included into the cGMP and Crisis plan as well.

12.3.1.1 Personnel suffering from infectious diseases or are carriers of, any infectious disease are not permitted to work in the distribution center or in the transportation of food, and shall not engage in food handling operations, or be permitted access to storage areas where the product is exposed.

RESPONSE: COMPLIANT

12.3.1.2 The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids from open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury which causes spillage of bodily fluid, properly trained employee shall ensure that all affected areas including handling and processing areas have been adequately cleaned and that all materials and products have been quarantined and disposed of.

RESPONSE: COMPLIANT

12.3.1.3 Personnel with exposed cuts, sores or lesions shall not be engaged in handling exposed product or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with protective bandage, or an alternative suitable dressing.

RESPONSE: COMPLIANT

12.3.1.4 Smoking, chewing, eating, or spitting is not permitted in any food handling or storage areas where the product is exposed. Drinking is permissible under conditions that prevent contamination or other food safety risks from occurring.

RESPONSE: COMPLIANT

12.3.2 Hand Washing

The hand wash basins are observed to be porcelain and were observed to be clean and in good condition. Liquid/foam soap is in place. Paper towels are used. Hand wash signage is observed in each of the 5 restrooms. Gloves are not used at the site.

12.3.2.1 Hand wash basins shall be available and accessible as required.

RESPONSE: COMPLIANT

12.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as a minimum supplied with a potable water supply at an appropriate temperature, supplied with liquid soap contained within a fixed dispenser, with paper towels with a means of containing used paper towels. An effective hand dryer may be used in instances where there is no direct hand contact of food or food contact surfaces.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.3.3 Clothing

The site does not have a need for a third party laundry service. The employees which work in the warehouse are issued company purchased cotton shirts. The shirts are not observed to be a food safety concern.

12.3.3.1 Clothing worn by staff shall be maintained, stored, laundered and worn so as not to present a contamination risk to product.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.3.4 Jewelry and Personal Effects

The site does not have exposed product. The wearing of jewelry with the exception of dangling jewelry is allowed. Within the site laboratory no jewelry is allowed to be worn. Emergency alert bracelets and or necklaces are allowed within the warehouse.

12.3.4.1 Jewelry and other loose objects shall not be worn or taken into any area where exposed food is recouped. The wearing of wedding rings and medical alert bracelets (plain bands with no stones) that cannot be removed can be permitted, however the site will need to consider their customer requirements and the applicable food legislation.

RESPONSE: COMPLIANT

12.3.5 Visitors

The visitor program is documented within the cGMP program. Visitors are to be escorted. The visitor log in the front foyer is observed to be actively used and found to be current. Visitors entering the warehouse are required to read and sign the cGMP training. The management of drivers is documented within the cGMP program. The drivers are allowed to use the site restroom when requested. The amount of trucks at the site at one time is less than 3 trucks and the drivers are easily watched/controlled. Temporarily, during the Covid-19 pandemic the site is not allowing the drivers to enter the building past the receiving/shipping desk.

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

RESPONSE: COMPLIANT

12.3.5.2 All visitors shall be required to follow the GDPs outlined by the site.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.3.5.5 Facility shall have a policy for how drivers are managed and designated driver areas are maintained to prevent contamination or other food safety risks.

RESPONSE: COMPLIANT

12.3.6 Staff Amenities

The site amenities are observed to have appropriate lighting and ventilation.

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

RESPONSE: COMPLIANT

12.3.7 Change Rooms

The site does not have changing rooms. Should a person want to change their clothes single person restrooms are available for changing.

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

RESPONSE: COMPLIANT

12.3.7.2 Provisions shall be made for staff to store their personal items separate from food contact zones and food and packaging storage areas.

RESPONSE: COMPLIANT

12.3.8 Sanitary Facilities

The 5 toilet rooms are each observed to be clean, odorless and fully stocked with toilet paper, paper towels, soap and a covered trash can.

12.3.8.1 Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any food handling operations; ii. Accessed from the warehouse or product handling area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; and v. Kept clean and tidy.

RESPONSE: COMPLIANT

12.3.8.2 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system. Procedure shall be documented and implemented to properly manage sewage back-ups in order to minimize the potential for contamination.

RESPONSE: COMPLIANT

12.3.8.3 Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 12.3.2.2.

RESPONSE: COMPLIANT

12.3.9 Lunch Rooms

The lunch room is a fully stocked kitchen with microwaves, sink, soap, refrigerator, dishwasher, stove/oven and plenty of tables and seating available. The room has a stocked vending machine which is serviced monthly. The vending machine does include snacks which carry peanuts and allergens. The site is trained in allergen controls annually, last trained on 9/30/20. The provider is on the service provider register. Handwashing signage is posted within the room. During the pandemic the site has removed a few tables to insure a more than 6' space is between them. The lunchroom has been temporarily reduced to 6 or less people allowed at one time.

12.3.9.1 Separate lunch room facilities shall be provided away from a food handling or storage areas. Lunch rooms shall be kept clean and tidy and free from waste materials and pests.

RESPONSE: COMPLIANT

12.3.9.2 Signage in appropriate languages advising people to wash their hands before entering the food storage areas shall be provided in a prominent position in lunch rooms and at lunch room exits.

RESPONSE: COMPLIANT

12.4.1 Staff Engaged in Food Handling and Repack/Recoup Operations

The area of the warehouse that would be used to recoup is controlled though the cGMP program which covers each of the elements of this section of the code.

12.4.1.1 All personnel engaged in the direct handling of exposed food shall comply with the following practices: i. Personnel entry to food handling areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or stock transfer; iii. The wearing of false fingernails or fingernail polish is not permitted when handling food; iv. Materials and products shall be kept in appropriate containers as required and off the floor; v. Waste shall be contained in the bins identified for this purpose and removed from the operational area on a regular basis and not left to accumulate; vi. Staff shall not eat or taste any product in the food storage or handling area.

RESPONSE: COMPLIANT

12.4.1.2 All personnel engaged in storage, transport and handling of packaged products and materials shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination.

RESPONSE: COMPLIANT

12.5.1 Water Supply

The 2019 Baltimore City Water Quality Report was reviewed and within the report testing of Radiological contaminants, Beta Photon Emitters and Alpha Emitters are reported. Total Coliforms are tested and documented as within the sited acceptable range. Hot and cold water is available at the restroom basins and utensil sink.

12.5.1.1 Adequate supplies of water drawn from a known clean source shall be provided for use during holding or storage and for cleaning the premises and equipment.

RESPONSE: COMPLIANT

12.5.1.2 Supply of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

12.5.2 Water Quality

The site does not use ice. Water samples are not tested as this is a warehouse only process. The product is enclosed at all times during the warehousing process.

12.5.2.1 Microbiological analysis of the water and ice supply that is in contact with food or food contact surfaces shall be conducted to verify the cleanliness of the supply, the monitoring activities and the effectiveness of the treatment measures implemented.

RESPONSE: COMPLIANT

12.5.2.2 Water and ice, that contacts food or food contact surfaces, shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

12.5.3 Water Delivery

The site has the backflow device tested annually which was last completed on 9/22/20. The two check valves passed.

12.5.3.1 The delivery of water within the premises shall ensure potable water is not contaminated.

RESPONSE: COMPLIANT

12.5.3.2 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.

RESPONSE: COMPLIANT

12.5.4 Ice Supply

The site does not use ice.

12.5.4.1 Ice rooms and receptacles shall be constructed of materials as outlined in elements 12.2.1, 12.2.2 and 12.2.3 and designed to minimize contamination of the ice during storage and distribution.

RESPONSE: COMPLIANT

12.5.5 Analysis

Not applicable.

12.5.5.1 Microbiological analysis of the water and ice supply that is in contact with food or food contact surfaces shall be conducted to verify the cleanliness of the supply, the monitoring activities and the effectiveness of the treatment measures implemented.

RESPONSE: COMPLIANT

12.5.5.2 Water and ice, that is contact with food or food contact surfaces, shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

12.5.6 The Quality of Air and Other Gases

The site does not use compressed air, nitrogen, carbon dioxide or other gases.

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

RESPONSE: COMPLIANT

12.5.6.2 Compressed air systems, and systems used to store or dispense other gasses used in the storage and distribution process shall be maintained and regularly monitored for quality and microbiological purity.

RESPONSE: COMPLIANT

12.6.1 Storage and Handling of Goods

Within the Storage and Distribution Plan SOP 005-4 dated 7/23/20 the stock rotation is documented to be first in-first out principles. Stock rotation is observed to be as the program indicates. The site has a MRP system which tracks the date of product receiving through to shipment of materials to the 3 co-manufacturers and then again when it is received back as a finished product. The product shelf life is two years for all products. The software tracks the shelf life and has an aging report available for selection.

12.6.1.1 The site shall implement an effective storage plan that allows for the safe, hygienic storage of ice, food products (frozen, chilled, and ambient), packaging materials, equipment, and chemicals.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.6.1.3 Procedures are in place to ensure that all food products, and recouped product, are utilized within their designated shelf-life.

RESPONSE: COMPLIANT

12.6.2 Cold Storage, Freezing and Chilling of Foods

The site is ambient. All materials are transported at ambient temperatures.

12.6.2.1 The site shall provide confirmation of the effective operational performance of freezing, chilling and cold storage facilities. Chillers, blast freezers and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient cold/frozen storage of food, easily accessible for inspection and cleaning.

RESPONSE: COMPLIANT

12.6.2.2 Sufficient refrigeration capacity shall be available to store chilled or frozen food at the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.6.2.4 Cold and chilled storage rooms shall be fitted with temperature monitoring equipment and located so as to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.6.3 Storage of Shelf Stable Packaged Goods

The site does not have wet areas. The steel racks are observed to be clean and in good condition. The forklifts and hand trucks are observed to be very clean and on the master cleaning schedule to be cleaned on a monthly basis. Because of Covid-19 the forklifts and hand trucks are being wiped down daily.

12.6.3.1 Rooms used for the storage of dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.6.3.3 Vehicles used in storage rooms shall be designed and operated so as not to present a food safety hazard.

RESPONSE: COMPLIANT

12.6.4 Storage of Equipment and Containers

The sanitation and office supplies are stored in cabinets which were observed to be organized and clean.

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

RESPONSE: COMPLIANT

12.6.5 Storage of Hazardous Chemicals and Toxic Substances

The site does not use hazardous chemicals. The sanitation over-the-counter cleaning supplies are located in a segregated closet. All chemicals were observed labeled and in their original containers.

12.6.5.1 Hazardous chemicals and toxic substances that are for use in the site with the potential for food contamination shall be stored separate from the distribution storage area so as not to present a hazard to staff, product, packaging, product handling equipment. Hazardous chemicals shall be stored in their original containers, or in clearly labeled secondary containers if allowed by applicable legislation.

RESPONSE: COMPLIANT

12.6.6 Alternative Storage and Handling of Goods

The site does not have overflow conditions.

12.6.6.1 Where goods described in 12.6.1 to 12.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety and quality.

RESPONSE: COMPLIANT

12.6.7 Loading, Transport and Receiving Practices

Within the Storage and Distribution Plan SOP 005-4 dated 7/23/20 and signed by the EVPOP the condition of the in-bound and out-bound vehicles are to be inspected and documented. The condition of product integrity is to be inspected and documented. The records of inspections and storage conditions for the month of September through to Oct. 2, 2020 were reviewed and found to be acceptable. The trailers are inspected for condition of ceiling, side boards, floors, odor and product. See 2.7.1.2.

12.6.7.1 The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity.

RESPONSE: COMPLIANT

12.6.7.2 Trailers shall be washed in a segregated area away from the distribution site in a manner so as to not pose a risk to the products.

RESPONSE: COMPLIANT

12.6.7.3 Practices shall be in place for loading, transport and unloading receiving to protect against the contamination from biological, chemical and physical risks.

RESPONSE: COMPLIANT

12.6.7.4 Records of compliance activities shall be accessible.

RESPONSE: COMPLIANT

12.6.7.5 Sites shall have a procedure in place that is documented and implemented to ensure trailers are inspected prior to receiving shipments or loading to ensure that the trailer is in good repair, clean, secured and at required environmental conditions and temperatures.

RESPONSE: COMPLIANT

EVIDENCE: See 2.7.1.2. The site Food Defense Plan does not document the process of recording the trailer lock and or seal and seal numbers. The loading and unloading inspection forms are not documenting the method the trailers are secured.

12.6.8 Staging and Loading

The crew that is loading the trailers are the same crew picking the orders from the racks. The product is picked from the floor level of the racking area of the warehouse then as the work orders are received the product is moved to the staging area and loaded into the trucks. The fork trucks are cleaned monthly.

12.6.8.1 Vehicles (e.g. trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product.

RESPONSE: COMPLIANT

12.6.8.2 Staging and loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product integrity.

RESPONSE: COMPLIANT

12.6.8.3 Food transport vehicle's refrigeration unit shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and product temperatures monitored at regular intervals during loading as appropriate.

RESPONSE: COMPLIANT

12.6.9 Transport

The product is transported ambient.

12.6.9.1 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature checked at regular intervals during transit.

RESPONSE: COMPLIANT

12.7.1 Process Flow

The process flow is well designed and does not pose a food safety concern.

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

RESPONSE: COMPLIANT

12.7.2 Receiving

Within the Storage and Distribution Plan SOP 005-4 dated 7/23/20 and approved by the EVPOP the receiving procedure is documented. The site unloads directly through the dock door into the warehouse building. The 3 receiving dock doors have dock socks which are observed to be in good condition and do not expose the product to weather elements. All materials are received at ambient temperatures.

12.7.2.1 Prior to opening the doors the food transport vehicle's refrigeration unit storage temperature settings and operating temperature shall be checked and recorded. Receiving shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

12.7.3 Control of Foreign Matter

Foreign Material Program SOP 035-2 is dated 7/24/20 and is approved by the EVPOP. The program is verified during the monthly internal audit inspections. The glass and brittle plastic register 035-001-1 is developed and dated 7/22/20. The site program documents the register will be reviewed annually and was last inspected on 6/24/20. A breakage and clean-up procedure is written within the Foreign Material Program SOP 035-2. The site has breakage incident form 035-002 dated 8/20/19 to record any breakage incidents. The site has not had a glass breakage event in several years. Wood is addressed within the policy and describes the warehouse to be swept daily to remove any wood pieces. Throughout the audit loose metal was not observed.

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

RESPONSE: COMPLIANT

12.7.3.2 Inspections shall be performed to ensure plant and equipment remains in good condition and potential contaminants have not detached or become damaged or deteriorated.

RESPONSE: COMPLIANT

12.7.3.3 The following preventative measures shall be implemented where applicable to prevent glass contamination: i. All glass objects or similar material used by the site in storage and handling areas shall be listed in a glass register including details of their location. ii. Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing/contact zones. iii. Product that is in glass or similar material that is for distribution purposes shall be stored in a manner that prevents contamination. iv. Conduct regular inspections of storage and handling areas to ensure they are free of glass or other like material and to establish no changes to the condition of the objects listed in the glass register. v. Glass instrument dial covers on equipment and MIG thermometers shall be inspected at regular intervals.

RESPONSE: COMPLIANT

12.7.3.4 Wooden pallets used in food storage shall be dedicated for that purpose, clean, maintained in good order and their condition subject to regular inspection.

RESPONSE: COMPLIANT

12.7.3.5 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly affixed so as not to present a hazard.

RESPONSE: COMPLIANT

12.7.4 Managing Foreign Matter Contamination Incidents

The site has not received a complaint for foreign matter contamination. The site has not had an internal incident of foreign material.

12.7.4.1 In all cases of foreign matter contamination the affected food product shall be isolated, inspected, reworked or disposed of.

RESPONSE: COMPLIANT

12.7.4.2 In circumstances where glass or similar material breakage occurs, the affected area is to be isolated, cleaned and thoroughly inspected (including cleaning equipment and footwear) and cleared by a suitably responsible person.

RESPONSE: COMPLIANT

12.8.1 Dry and Liquid Waste Disposal

Waste collection and disposal is addressed within the Waste Management SOP 034 dated 10/16/19 and approved by the EVPOP. The site removes waste daily to an external receptacle. The receptacle is observed to be maintained clean, with lid in the down position and on a cleanable surface. The receptacle is removed from the site twice weekly. The recycle materials are removed to an external recycle bin which is removed from the site twice weekly.

12.8.1.1 The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented.

RESPONSE: COMPLIANT

12.8.1.2 Waste shall be removed on a regular basis and not build up in food handling or storage areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until such time as external waste collection is undertaken.

RESPONSE: COMPLIANT

12.8.1.3 Trolleys, vehicles, waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition and cleaned and sanitized regularly so as not to attract pests and other vermin.

RESPONSE: COMPLIANT

12.8.1.4 Reviews of the effectiveness of waste management will form part of regular hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.

RESPONSE: COMPLIANT

12.8.1.5 Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or risk to other food designated for further processing for human consumption.

RESPONSE: COMPLIANT

12.9.1 Grounds and Roadways

The grounds and surrounding areas are maintained through the sanitation schedule. Daily the grounds and smoking area are patrolled for trash. The cigarette butt can is dumped on a monthly cycle which is observed to be appropriate. The sidewalks are sealed and parking lot is asphalted. The landscaped grounds are away from the building and appear to be well groomed.

12.9.1.1 The grounds and area surrounding the premises shall be maintained to minimize dust and be kept free of waste or accumulated debris so as not to attract pests and vermin.

RESPONSE: COMPLIANT

12.9.1.2 Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises.

RESPONSE: COMPLIANT

12.9.1.3 Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises, or harborage for pests.

RESPONSE: COMPLIANT