SQF Food Safety Audit Edition 9

Nettie's Kitchen - Nettie's Kitchen

Summary

AUDIT DECISION
CERTIFIED WITH EXTENSIONS

CERTIFICATION NUMBER
49002 | 157571

AUDIT RATING
91
Good

DECISION DATE
08/01/2022

AUDIT TYPE
UNANNOUNCED

RECERTIFICATION DATE
07/01/2023

AUDIT DATES
07/06/2022 - 07/07/2022

EXPIRATION DATE
09/14/2023

ISSUE DATE
08/02/2022

Facility & Scope

Nettie's Kitchen (59077)
Nettie's Kitchen
457 Busse Rd
Elk Grove Village, IL 60007
United States

Food Sector Categories:
13. Bakery and Snack Food Processing

Products:
":Protein and snack bars keto pudding"

Scope of Certification:
"13. Bakery and Snack Food Processing: Protein and Snack Bars, Keto Pudding "

Certification Body & Audit Team

FoodChain ID Certification L.C.

500 N. 3rd Street
Suite 204
Fairfield, IA 52556
United States

CB#: CB-1-FoodChain ID
Accreditation Body: ANSI
Accreditation Number: 0969

Lead Auditor: Sherman, John (134073)
Technical Reviewer: Pappin , Jane (203456)

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

Non-Conforming

2.3.1 Specification, Formulation and Realization

Senior Management is responsible for working with perspective customers that supply formulas, ingredients, packaging materials and labels. If the desired product fits within the sites existing product line. The site does have a Product Specification Checklist that potential customers fill in. The list includes, receiving and storage requirements of raw materials and finished goods, production process, the establishment of “use by”, microbiological criteria, consumer preparation. If Shelf Life Trials are requested by the customer, the customer is directed to a third party that will conduct the tests. All existing and new products are required to be compatible with the current process flow to avoid cross contamination. Minor: Two new product commercialization checklists were reviewed during the audit. These did not have dates or who/whom was making the approvals.

2.3.1.6 Records of product design, formulations, label compliance, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.

RESPONSE: MINOR

EVIDENCE: Two new product commercialization checklists were reviewed during the audit. These did not have dates or who/whom was making the approvals.

ROOT CAUSE: The root cause of our form being non-conforming was due to our SQF consultant assuring me that the form was sufficient to comply with 2.3.1.6 of the SQF code when in reality it was not.

CORRECTIVE ACTION: This non-conformance is being corrected by adding date and signature lines by each of the approval categories listed on the commercialization check list.

Commercialization Checklist 2.3.1.6.pdf

Commercialization Checklist(1) 2.3.1.6.pdf

VERIFICATION OF CLOSEOUT: Evidence of Commercialization was reviewed and approved.

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

2.4.2 Good Manufacturing Practices (Mandatory)

Good Manufacturing Practices that are applicable to the scope of certification are outlined in the sites 2.4.2 Food Safety Policy. The Policy outlines the means by which food safety is controlled, documented and implemented. Policies and employee practices are addressed in new employee orientation and again during annual refresher training for all employees. Sign in sheets from GMP training sessions from 6/7/22, 6/8/22 and 6/22/22 were reviewed during the audit. Along with the sign in sheets were copies of quizzes that those being trained filled out. Minor:During a tour of a storage area an uncovered partial roll of product contact film was observed mixed in with equipment parts and damaged cardboard boxes.

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

RESPONSE: MINOR

EVIDENCE: During a tour of a storage area an uncovered partial roll of product contact film was observed mixed in with equipment parts and damaged cardboard boxes.

ROOT CAUSE: The root cause of this non-conformance is that the warehouse and production management had either forgotten or gotten lax on their responsibility to log raw material on hold or that had been marked for disposal.

CORRECTIVE ACTION: "The corrective action was the disposal of the roll (which was garbage) and other garbage on the pallet. The preventative action was that the warehouse and production management were re-trained on quarantining, identifying, handling, and disposal of non-conforming materials as per our policy on section 2.4.5 of the SQF code (non-conforming materials and product). The training log is attached herewith"

2.4.2.1 corrective action training log.pdf

VERIFICATION OF CLOSEOUT: Evidence of corrective action log was reviewed and approved.

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

2.4.8 Environmental Monitoring

The site has performed a "Risk Assessment" on their Environmental Monitoring program, the site has determined that a limited environmental swabbing is adequate to monitor potential microbial contamination. Per the sites SQF Policy Manual, the responsibility and methods for the environmental monitoring program are documented with the SQF Practitioner being responsible for the program. On a monthly basis the site swabs and tests for APC. On a quarterly basis the site pulls swabs selects zone one locations in the processing area. These swabs are sent to an ISO:IEC 17025 certified lab for analysis. Swab results from 3/28/22, 4/18/22, 5/2/22 and 6/20/22 were reviewed during the audit. Minor: The site's written policy/procedure does not agreee with what the site is doing for environmental testing. Their program calls for zone 1 testing for Salmonella and Listeria. In actuality the site is pulling two samples that are tested for APC monthly.

2.4.8.2 An environmental sampling and testing schedule shall be prepared. It shall at a minimum: i. Detail the applicable pathogens or indicator organisms to test for in that industry; ii. List the number of samples to be taken and the frequency of sampling; iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and iv. Describe the methods to handle elevated or undesirable results.

RESPONSE: MINOR

EVIDENCE: The site's written policy/procedure does not agreee with what the site is doing for environmental testing. Their program calls for zone 1 testing for Salmonella and Listeria. In actuality the site is pulling two samples that are tested for APC monthly.

ROOT CAUSE: The root cause of this non-conformance was that there was a change in SQF practitioner and the previous practitioner updated the practice, but not the policy. I, the current SQF practitioner, should also have caught this in our monthly policy review. I will need to make sure I read through our policies more thoroughly in future policy reviews.

CORRECTIVE ACTION: The corrective/preventative action for this non-conformance was that the Nettie's Kitchen Policy manual was updated to reflect our current practice and to maintain that practice. If the practice is changed again then the policy will also be updated.

corrective actions 2022 swab policy 2.4.8.2.pdf

VERIFICATION OF CLOSEOUT: Corrective action swab policy was reviewed and approved.

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

2.5.4 Internal Audits and Inspections (Mandatory)

The site follows the directives in their SQF Policy Manual, which calls for the site to schedule and conduct internal audits on a monthly basis to verify the effectiveness of the SQF system. Auditors perform internal audits on a monthly basis against an audit checklist. The audits include facility and equipment inspections, pre-requisite programs, food safety plans, food security, GMPs, and legislative controls. Staff conducting audits were trained in auditing by a Consultant and have experience and knowledgeable in areas that they are auditing. Audit results are communicated to relevant management personnel and staff. All deficiencies are investigated and corrective actions implemented and followed up on to ensure corrective actions are effective. Records are maintained for two years. Internal audits for the months of January, March and April of 2022 were reviewed during the audit. The audit from January listed floor drains as needing cleaning due to a buildup in the lines. The site had a vendor come in and clean the lines but could not show documentation that this was done or when. Minor: While reviewing the internal audit from January there was a listing for floor drains as needing cleaning due to a build-up in the lines. Per a conversation with the Practitioner, the site had a vendor come in and clean the lines but could not show documentation that this was done or when.

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

RESPONSE: MINOR

EVIDENCE: While reviewing the internal audit from January there was a listing for floor drains as needing cleaning due to a build-up in the lines. Per a conversation with the Practitioner, the site had a vendor come in and clean the lines but could not show documentation that this was done or when.

ROOT CAUSE: The root cause of this non-conformance is that the designation of responsibilities regarding our maintenance logging policy was not clear after there were staff changes. Each employee was under the impression that one of the others was logging the maintenance and invoices from the maintenance.

CORRECTIVE ACTION: The corrective and preventative action for this non-conformance was a staff meeting to re-emphasize the necessity that production management and weekend management give all maintenance invoices to the SQF practitioner and that the SQF practitioner must be aware of and log all maintenance being done in the facility.

2.5.4.4 corrective action training log.pdf

VERIFICATION OF CLOSEOUT: Evidence of corrective actions training was reviewed and approved.

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

11.1.2 Building Materials

Product contact surfaces, surfaces not in contact with food and storage areas are constructed of suitable materials including stainless and food grade plastic. They were observed during the audit to be properly maintained so that food safety is not compromised. Floors are constructed of smooth and dense impact resistant material and properly graded for effective drainage of overflow or waste water. Waste water flows directly to the city waste water treatment system. Drains were observed to be located and constructed for ease of cleaning and inspection. The site does not have overhead pipes carrying sanitary waste or waste water. Walls and doors are of durable construction with smooth and light colored surfaces. These areas were observed to be clean during the audit tours. Wall to wall and wall to floor junctures were observed to be sealed and free of debris. Ducting, piping and conduit conveying services were observed to be installed for ease of cleaning. Overhead cleaning was found to be part of the master cleaning schedule. Doors, windows and frames were observed to be properly constructed of materials with the same functional requirements as internal walls and partitions. The site does not have overhead pipes carrying sanitary waste or waste water. The site does not have exposed product under stairs or platforms. There are no catwalks in the plant. Minor: During the inspection of the warehouse at 500 E. Touhy Ave. a separation/gap at the intersection of the floor and walls of was observed. This creates a harborage for insects/pests.

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

RESPONSE: MINOR

EVIDENCE: During the inspection of the warehouse at 500 E. Touhy Ave. a separation/gap at the intersection of the floor and walls was observed. This creates a harborage for insects/pests.

ROOT CAUSE: The root cause of this non-conformance was our landlords refusal to perform regular maintenance on the facility as he should.

CORRECTIVE ACTION: The corrective and preventative action for this non-conformance is filling the crack with expanding foam and caulk. We have attempted to get the landlord to fill these gaps in the past to no avail. If we are continually unable to get our landlord to assist us we will perform the corrective measures ourselves.

flooring work order 500 touhy 2022 11.1.2.4.eml

VERIFICATION OF CLOSEOUT: Evidence of flooring work order was reviewed and approved.

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

11.1.8 Grounds and Roadways

The exterior of two buildings and grounds are included in the internal audit program. The grounds and surrounding areas of both sites were observed to be neat, well maintained, free of dust and waste and not present a hazard to the sanitary operation of the plant. The parking lot, roadways and dock areas at 457 Busse Rd. were paved and well maintained with no pooling of water. . Minor: While inspecting the warehouse at 500 E. Touhy Ave. the loading dock area was observed to have a substantial amount of water and debris pooling at the bottom of the ramp which creates a potential contamination and pest issue.

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

RESPONSE: MINOR

EVIDENCE: While inspecting the warehouse at 500 E. Touhy Ave. the loading dock area was observed to have a substantial amount of water and debris pooling at the bottom of the ramp which creates a potential contamination and pest issue.

ROOT CAUSE: The root cause of this non-conformance was lack of proper inspection of the shared dock. If the dock had been thoroughly inspected, then we could have noticed the trash issue that may have been the root cause of the clog in the sump pump or noticed that the sump pump was not operational.

CORRECTIVE ACTION: The corrective action for this non-conformance was to put in a work order to our landlord to service the sump pump in the dock space. The preventative action for this non-conformance was to add a section to the internal audit form for the Touhy location regarding inspection of the shared dock area.

11.1.8.2 and 11.6.5.1 corrective action

11.1.8.2 corrective action sum... repair.pc

VERIFICATION OF CLOSEOUT: Evidence of replaced sumpump and internal audit was reviewed and approved.

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

11.2.3 Calibration

The site adheres to the protocols listed in their Policy 11.2.1. The SQF Practitioner or their designee is responsible for scheduling the calibration and re-calibration of measuring, and inspection equipment. The methods for calibrating all measuring, testing and/or inspection equipment are outlined in different SOP's. The SOP's contains the calibration schedules along with who is responsible for scheduling or performing calibrations. All equipment is calibrated to manufacturers recommendations or regulatory requirements. Scales are calibrated daily before production by the Production Manager and annually by a certified lab. Daily calibration records from 6/1/22, 6/13/22, 6/19/22 and 6/28/22 . Calibration records are maintained for two (2) years. Minor: The site has a policy that they will have their scales calibrated and certified by a third party annually, the site could not provide documentatin that their scales have been calibrated by a third party within the last year.

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

RESPONSE: MINOR

EVIDENCE: The site has a policy that they will have their scales calibrated and certified by a third party annually, the site could not provide documentatin that their scales have been calibrated by a third party within the last year.

ROOT CAUSE: The root cause of this non-conformance was that I was under the impression that our pre-operational scale checks were sufficient. I did not write our Policy manual (our previous practitioner did), so I missed the line about the annual calibration. Our auditor brought this to my attentions and it will not be a problem moving forward.

CORRECTIVE ACTION: The corrective action for this non-conformance was to put in a work order with Data Weighing Systems to get our scales calibrated.

11.2.3.1 corrective action work order.pdf

VERIFICATION OF CLOSEOUT: Evidence of corrective action work order was reviewed and approved.

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

11.5.3 Water Quality

The site performs annual water testing for Coliform, E-Coli, Staph, Mold, EB and Yeast as indicators of water potability. The Village of Elk Grove provides an annual water quality report, the report for 2021 was reviewed during the audit, all levels were within EPA guidelines for coliform and E-Coli. Minor: The site could not provide microbiological analysis of water samples taken from inside the site.

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

RESPONSE: MINOR

EVIDENCE: The site could not provide microbiological analysis of water samples taken from inside the site.

ROOT CAUSE: The root cause of this non-conformance was that I (the SQF practitioner) was under the impression that our backflow test was our water test. Our auditor made the distinction clear and this will not be an issue moving forward.

CORRECTIVE ACTION: The corrective action for this non-conformance was to request the supplies to have the water test completed with Matrix Sciences our 3rd party testing facility.

11.5.3.2 water analysis request.eml

Verification Validation Schedule.pdf

VERIFICATION OF CLOSEOUT: Evidence of water analysis and validation were reviewed and approved.

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

11.6.5 Loading, Transport, and Unloading Practices

The site adheres to the directives in their Policy 11.6 which requires all trailers to be inspected for cleanliness, infestation, odors, damage before loading or unloading. All loads are staged on an enclosed dock prior to the trailer/truck being backed in and loaded. It was observed during the audit that loading practices do not unnecessarily expose products to detrimental conditions. The company ships the majority of the product they produce on their own trucks which are locked upon loading and noted on the BOL and the Shipping Log. The site does not arrange shipping for their products. All shipments are arranged by the customers as third party pick-ups. Shipping records from 4/22/22, 5/2/22, 5/14/22, 5/26/22 and 6/8/22 were reviewed doing the audit. At the point of loading and release of product, ownership and responsibility is transferred to the customer. At that point it is the responsibility of the customer to ensure that trailers are either locked or sealed. All secondary containers are sealed and all pallets are stretch wrapped prior to loading. It was observed during the audit tours that these loading practices do not expose products to detrimental conditions. Receiving records from 5/10/22, 6/3/22, 6/9/22, 6/27/22 and 7/1/22 were reviewed doing the audit. The receiving check sheets showed that trailer inspections were being performed, the BOL's were being checked against the order and seals/locks were being verified. Warehouse interviews revealed that employees are aware of the proper procedures and follow them. The site does not ship finished goods on refrigerated transports. The site does not receive ingredients on refrigerated transports. Unloading practices appeared to be designed to prevent product distress and contamination of product. Minor: Clause 11.6.5.1 calls for foods to be loaded, transported and unloaded under conditions suitable to prevent contamination. The loading doce at the site's warehouse at 500 E. Touhy Ave. had a trash container that was overflowing onto the dock which creates a pest problem.

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: MINOR

EVIDENCE: Clause 11.6.5.1 calls for foods to be loaded, transported and unloaded under conditions suitable to prevent contamination. The loading doce at the site's warehouse at 500 E. Touhy Ave. had a trash container that was overflowing onto the dock which creates a pest problem.

ROOT CAUSE: The root cause of this non-conformance was that there was not enough monitoring of the shared dock to ensure that the site was regularly inspected and maintained up to SQF standards.

CORRECTIVE ACTION: The corrective action for this non-conformance was to gather up and throw the trash away in the dumpster. The preventative action for this non-conformance was to add a shared dock inspection section to the internal audit checklist for the touhy ave location. I also spoke with our warehouse manager and the manager of the business that shares the dock with Nettie's Kitchen about ensuring that the trash is taken out in a timely manner moving forward.

11.6.5.1 corrective action training log.pdf

VERIFICATION OF CLOSEOUT: Training was reviewed and approved.

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

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Kevin DeLozier
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** Kevin@nettieskitchen.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Kevin DeLozier: SQF Practitioner, Annette Del Prete: Owner, John Sherman: 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 has two facilities. The building at 457 Busse Rd. Elk Grove Village has approximately 3,000 sq. ft. of production space, 7,000 sq. ft. of storage and approximately 500 sq. ft. dedicated to administration. The site is part of a one story newer masonry and steel building located in an Industrial Park in Elk Grove Village. The site has one production line on which they co-pack shelf stable protein bars. The site has 49 employees that work two shifts 5 days a week. Production employees and management perform sanitation after and prior to the next production run. The building at 500 E. Touhy, Elk Grove Village has approximately 10,000 sq, ft. of which 9,000 is used for storage of packaging and finished goods. The building is of concrete and steel construction and is part of a newer industrial/commercial building. There is another 1,000 sq. ft. that is reserved for administration. The warehouse at 500 E. Touhy is not manned fulltime. An employee from 457 Busse Rd. travels to the warehouse during times when finished product is either being transferred in from 457 Busse Rd. or when finished product is being loaded out for shipment.The company does store ingredients and packaging at a SQF Certified Warehouse at 814 Golf Ln. Bensenville IL. which is approximately 25 miles from the Busse Rd. site.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Kevin DeLozier: SQF Practitioner, Annette Del Prete: Owner, Filippo Del Prete: Owner, Kyle Lasser: Backup SQF Practitioner, John Sherman: Auditor
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Grant Recertification upon verification that all non-conformances have been rectified.

Section Responses

2.1.1 Management Responsibility (Mandatory)

Within the site's Policy Statement is a commitment to producing safe food products that meet or exceed the requirements of their customers and the food safety regulations. The Policy Statement is posted in the breakroom and on a bulletin board next to the entrance to the production area. Employees have been given the authority and are expected to stop production if they oberve a food safety or quality issue. To encourage employees to take an active role in their food safety goals, the site has a policy if there are no food safety or quality complaints in a quarter the site provides lunch to the staff. The site pledges to meet or exceed their customer expectations, operate in compliance with the SQF Food Safety Code and all other applicable food legislation by providing all of the necessary resources to drive continuous improvement. The site is committed to continually improving its food safety system through monthly Food Safety Review Meetings and Annual SQF Systems Validation. The document has a date of 6/21/22, is signed by the owner/CEO and posted in the breakroom and by the time clock. Policy 2.1.2. outlines the structure of staff having responsibility for food safety. Senior management has communicated this to the organization through meetings and training. The site provides the resources for implementation of the food safety Systems. Kevin DeLozier has been appointed as SQF Practitioner, is a full time employee of the facility and has a HACCP Certificate from NC State. Kyle Lasser has been named as the back up SQF Practitioner. The SQF Practitioner is responsible for the development, implementation and maintenance of the SQF System. Senior site management ensures adequate resources are available to achieve their food safety objectives and to support the development, implementation, maintenance and ongoing improvement of the SQF system. Site management ensures that the training needs of the site are implemented and meet the requirements as outlined in elements 2.9. Company job descriptions ensures the integrity and continued operation of the food safety system in the event of organizational or personnel changes. Plant staff is required to report food safety/quality issues to management. Effectiveness of the SQF System is measured by monitoring customer complaints, 3rd party audits and HACCP deviations. The company does not have defined "blackout" periods. Per site Policy 2.1.1 the company will give the Certifying Body at least 30 days notice prior to the recertification period of any "blackout dates".

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.1.5 The primary and substitute SQF practitioner shall: i. Be employed by the site; ii. Hold a position of responsibility related to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code: Food Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2 Management Review (Mandatory)

The site follows the directive in their Policy 2.1.3 which states that senior management will review the SQF System and document the review procedure at least annually. The review includes the policy manual, internal and external audit findings along with the corrective actions, investigations and the resolution. Records of all management reviews and updates are maintained for a minimum of two years. Meeting notes from the most recent Management Review conducted on 6/18/22 were reviewed. The review included customer complaints, the resulting investigations and the resolution. Effectiveness of the SQF System is measured by monitoring customer complaints, 3rd party audits and HACCP deviationsThe major topic was moving forward on refining their finished goods release program. The SQF practitioner updates senior site management at a minimum of a monthly basis on matters impacting the implementation and maintenance of the SQF System. Notes from 6/10/22 centered on the site getting ready for the upcoming SQF Audit. Specific things discussed were bringing in an outside contractor to clean the overheads and having the pest control company update the device map

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.3 Complaint Management (Mandatory)

The site follows the protocols in their Policy 2.1.4, when handling customer complaints. Complaints are received, investigated, analyzed, trended and documented by Senior Management. Response's adhere to all appropriate legislation regarding food safety. Complaints are investigated and if warranted a root cause is determined along with a corrective and a preventative action is implemented. All complaint records are maintained for a minimum of 2 years. The site's Complaint Log was reviewed during the audit. The log included 5 complaints regarding oil permeating from the bars to the film. The investigation determined that the root cause was the film. The corrective action was to replace the film supplier. A summary of all complaints along with a trend line are reviewed by management.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

Their Food Safety Management Program calls for the entire SQF System to be reviewed and updated at least annually. The program was reviewed on 6/21/22. The program Is in electronic format and hard copy. The SQF Practitioner is the only person that has editing rights. The program(s) have been made available to the rest of the employees. The plan gives a summary of their Food Safety Policies, the Organizational Chart, along with food safety procedures, process controls and prerequisite programs. The scope is FSC 13, Bakery and Snack Food Processing. The site has a register of finished products with specifications and a register of raw materials that includes specifications. The plan also specifies that all supporting programs and/or changes to the Food Safety Plan will be validated.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

The site follows the protocols in their Document Control Policy which assigns the SQF Practitioner as responsible for document control. Product records are maintained for two years. The register of SQF documents listed in the SQF Food Safety Manual is current with the most recent update of 6/21/22.

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

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

The site follows the protocols in their Management & Retention Policy which has specific requirements for verifying and retention of food safety/quality and other related documents. All management, supervisors, and plant personnel have a role in ensuring that all records are accurate and complete and that the records reflect the actual operating conditions. Retention time for records is based on historical, contractual and/or legal requirements but no less than two years.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.1 Specification, Formulation and Realization

Senior Management is responsible for working with perspective customers that supply formulas, ingredients, packaging materials and labels. If the desired product fits within the sites existing product line. The site does have a Product Specification Checklist that potential customers fill in. The list includes, receiving and storage requirements of raw materials and finished goods, production process, the establishment of “use by”, microbiological criteria, consumer preparation. If Shelf Life Trials are requested by the customer, the customer is directed to a third party that will conduct the tests. All existing and new products are required to be compatible with the current process flow to avoid cross contamination. Minor: Two new product commercialization checklists were reviewed during the audit. These did not have dates or who/whom was making the approvals.

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

RESPONSE: COMPLIANT

2.3.1.2 New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure product safety. Product formulations shall be developed by authorized persons to ensure that they meet the intended use. Where necessary, shelf life trials shall be conducted to validate and verify a new product’s: i. Pre-consumer handling and storage requirements, including the establishment of “use by,” “best before dates,” or equivalent terminology; ii. Microbiological criteria, where applicable; and iii. Consumer preparation, where applicable, and storage and handling requirements.

RESPONSE: COMPLIANT

2.3.1.3 A food safety plan shall be validated and verified by the site food safety team for each new product and its associated process through conversion to commercial production and distribution or where a change to ingredients, process, or packaging occurs that may impact food safety.

RESPONSE: COMPLIANT

2.3.1.4 Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment.

RESPONSE: COMPLIANT

2.3.1.5 The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination.

RESPONSE: COMPLIANT

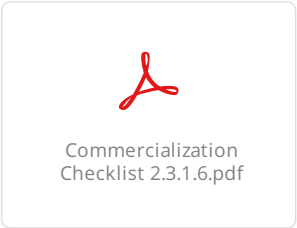
2.3.1.6 Records of product design, formulations, label compliance, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.

RESPONSE: MINOR

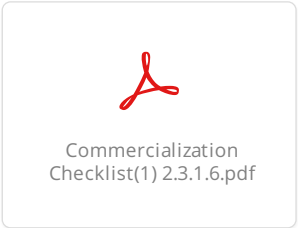
EVIDENCE: Two new product commercialization checklists were reviewed during the audit. These did not have dates or who/whom was making the approvals.

ROOT CAUSE: The root cause of our form being non-conforming was due to our SQF consultant assuring me that the form was sufficient to comply with 2.3.1.6 of the SQF code when in reality it was not.

CORRECTIVE ACTION: This non-conformance is being corrected by adding date and signature lines by each of the approval categories listed on the commercialization check list.



Commercialization Checklist 2.3.1.6.pdf



Commercialization Checklist(1) 2.3.1.6.pdf

VERIFICATION OF CLOSEOUT: Evidence of Commercialization was reviewed and approved.

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

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

Specifications for raw materials, packaging, ingredients, additives are developed and maintained by the customer. There are current registers in place for raw materials, packaging materials and labels. The specification sheet for Kosher Acerola Juice Powder with Dextrose was reviewed during the audit. The specifications lists required moisture levels, Ascorbic Acid Levels and Microbiological Analysis. A policy defining the methods and responsibilities for developing and maintaining specifications has been documented and implemented in Raw and Packaging Materials. Raw and packaging materials are validated to ensure product safety; regulatory requirements and quality are met by means of testing of raw materials, Letters of Guarantee or Certificates of Analysis. The site's Register of finished product specifications are current and developed by the customer. Specifications for Jimmy Bar Chocolate Peanut Butter being produced for Keto. The specifications include packaging, weight, dimensions, ingredient statement along with code dating.

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

RESPONSE: COMPLIANT

2.3.2.2 Specifications for all raw materials and packaging, including, but not limited to, ingredients, additives, hazardous chemicals, processing aids, and packaging that impact finished product safety shall be documented and kept current.

RESPONSE: COMPLIANT

2.3.2.3 All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation in the country of manufacture and country(ies) of destination if known.

RESPONSE: COMPLIANT

2.3.2.4 Raw materials, packaging, and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose.

RESPONSE: COMPLIANT

2.3.2.5 Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may vary by crop or by season).

RESPONSE: COMPLIANT

2.3.2.6 Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

RESPONSE: COMPLIANT

2.3.2.7 Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.2.9 Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable: i. Microbiological, chemical, and physical limits; ii. Composition to meet label claims; iii. Labeling and packaging requirements; and iv. Storage conditions.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.3 Contract Manufacturers

N/A: The site does not utilize Contract Manufacturers

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

2.3.4 Approved Supplier Program (Mandatory)

The Owner/CEO has overall responsible for overseeing the Approved Supplier Program. The program is based on the prior performance of a supplier. The site has performed a risk assessment of the raw materials, ingredients, packaging materials, and services supplied. Risk assessments for raw materials is performed annually. All materials used in production are purchased and owned by the company that the site co-packs for. Suppliers at a minimum must have a documented HACCP plan, documented GMP Policies, an environmental testing plan and a current 3rd Party Audit. A third party audit for a supplier of Blueberries dated 4/8/22 by BRC was reviewed during the audit. The supplier register is reviewed annually with the last review 6/1/22. In the event that an approved supplier can not fill demands, non-approved suppliers can be utilized provided that the incoming materials meet established specifications and are inspected or analyzed before use. Specifications are covered under LOG's or COA's. Food Fraud is addressed in site Document 2.7.2 Food Fraud. The site performs two food fraud vulnerability assessments annually. This is a stand-alone operation.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

EVIDENCE: N/A: This is a stand alone operation.

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

RESPONSE: COMPLIANT

EVIDENCE: The site does not conduct supplier audits.

2.4.1 Food Legislation (Mandatory)

The site ensures that at the time of delivery to its customer that the food supplied complies with legislation that applies to the food in the country of production and eventual use or sale this follows the guidelines in 2.4.1 of their SQF Manual. The SQF Practitioner is responsible for keeping the site updated about changes in relevant legislation. The site stays current on all regulatory updates through electronic e-mail notification via the FDA website. The site has documented that the certification body and SQF will be notified within 24 hours via e-mail if a food safety event requiring public notification occurs.

2.4.1.1 The site shall ensure that at the time of delivery to customers finished products shall comply with food safety legislation applicable in the country of manufacture and sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.1.3 SQFI and the certification body shall be notified in writing within twenty-four (24) hours as a result of a regulatory warning or event. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

Good Manufacturing Practices that are applicable to the scope of certification are outlined in the sites 2.4.2 Food Safety Policy. The Policy outlines the means by which food safety is controlled, documented and implemented. Policies and employee practices are addressed in new employee orientation and again during annual refresher training for all employees. Sign in sheets from GMP training sessions from 6/7/22, 6/8/22 and 6/22/22 were reviewed during the audit. Along with the sign in sheets were copies of quizzes that those being trained filled out. Minor:During a tour of a storage area an uncovered partial roll of product contact film was observed mixed in with equipment parts and damaged cardboard boxes.

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

RESPONSE: MINOR

EVIDENCE: During a tour of a storage area an uncovered partial roll of product contact film was observed mixed in with equipment parts and damaged cardboard boxes.

ROOT CAUSE: The root cause of this non-conformance is that the warehouse and production management had either forgotten or gotten lax on their responsibility to log raw material on hold or that had been marked for disposal.

CORRECTIVE ACTION: "The corrective action was the disposal of the roll (which was garbage) and other garbage on the pallet. The preventative action was that the warehouse and production management were re-trained on quarantining, identifying, handling, and disposal of non-conforming materials as per our policy on section 2.4.5 of the SQF code (non-conforming materials and product). The training log is attached herewith"

2.4.2.1 corrective action training log.pdf

VERIFICATION OF CLOSEOUT: Evidence of corrective action log was reviewed and approved.

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

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

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

The food safety plan was developed and maintained by a multidisciplinary team that includes the SQF practitioner and site personnel that possess technical, production, and/or engineering knowledge of the relevant products and associated processes. The plan was reviewed on 6/8/22 with no changes. The sites Food Safety Plan follows the principals of HACCP as outlined in Nettie's Kitchen Food Safety Policy and is prepared and implemented in accordance with the Codex Alimentarius Commission HACCP Guidelines. The intended use of each product is determined and documented by the food safety team. This includes 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. The site has one HACCP plan which is shelf stable protein bars. The plan has 1 CCP which is metal detection. CCP checks are performed according to their documented policy. The employee that performs the checks on the metal detector was interviewed and demonstrated he knew why he was performing that task. The plan includes the identification of the HACCP team, product description, log of changes, process flow chart, hazard analysis for each step in the flow chart, CCP's identification, monitoring procedures, corrective action procedures, verification procedures and record keeping requirements. The food safety team validates 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 effectively provide the level of control required. A full review of the documented and implemented plans are conducted at least annually, or when changes to the process are made. The decisions made in the hazard analysis are validated and the critical limits are validated through industry/scientific publications. All suppliers of raw materials, packaging supplies and other ingredients are required to have a documented HACCP plan, GMP Policies, and provide proof of a third-party audit. All countries that product is sent to adhere to HACCP Guidelines.

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented and maintained and shall outline how the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.4 Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.6 The food safety team shall develop and document a flow diagram covering the scope of each food safety plan The flow diagram shall include every step in the process, all raw materials, packaging, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation.

RESPONSE: COMPLIANT

2.4.3.7 The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

RESPONSE: COMPLIANT

2.4.3.8 The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.

RESPONSE: COMPLIANT

2.4.3.9 The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.

RESPONSE: COMPLIANT

2.4.3.10 Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

RESPONSE: COMPLIANT

2.4.3.11 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard(s) and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

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 Product Sampling, Inspection and Analysis

Methods and frequency of sampling procedures are listed in SOP's and fall under the responsibility of the SQF Practitioner or their designee. Testing is performed to ensure product meets both food safety and customer requirements. The site does not have personnel that conduct testing. On a weekly basis the site pulls two samples of finished product and sends the samples to an ISO:IEC 17025 certified lab where product is tested for water activity, coliform, lead, mold and yeast. All testing is performed to nationally recognized methods or equivalent. Test results for finished product from 4/18/22, 5/30/22 and 6/6/22 were reviewed during the audit. The site does not have an on-site laboratory.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have an on-site laboratory.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have an on-site laboratory.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not retain samples.

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Materials and Product

The site follows the protocols in their Policy 2.4.5 in controlling non-conforming product or equipment. All non-conforming product and equipment is entered into the sites Hold and Release Program. Non-conforming product or equipment 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. Appropriate records are maintained for all non-conforming product and equipment and is available to all key team members. The site's current "Hold Log" did not include product that was put on hold for being non-conforming but did include several pieces of equipment that has been brought in as a paart of an expansion project but due to delays in the project have not been put into production yet.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.6 Product Rework

N/A: The site does not use rework in their process.

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

RESPONSE: NOT APPLICABLE

2.4.7 Product Release (Mandatory)

The site follows the protocols listed in site Policy 2.4.7 for releasing finished goods for shipment. Product release is the responsibility of either the SQF Practitioner or the Production Manager. Samples of products are reviewed throughout the process to determine if they meet the specification. Product and production records are reviewed and compared to the specification for each lot. The product is inspected to insure that it meets specifications, Food Safety, HACCP controls, Food Quality and legislative controls. Product that complies for all of the checks performed is available for shipment to customers. Records of releases are retained. Release for product produced on 6/1/22, 6/13/22, 6/19/22 and 6/28/22 were reviewed during the audit.

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel, and only after all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met. Records of all product releases shall be maintained.

RESPONSE: COMPLIANT

2.4.7.2 Product release shall include a procedure to confirm that product labels comply with the food legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1). If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

The site has performed a "Risk Assessment" on their Environmental Monitoring program, the site has determined that a limited environmental swabbing is adequate to monitor potential microbial contamination. Per the sites SQF Policy Manual, the responsibility and methods for the environmental monitoring program are documented with the SQF Practitioner being responsible for the program. On a monthly basis the site swabs and tests for APC. On a quarterly basis the site pulls swabs selects zone one locations in the processing area. These swabs are sent to an ISO:IEC 17025 certified lab for analysis. Swab results from 3/28/22, 4/18/22, 5/2/22 and 6/20/22 were reviewed during the audit. Minor: The site's written policy/procedure does not agreee with what the site is doing for environmental testing. Their program calls for zone 1 testing for Salmonella and Listeria. In actuality the site is pulling two samples that are tested for APC monthly.

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food manufacturing processes and immediate surrounding areas, which impact manufacturing processes. The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.8.2 An environmental sampling and testing schedule shall be prepared. It shall at a minimum: i. Detail the applicable pathogens or indicator organisms to test for in that industry; ii. List the number of samples to be taken and the frequency of sampling; iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and iv. Describe the methods to handle elevated or undesirable results.

RESPONSE: MINOR

EVIDENCE: The site's written policy/procedure does not agreee with what the site is doing for environmental testing. Their program calls for zone 1 testing for Salmonella and Listeria. In actuality the site is pulling two samples that are tested for APC monthly.

ROOT CAUSE: The root cause of this non-conformance was that there was a change in SQF practitioner and the previous practitioner updated the practice, but not the policy. I, the current SQF practitioner, should also have caught this in our monthly policy review. I will need to make sure I read through our policies more thoroughly in future policy reviews.

CORRECTIVE ACTION: The corrective/preventative action for this non-conformance was that the Nettie's Kitchen Policy manual was updated to reflect our current practice and to maintain that practice. If the practice is changed again then the policy will also be updated.

corrective actions 2022 swab policy 2.4.8.2.pdf

VERIFICATION OF CLOSEOUT: Corrective action swab policy was reviewed and approved.

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

2.4.8.3 Environmental testing results shall be monitored, tracked, and trended, and preventative actions (refer to 2.5.3.1) shall be implemented where unsatisfactory results or trends are observed.

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

The site follows their Policy 2.5.1 which calls for the SQF Practitioner or his designee to validate the effectiveness of GMP's, CCP's and all associated programs at least annually. During the audit validation studies of the effectiveness of their metal detection program and the validation of their Calibration program were reviewed. Records are maintained for a minimum of two years.

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

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

Site Policy 2.5.1 calls for a verification schedule that outlines verificatio activities and directs the SQF Practitioner or designee to verify the effectiveness of GMP's, CCP's and all associated programs annually. The Verification Schedule which includes methods of verification was reviewed during the audit. Verification studies of the effectiveness of Metal Detection (CCP) and Pest Control were reviewed. Records are maintained for a minimum of two years.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

Site policy 2.5.3 identifies the SQF Practitioner as responsible for investigating and determining the root cause and identifying and implementing whatever corrective actions that are needed. All records are to be maintained for a minimum of two years. During a review of the site's internal audit policy by an outside consultant on 3/15/22 it was discovered that the Internal Audit that was due to be performed in February had been missed. The corrective action was to write a deviation, the root cause was determined to be that the person that was responsible to perform the audit got involved with his other duties and simply forgot to perform the audit. The corrective action was to perform the audit in March. The preventative action was to schedule a time frame each month that internal audits are to be perfomed and then discussed with upper management.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4 Internal Audits and Inspections (Mandatory)

The site follows the directives in their SQF Policy Manual, which calls for the site to schedule and conduct internal audits on a monthly basis to verify the effectiveness of the SQF system. Auditors perform internal audits on a monthly basis against an audit checklist. The audits include facility and equipment inspections, pre-requisite programs, food safety plans, food security, GMPs, and legislative controls. Staff conducting audits were trained in auditing by a Consultant and have experience and knowledgeable in areas that they are auditing. Audit results are communicated to relevant management personnel and staff. All deficiencies are investigated and corrective actions implemented and followed up on to ensure corrective actions are effective. Records are maintained for two years. Internal audits for the months of January, March and April of 2022 were reviewed during the audit. The audit from January listed floor drains as needing cleaning due to a buildup in the lines. The site had a vendor come in and clean the lines but could not show documentation that this was done or when. Minor: While reviewing the internal audit from January there was a listing for floor drains as needing cleaning due to a build-up in the lines. Per a conversation with the Practitioner, the site had a vendor come in and clean the lines but could not show documentation that this was done or when.

2.5.4.1 The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code: Food Manufacturing are audited per the SQF audit checklist or a similar tool; ii. Objective evidence is recorded to verify compliance and/or non-compliance; iii. Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and iv. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative actions.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: While reviewing the internal audit from January there was a listing for floor drains as needing cleaning due to a build-up in the lines. Per a conversation with the Practitioner, the site had a vendor come in and clean the lines but could not show documentation that this was done or when.

ROOT CAUSE: The root cause of this non-conformance is that the designation of responsibilities regarding our maintenance logging policy was not clear after there were staff changes. Each employee was under the impression that one of the others was logging the maintenance and invoices from the maintenance.

CORRECTIVE ACTION: The corrective and preventative action for this non-conformance was a staff meeting to re-emphasize the necessity that production management and weekend management give all maintenance invoices to the SQF practitioner and that the SQF practitioner must be aware of and log all maintenance being done in the facility.

2.5.4.4 corrective action training log.pdf

VERIFICATION OF CLOSEOUT: Evidence of corrective actions training was reviewed and approved.

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

2.6.1 Product Identification (Mandatory)

The site adheres to the directives in site policy 2.6.1 which identifies the methods and who is responsible for ensuring that products/components are properly identified with unique lot numbers and labeled during all stages of receipt, production, storage and shipment. Finished goods incorporate the lot numbers of the individual ingredients that are used in producing the product. The policy is to maintain identification records. The site does have a written product start up and changeover procedure that requires documentation. The site does utilize a startup checklist where they are matching product against film and label at startup. Startup sheets from 6/1/22, 6/13/22, 6/19/22 and 6/28/22 were reviewed during the audit. The site does not perform changeovers during production runs.

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

RESPONSE: COMPLIANT

2.6.1.2 Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person. Procedures shall be implemented to ensure that label use is reconciled and any inconsistencies investigated and resolved. Product changeover and label reconciliation records shall be maintained.

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

The site follows their Policy 2.6.2 while performing traceability exercises. The SQF Practitioner or their designee is responsible to ensure that the methods used to trace product is documented and implemented to ensure 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 and other inputs (one back). Traceability is to be tested once a year. The site does not use rework or recoup product. During the audit a traceability exercise that was performed on 7/6/22 for 9,440 lbs. of Gluten Free Chocolate Cookie Crumble with lot code 2023MAR09 was reviewed. The site used 6965 lbs. of the ingredient to produce a total of 47,092 lbs. of finished product over 8 different dates. There was 1,778 lbs. of the ingredient still in inventory. The 47,092 lbs. of finished product was produced for and shipped to four different customers.

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier; ii. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products.); iii. Traceability is maintained where product is reworked (refer to 2.4.6); and iv. The effectiveness of the product trace system is reviewed at least annually, as part of the product recall and withdrawal review (refer to 2.6.3.2). Records of raw and packaging material receipt and use and finished product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

Per the site's Policy 2.6.2: The Owner/CEO is responsible for overseeing all tasks associated with recalling or with drawing suspected product from the market and communicating the recall with customers and media. Further it describes procedures to be implemented including sources of legal and expert advice and outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner. Mock recall exercises are completed annually and completed in less than two hours. The Recall Plan calls for SQFI and the Certifying Body to be notified via e-mail upon identification of an event that requires public notification. On 7/6/22 the site performed a mock recall for 16,245 lbs. of Jimmy Bars-Chocolate Peanut Butter that were produced on 4/27/22. The site produced 122,560 bars on that date with 573 lbs. of batter disposed of as inedible. All 122,560 bars were shipped in one shipment on 6/23/22. The recall process took 30 minutes. If this would have been an actual recall the customer would have been notified to put all product with that lot code on quarantine. The FDA would have been notified.

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

RESPONSE: COMPLIANT

2.6.3.2 The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability one step forward). Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.4 Crisis Management Planning

The site's written Crisis Management Plan 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. A crisis management team has been identified and trained. The SQF Practitioner or his designee has oversight of the plan. The Plan includes responses to an extended business interruption, isolating and identifying affected product and a current crisis alert list. The crisis plan includes internal/external communications and sources of legal and expert advice. Per the Food Safety Plant: the Crisis Management Plan is challenged at least annually and all records of challenges/tests will be maintained. The site produced notes that the Crisis Management Plan had been challenged on 5/13/22. The mock scenario was a hail storm hit the area the night before and knocked out windows on the West side of the building spreading glass on the flow wrapper conveyors and the floor. The second shift Operations Manger immediately shut down operations, tagged up all packaged and exposed product in the area and notified the owners and the SQF Practitioner of the issue. The windows were sealed off with plywood. The equipment and floor were cleaned and sanitized. All product that was in the immediate area was deemed contaminated and sent to waste disposal. The site disposed of 175 lbs of finished product and 110 lbs. of in process product that was setting on racks. Production was resumed the followiung shift. No customers were affected.

2.6.4.1 A crisis management plan based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather events, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe food shall be documented by senior management, outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include at a minimum: i. A senior manager responsible for decision making, oversight, and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure any responses do not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.

RESPONSE: COMPLIANT

2.6.4.2 The crisis management plan shall be reviewed, tested, and verified at least annually with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

Site Policy SQF 2.7.1 outlines the methods, responsibilities and criteria for preventing food adulteration. The SQF Practitioner oversees food defense, security and anti-fraudulent activity within the plant. Security measures include a security alarm that is armed by the last employee to exit for the day, all outside doors are locked at all time and the warehouse parking lot gate is to be shut and padlocked at the end of each workday. The storage of hazardous chemicals is controlled. Visitors are required to sign in and out and be in the company of a designated company representative at all times. Per site policy the Food Defense Plan is challenged annually. The Food Defense Plan was challenged on 4/12/22 utilizing the FDA Food Defense Challenge. The site scored 275 out of a possible 300 points which gave them a 92%, which is defined as an excellent score.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.2 Food Fraud (Mandatory)

Food Fraud is addressed in the site's Policy 2.7.2 Food Fraud. The policy calls for the Food Fraud Plan is to be assessed on an annual basis. The site performed a vulnerability assessment for raw materials and packaging on 4/12/22. All materials are received from approved suppliers under LOG's or COA's. Per the sites assessment the chance of substitution is low, while the likelihood of discovering substitution during inspection is likely. Sampling plans, testing, corrective actions and record keeping requirements for raw materials, ingredients, and finished products are all part of the sites mitigation plan. In the event that a food fraud concern is found during the receiving process or the quality checks throughout production, an investigation will be completed. In the event that the investigation leads to what may be construed as food fraud, a corrective action will be completed for this event.

2.7.2.1 The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.8.1 Allergen Management (Mandatory)

The site's Policy 2.8.1, defines how the plant controls allergens and prevents cross contamination of other products. The site does have an Allergen Register which lists the eight recognized allergens in this country along with the list of allergens that are used in the site's products. A risk analysis of raw materials that contain allergens is maintained. All food grade lubricants are reviewed to determine if allergens are present in the product. Employees are trained in the handling of allergens. The last Allergen training was completed on 6/22/22. During the audit, allergen materials, WIP and finished goods containing allergens are kept separate from products that do not. The site does include allergens in their trace/recall procedures. During the audit employees were observed to be using color coded scoops to scoop out ingredients containing that specific allergen. The sites policy for start up and changeover includes verifying labeling and packaging. Labels show the specific allergen(s) as ingredients. The site does not utilize rework in their process. The site does handle allergens.

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors; iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known; iv. A list of allergens that is accessible to relevant staff; v. The control of hazards associated with allergens and incorporated into the food safety plan, and vi. Management plans for control of the identified allergens.

RESPONSE: COMPLIANT

2.8.1.2 Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens.

RESPONSE: COMPLIANT

2.8.1.3 Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

RESPONSE: COMPLIANT

2.8.1.4 Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.

RESPONSE: COMPLIANT

2.8.1.5 Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.

RESPONSE: COMPLIANT

2.8.1.6 Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

RESPONSE: COMPLIANT

2.8.1.7 The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured.

RESPONSE: COMPLIANT

2.8.1.8 The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.

RESPONSE: COMPLIANT

2.8.1.9 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures.

RESPONSE: COMPLIANT

2.8.1.10 Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable.

RESPONSE: COMPLIANT

EVIDENCE: N/A: The site does not utilize rework in their process.

2.8.1.11 Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.

RESPONSE: COMPLIANT

EVIDENCE: NA Site does handle allergens

2.9.1 Training Requirements

Per the sites Policy 2.9.2: The SQF Practitioner or designee is responsible for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions that affect products, quality, food safety and legality.

2.9.1.1 The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented (refer to 2.1.1.6).

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

Site Policy 2.9.1 outlines the training program in which all employees are to be trained in. These topics include food safety, HACCP, GMP's, regulatory, food defense, sanitation, personnel hygiene, allergen handling and food defense. Training and training and training materials are provided in English and, Spanish during new employee orientation and during annual refresher training. Training documents from 6/7/22, 6/8/22 and 6/22/22 showed that employees were trained in GMP's, HACCP, PPE, Sanitation and Allergen Control. Sign off sheets had the topics, name of employee, name of trainer and verification through a quiz that the employee understood the training. The employee that performs the checks on the metal detector (CCP) was interviewed and demonstrated he knew why he was performing that task.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

The company has two buildings the production facility at 457 Busse Rd. The company has a warehouse at 500 E. Touhy. Both sites are part of larger complexes located in newer Industrial Parks in the town of Elk Grove. The buildings, property and surroundings were observed during the audit were well kept and do not create an issue for hygienic operations. Measures have been established to maintain a suitable external environment and the facilities performs external inspections as part of their internal audit program. The sites are inspected by the FDA and the company has a Business License issued by the City of Elk Grove. The properties are zoned for commercial use by the city.

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

RESPONSE: COMPLIANT

11.1.2 Building Materials

Product contact surfaces, surfaces not in contact with food and storage areas are constructed of suitable materials including stainless and food grade plastic. They were observed during the audit to be properly maintained so that food safety is not compromised. Floors are constructed of smooth and dense impact resistant material and properly graded for effective drainage of overflow or waste water. Waste water flows directly to the city waste water treatment system. Drains were observed to be located and constructed for ease of cleaning and inspection. The site does not have overhead pipes carrying sanitary waste or waste water. Walls and doors are of durable construction with smooth and light colored surfaces. These areas were observed to be clean during the audit tours. Wall to wall and wall to floor junctures were observed to be sealed and free of debris. Ducting, piping and conduit conveying services were observed to be installed for ease of cleaning. Overhead cleaning was found to be part of the master cleaning schedule. Doors, windows and frames were observed to be properly constructed of materials with the same functional requirements as internal walls and partitions. The site does not have overhead pipes carrying sanitary waste or waste water. The site does not have exposed product under stairs or platforms. There are no catwalks in the plant. Minor: During the inspection of the warehouse at 500 E. Touhy Ave. a separation/gap at the intersection of the floor and walls of was observed. This creates a harborage for insects/pests.

11.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions. Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.2.3 Waste trap system shall be located away from any food handling areas or entrances to the premises.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have a waste trap system.

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

RESPONSE: MINOR

EVIDENCE: During the inspection of the warehouse at 500 E. Touhy Ave. a separation/gap at the intersection of the floor and walls was observed. This creates a harborage for insects/pests.

ROOT CAUSE: The root cause of this non-conformance was our landlords refusal to perform regular maintenance on the facility as he should.

CORRECTIVE ACTION: The corrective and preventative action for this non-conformance is filling the crack with expanding foam and caulk. We have attempted to get the landlord to fill these gaps in the past to no avail. If we are continually unable to get our landlord to assist us we will perform the corrective measures ourselves.

flooring work order 500 touhy 2022 11.1.2.4.eml

VERIFICATION OF CLOSEOUT: Evidence of flooring work order was reviewed and approved.

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

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have overhead pipes carrying sanitary waste or waste water

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have platforms, catwalks or stairs in food processing areas.

11.1.3 Lightings and Light Fittings

Lighting is of appropriate intensity for employees to carry out their tasks efficiently. All lighting has either shatterproof bulbs or are covered with shatter proof shields.

11.1.3.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light-intensity regulations or industry standards.

RESPONSE: COMPLIANT

11.1.3.2 Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling. Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.1.3.3 Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination.

RESPONSE: COMPLIANT

11.1.4 Inspection/ Quality Control Area

N/A: The site does not have a dedicated inspection area in production areas.

11.1.4.1 If online inspection is required, a suitable area close to the processing line shall be provided for the inspection of product (refer to 2.4.4). The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to handwashing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

RESPONSE: NOT APPLICABLE

11.1.5 Dust, Insect, and Pest Proofing

Windows, doors and other openings were observed during facility tours to be properly sealed to prevent pests or dust from coming into the facility. Personnel access doors are self-closing and sealed to prevent any pest infestation. Electric insect devices, interior and exterior rodent stations are located so product is not at risk for contamination. Bait is used only on the exterior of the facility.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.5.3 Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or exposed.

RESPONSE: COMPLIANT

11.1.6 Ventilation

Adequate ventilation was observed to be adequate throughout the facility. The site does not require positive air. Inspecting/replacing of filters is part of the sites PM Schedule. The site does not have a cooking operation.

11.1.6.1 Adequate ventilation shall be provided in enclosed processing and food handling areas. Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination.

RESPONSE: COMPLIANT

11.1.6.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.5 to prevent unsanitary conditions.

RESPONSE: COMPLIANT

11.1.6.3 Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s).

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have a cooking system.

11.1.6.4 Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and shall be kept clean.

RESPONSE: COMPLIANT

11.1.7 Equipment and Utensils

The site follows the directives their Policy 11.2.9 when purchasing equipment, utensils and protective clothing. The policy is that all equipment used in their process must conform to 3A Sanitary Standards or NSF Standards. The equipment in the facility is constructed of materials that are impervious and facilitate the process of cleaning. Inedible bins are labeled as such and easily cleanable. Protective clothing is sent out for cleaning. Clean clothing is stored in a dry area away from the production floor. Racks/hooks are provided for temporary storage of protective clothing when staff leaves the processing area. All processing equipment is cleaned and sanitized at the end of the day or prior to the next day's production. Tubs used in processing along with inedible containers are constructed smooth non-permeable materials and are cleaned at the end of the day. Non-conforming equipment is handled in accordance of the sites Hold program. Material handling equipment are designed and operated in a manner that does not create a food safety issue. Equipment that falls into this category is issued a Hold Tag, entered on the site's Hold Log and is either repaired and put back into service or disposed of. Hand trucks and other vehicles in processing areas and storage areas do not present a food hazard.

11.1.7.1 Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.7.3 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. Where possible, food contact equipment shall be segregated from non-food contact equipment.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.7.6 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned as per 11.2.5.1. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

11.1.7.7 All equipment and utensils shall be cleaned after use (refer to 11.2.5.1) or at a set and validated frequency to control contamination and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.1.8 Grounds and Roadways

The exterior of two buildings and grounds are included in the internal audit program. The grounds and surrounding areas of both sites were observed to be neat, well maintained, free of dust and waste and not present a hazard to the sanitary operation of the plant. The parking lot, roadways and dock areas at 457 Busse Rd. were paved and well maintained with no pooling of water. . Minor: While inspecting the warehouse at 500 E. Touhy Ave. the loading dock area was observed to have a substantial amount of water and debris pooling at the bottom of the ramp which creates a potential contamination and pest issue.

11.1.8.1 A suitable external environment shall be established, and the effectiveness of the measures shall be monitored and periodically reviewed. The premises, its surrounding areas, storage facilities, machinery, and equipment shall be kept free of waste or accumulated debris, and vegetation shall be controlled so as not to attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: While inspecting the warehouse at 500 E. Touhy Ave. the loading dock area was observed to have a substantial amount of water and debris pooling at the bottom of the ramp which creates a potential contamination and pest issue.

ROOT CAUSE: The root cause of this non-conformance was lack of proper inspection of the shared dock. If the dock had been thoroughly inspected, then we could have noticed the trash issue that may have been the root cause of the clog in the sump pump or noticed that the sump pump was not operational.

CORRECTIVE ACTION: The corrective action for this non-conformance was to put in a work order to our landlord to service the sump pump in the dock space. The preventative action for this non-conformance was to add a section to the internal audit form for the Touhy location regarding inspection of the shared dock area.

11.1.8.2 and 11.6.5.1 corrective action

11.1.8.2 corrective action sum... repair.pc

VERIFICATION OF CLOSEOUT: Evidence of replaced sumpump and internal audit was reviewed and approved.

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

11.1.8.3 Paths from amenities leading to site entrances shall be effectively sealed.

RESPONSE: COMPLIANT

11.2.1 Repairs and Maintenance

The site follows the directives in their Policy 11.2.10. The SQF Practitioner is responsible for ensuring that all maintenance procedures are designed to maintain equipment and building. Routine (planned) maintenance of plant and equipment in all food processing, handling or storage areas is performed according to a Preventive Maintenance Schedule that is maintained by the SQF Practitioner. The schedule is broken down into weekly, monthly, quarterly and annual projects. These cover the facility, equipment and other areas of the premises critical to maintaining product safety and quality. Failures of plant and equipment in any food processing, handling or storage area will be documented, reviewed and their repair incorporated into the maintenance control schedule. If a temporary repair is deemed essential, the repair is entered in a log that the SQF Practitioner maintains they are monitored on a daily basis until a permanent repair can be made. Machinery, conveyors and other equipment over or near food or food contact surfaces are lubricated with food grade materials. Food grade lubricants were observed to be stored separately and labeled properly in metal cabinets. Paint is not used on food contact surfaces and any paint in processing areas was noted to be in good condition with no flaking noted. During the audit annual PM's for the flow wrapper and the mixer on 11/16/21 and 6/30/22 were reviewed. The form does acknowledge that tools have been removed and the supervisor has been notified that the area should be cleaned and sanitized prior to restart of production.

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

RESPONSE: COMPLIANT

11.2.1.2 Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety.

RESPONSE: COMPLIANT

11.2.1.3 Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: COMPLIANT

11.2.1.7 Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product.

RESPONSE: COMPLIANT

11.2.1.8 Paint used in a food handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces.

RESPONSE: COMPLIANT

11.2.2 Maintenance Staff and Contractors

The site's visitors policy requires contractors to be trained and to follow the same company food safety and hygiene procedures as company employees. Maintenance personnel are trained in the same good manufacturing practices and food safety procedures as production employees. When repairs and maintenance work are completed, personnel document the accounting of tools and cleanliness of the work areas.

11.2.2.1 Maintenance staff and contractors shall comply with the site’s personnel and process hygiene requirements (refer to 11.3).

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.3 Calibration

The site adheres to the protocols listed in their Policy 11.2.1. The SQF Practitioner or their designee is responsible for scheduling the calibration and re-calibration of measuring, and inspection equipment. The methods for calibrating all measuring, testing and/or inspection equipment are outlined in different SOP's. The SOP's contains the calibration schedules along with who is responsible for scheduling or performing calibrations. All equipment is calibrated to manufacturers recommendations or regulatory requirements. Scales are calibrated daily before production by the Production Manager and annually by a certified lab. Daily calibration records from 6/1/22, 6/13/22, 6/19/22 and 6/28/22 . Calibration records are maintained for two (2) years. Minor: The site has a policy that they will have their scales calibrated and certified by a third party annually, the site could not provide documentatin that their scales have been calibrated by a third party within the last year.

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

RESPONSE: MINOR

EVIDENCE: The site has a policy that they will have their scales calibrated and certified by a third party annually, the site could not provide documentatin that their scales have been calibrated by a third party within the last year.

ROOT CAUSE: The root cause of this non-conformance was that I was under the impression that our pre-operational scale checks were sufficient. I did not write our Policy manual (our previous practitioner did), so I missed the line about the annual calibration. Our auditor brought this to my attentions and it will not be a problem moving forward.

CORRECTIVE ACTION: The corrective action for this non-conformance was to put in a work order with Data Weighing Systems to get our scales calibrated.

11.2.3.1 corrective action work order.pdf

VERIFICATION OF CLOSEOUT: Evidence of corrective action work order was reviewed and approved.

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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.3.4 Procedures shall be documented and implemented to address the resolution of potentially affected products when measuring, testing, or inspection equipment is found to be out of calibration.

RESPONSE: COMPLIANT

11.2.3.5 Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use.

RESPONSE: COMPLIANT

11.2.3.6 A directory of measuring, testing, and inspection equipment that require calibration and records of the calibration tests shall be maintained.

RESPONSE: COMPLIANT

11.2.4 Pest Prevention

The site has retained Smithereen Pest Management Services as their PCO for pest management. An updated scope of service dated 5/21/22 defines the methods of pest control, frequency of interior and exterior inspections and targeted pests. The site map for 457 Busse is dated 6/28/22 and accurately show the location of 7 external bait stations, 20 internal traps and 2 insect traps at the 457 Busse R. location. The site map for 500 E. Touhy Ave. shows 18 interior traps and 7 exterior bait stations. The site's are serviced twice a month by a licensed technician that meets with the SQF Practitioner or designee after each service call to review the trip report. A pesticide application log gives details and dates of all chemical usage. The License for the Pest Control Operator has an expiration date of 12/31/22 from the Illinois Dept. of Public Health. The applicators licenses are current and indicate they are trained and competent. A list of chemicals used by the Pest Control Operator is found in the pest control binder and includes SDS information. SDS sheets for Alpine Gel Bait and Final All Weather Blox were reviewed during the audit. Employees are trained in pest control as part of GMP Training. Inspection activity reports are signed by a management representative after the weekly inspections and were reviewed and found to be completed as scheduled. Any observations or issues highlighted by the Pest Control Operator are addressed and documented by the site. In reviewing the bi-monthly reports there has not been any pest activity reported for April and May for 457 Busse and April through June for 500 E. Touhy Ave. on the interior or the exterior of the buildings. Any packaging materials, raw material or finished product that is damaged/contaminated by pests are disposed of. The source of the damage is to be thoroughly investigated and brought under control. Pest control chemicals are not stored on site they are brought to the site by the PCO partial containers of unused chemicals are the property of the PCO and stay in their possession. Animals are not permitted in food handling or storage areas and none were observed during the audit.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Pesticides are not stored on site.

11.2.4.6 No animals shall be permitted on-site in food handling and storage areas.

RESPONSE: COMPLIANT

11.2.5 Cleaning and Sanitation

Sanitation procedures for equipment and areas are listed in individual SSOP's. The SSOP's call for all equipment and production areas to be cleaned after daily production or more frequently if needed and prior to the next days production. The SSOP's lists who is responsible for the procedures employed and who is responsible for verifying the effectiveness of the cleaning. The site has daily, weekly and cleaning checklists. Daily checklists from 4/15/22, 5/11/22, 5/16/22, 6/6/22 and 6/22/22 were reviewed as well as weekly and monthly checklists from April, May and June of 2022. All cleaning chemicals are listed and approved for use in a food manufacturing environment and labeled according to regulatory requirements. The site does not have CIP Systems. The site has an area designated for cleaning product tubs, knives and other utensils that does not interfere with production. Preoperational inspections are performed prior to the start of operations to verify the effectiveness of the cleaning. Restrooms and break areas are cleaned on a daily and are included in the daily pre-operational inspection. Pre-Operational Inspection reports from 6/1/22, 6/13/22, 6/19/22 and 6/28/22 were reviewed during the audit. Pre-op was observed on 7/7/22.

11.2.5.1 The methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Validation of the cleaning procedures for food contact surfaces (including CIP); vi. Methods used to confirm the correct concentrations of detergents and sanitizers; and vii. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.2.5.2 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use; ii. An inventory of all purchased and used chemicals is maintained; iii. Detergents and sanitizers are stored as outlined in element 11.6.4; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v. Only trained staff handle sanitizers and detergents.

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not mix cleaning detergents or sanitizers.

11.2.5.4 Cleaning-in-place (CIP) systems, where used, shall not pose a chemical contamination risk to raw materials, ingredients, or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored, and recorded (e.g., chemical and concentration used, contact time, and temperature). CIP equipment, including spray balls, shall be maintained, and any modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have CIP systems.

11.2.5.5 Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of processing areas, product handling equipment, and storage areas as well as the tools themselves.

RESPONSE: COMPLIANT

11.2.5.6 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these cleaning operations shall be controlled so they do not interfere with manufacturing operations, equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required.

RESPONSE: COMPLIANT

11.2.5.7 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start of production. Pre-operational inspections shall be conducted by qualified personnel.

RESPONSE: COMPLIANT

11.2.5.8 Staff amenities, sanitary facilities, and other essential areas shall be inspected by qualified personnel at a defined frequency to ensure the areas are clean.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.1 Personnel Welfare

The site adheres to the directives in their Policy 11.3.1 which addresses GMP's for all employees. Employees are prohibited from working in food handling areas when suffering from infectious and communicable diseases or have exposed cuts, sores or lesions. The site has language that states in the event of a pandemic, they will take guidance from the Federal, state and local governments as well as the CDC and implement those guidelines. Spilled bodily fluids is handled under the site's "Blood Borne Pathogen Policy", that requires the are along wit equipment that is affected to be isolated. A manager is called, a trained employee wearing appropriate PPE is to clean and sanitize the affected area and equipment (if affected). Any product that may have been involved is to be tanked. The area can only be inspected and released by a member of management. The policy requires that minor cuts or abrasions be covered with a waterproof, metal detectable and colored bandage or dressing. In the event of spillage of bodily fluids the

11.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed. Code Amendment #1 A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.2 Handwashing

The site's Policy 11.3.1 addresses hand washing requirements. Employees have been trained in the policy and during the audit it appeared to be followed. Hand wash basins are located at appropriate employee access points to processing areas. Hand wash sinks are made of non-corrosive materials and supplied with tempered potable water. Hands free operated taps and fixed soap dispensers are provided. Hands free towel dispensers along with hand sanitizers are adjacent to the sinks. Receptacles for used toweling are nearby. Signs are posted reminding employees to wash their hands before returning to work. Hand Wash Signs are posted at hand wash stations and in bathrooms. Employees are required to wash hands when wearing gloves. Interviews conducted with 2 line employees during the audit demonstrated that employees understand the hand washing requirements. Employees were observed to wash their hands properly during the audit and to follow proper glove procedures. This is not a high risk process

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

RESPONSE: COMPLIANT

11.3.2.2 Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: This is not a high risk process

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3 Clothing and Personal Effects

The site has performed a "risk analysis". All employees are required to wear clean clothing and shoes when they report to work. A commercial laundry service provides clean frocks twice a week. The site contracts with a commercial laundry that washes all frocks in 175 degree water with an antibacterial/sanitizing soap. The frocks are delivered to the site covered in plastic and placed in a storage area that is outside of production areas. Employees retrieve frocks from the storage area. All employees are required to wear hairnets and facial hair restraints if applicable. The site has not had a consumer complaint regarding physical or microbiological contamination that can be attributed to their clothing or hair restraint policy. The site believes that their clothing and hair policy is adequate. The site's policy defining clothing requirements has been documented and implemented. Clothing including shoes are required to be clean at the commencement of the shift and changed if they get excessively soiled. Disposable gloves are changed when soiled or damaged. The site supplies racks just outside of production areas for employees to hang frocks while using the restroom or breakroom. Employees were observed to be in compliance with the clothing requirements of the facility. The only jewelry allowed in production areas and shipping/receiving areas are single band wedding rings and medical alert bracelets. Employees were observed to be in compliance with the jewelry policy during the audit tours.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3.6 Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned. All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

11.3.3.7 Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities.

RESPONSE: COMPLIANT

11.3.3.8 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or into any area where food is exposed. Wearing plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted, provided these items are properly covered and do not pose a food safety risk. All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.

RESPONSE: COMPLIANT

11.3.4 Visitors

The site's visitors policy requires visitors and contractors to follow the same company rules as company employees. These rules include using proper access points, complying with hand wash requirements, use of suitable protective clothing and footwear, removal of jewelry and other loose objects and not exhibit visible signs of illness if entering food handling and processing areas. Visitors are required to be in the company of a company employee at all times.

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

RESPONSE: COMPLIANT

11.3.4.2 All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 11.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.5 Staff Amenities (change rooms, toilet, break rooms)

Staff amenities are cleaned on a daily basis by the site's janitorial staff. Employee bathrooms and break rooms were observed to be appropriately lit and ventilated and adequate in size for all personnel at the facility. There is an area for employees to change into and out of work clothes. Lockers are provided for storage of street clothing and personal items and are separate from processing and storage areas. Showers are not required. Rest rooms were constructed so that they are separate from food processing and handling areas and accessed via a separate room. Hand wash basins are properly designed as outlined in 11.3.5.6. Sanitary drainage is through the city sewer system. Restrooms and breakrooms are checked for cleanliness by the night manager. Check sheets from 4/15/22, 4/19/22, 5/2/22, 5/24/22 and and 6/15/22 were reviewed during the audit and were complete. Lunch rooms are separated from production areas, are well lit, properly ventilated and are appropriately sized for the number of facility employees. Lunch rooms include hot and cold potable water, food storage areas, refrigerators with hand and utensil washing capabilities. Signs were observed at the exit reminding employees to wash their hands before returning to work. Lunch rooms were observed to be clean and well-maintained during the audit tours. The site does not provide an outside eating area.

11.3.5.1 Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product.

RESPONSE: COMPLIANT

11.3.5.2 Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean.

RESPONSE: COMPLIANT

11.3.5.3 High-risk change areas shall be provided for staff engaged in the processing of high-risk foods or processing operations in which clothing can be soiled.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not provide an outside eating area.

11.4.1 Staff Engaged in Food Handling and Processing Operations

Food handling procedures are covered in GMP Training which all employees are trained in. Training documentation from 6/7/22, 6/8/22 and 6/22/22 were reviewed during the audit. Personnel are required to access the processing areas through personnel doors only and doors were observed to be kept closed. Waste is placed in waste containers throughout the day. Waste containers are removed as needed and emptied into a compactor. Employees are required to wear hair nets and facial hair restraints (when applicable) and are not allowed to eat food in processing areas. False fingernails and/or fingernail polish is prohibited under their GMP Policy. All employees are required to wear hair nets and facial hair restraints (if applicable). No violations were noted. Smoking and the use of other tobacco products is prohibited in the facility. Clear water bottles are allowed but are restricted to a controlled area. Ingredients were in labeled containers, sealed and kept off the floor. The site does not perform sensory evaluations in food contact/handling zones. Personnel conducting sensory evaluations are trained and maintain high hygienic standards. Wash down hoses were properly stored off the floor.

11.4.1.1 All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor.

RESPONSE: COMPLIANT

11.4.1.2 Personnel working in or visiting food handling or processing operations shall ensure that: i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 11.4.1.4; ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food; iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed. iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage.

RESPONSE: COMPLIANT

11.4.1.3 The flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not perform sensory evaluations in food contact/handling zones.

11.5.1 Water Supply

Potable water used in the facility for processing, drinking and sanitation is supplied by the Village of Elk Gove. It was determined that there was adequate hot and cold water for cleaning and processing. The plant does not have non-potable water on site. The site does have two backflow valves that are supposed to be serviced annually. A service report from 7/13/21 showed that the backflow valves were working as designed. The plant does not store water on site.

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility.

RESPONSE: COMPLIANT

11.5.1.2 Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The plant does not have non-potable water on site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The plant does not store water on site.

11.5.2 Water Treatment

N/A: The site does not treat water.

11.5.2.1 Water treatment methods, equipment, and materials, if required, shall be designed, installed, and operated to ensure water receives effective treatment. Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the specified indicators. Water treatment chemicals usage shall be monitored to ensure chemical residues are within acceptable limits. Records of testing results shall be kept.

RESPONSE: NOT APPLICABLE

11.5.3 Water Quality

The site performs annual water testing for Coliform, E-Coli, Staph, Mold, EB and Yeast as indicators of water potability. The Village of Elk Grove provides an annual water quality report, the report for 2021 was reviewed during the audit, all levels were within EPA guidelines for coliform and E-Coli. Minor: The site could not provide microbiological analysis of water samples taken from inside the site.

11.5.3.1 Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for: i. Washing, thawing, and treating food; ii. Handwashing; iii. Conveying food; iv. An ingredient or food processing aid; v. Cleaning food contact surfaces and equipment; vi. The manufacture of ice; or vii. The manufacture of steam that will come into contact with food or be used to heat water that will come into contact with food.

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: The site could not provide microbiological analysis of water samples taken from inside the site.

ROOT CAUSE: The root cause of this non-conformance was that I (the SQF practitioner) was under the impression that our backflow test was our water test. Our auditor made the distinction clear and this will not be an issue moving forward.

CORRECTIVE ACTION: The corrective action for this non-conformance was to request the supplies to have the water test completed with Matrix Sciences our 3rd party testing facility.

11.5.3.2 water analysis request.eml

Verification Validation Schedule.pdf

VERIFICATION OF CLOSEOUT: Evidence of water analysis and validation were reviewed and approved.

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

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

RESPONSE: COMPLIANT

11.5.4 Ice Supply

N/A: The site does not use ice in their process.

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

RESPONSE: NOT APPLICABLE

11.5.4.2 Ice that is purchased shall be from an approved supplier and included in the site's food safety risk assessment. Ice shall be supplied in containers that are appropriate for use, cleanable if reused, and tested as appropriate.

RESPONSE: NOT APPLICABLE

11.5.4.3 Ice rooms and receptacles shall be constructed of materials as outlined in element 11.1.2 and designed to minimize contamination of the ice during storage, retrieval, and distribution.

RESPONSE: NOT APPLICABLE

11.5.5 Air and Other Gasses

Compressed air does not come into contact with product. Contact surfaces are blown off with compressed air then sanitized prior to product coming into contact. The site does testing of compressed air on an annual basis in which they pulled samples from different outlets and test for APC. Test results from samples that were pulled on 6/29/22 showed results of <1 CFU for yeast and mold. The compressor has .5 micron filters which are serviced annually per manufacturers recommendations.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.1 Receipt, Storage and Handling of Goods

The site has implemented an effective storage plan that allows for the safe, hygienic storage of raw materials, ingredients, equipment, and chemicals. This includes a FIFO stock rotation program. Storage rooms are designed and constructed to allow for the hygienic and efficient storage of equipment and containers and are located away from wet areas. Vehicles used in food contact, handling or processing zones are designed and operated so as not to present a food safety hazard. Storage, loading and unloading is the responsibility of the Warehouse Manager. The site does not utilize temporary storage.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not utilize temporary storage.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not utilize temporary storage.

11.6.2 Cold Storage, Freezing and Chilling of Foods

N/A: The site does not receive, store or ship ingredients or finished goods that need to be refrigerated or frozen.

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

RESPONSE: NOT APPLICABLE

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: NOT APPLICABLE

11.6.2.3 The site shall have a written procedure for monitoring temperatures, including the frequency of checks, and corrective actions, if the temperature is out of specification. Freezing, chilling, and cold storage rooms shall be fitted with temperature monitoring equipment that is located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible. Records shall be kept of frozen, cold, and chilled storage room temperatures.

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

Storage areas for dry raw materials, packaging and finished goods were observed to be located away from any wet areas. the areas were clean and well maintained. Product is protected from contamination and deterioration. Racking is designed and constructed from impervious materials and located so storage areas can be cleaned and inspected. Hand trucks and other vehicles in processing areas and storage areas do not present a food hazard.

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

RESPONSE: COMPLIANT

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and behind the racks. Storage areas shall be cleaned at a pre-determined frequency.

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

There were no processing utensils or packaging being stored next to chemicals. Chemical storage areas at both facilities were observed to be locked and had instructions on handling hazardous chemicals. The site maintains an up-to-date inventory of all chemicals. SDS Sheets, first aid kits and spill containment equipment were nearby. Daily supplies of chemicals were stored properly. All stored chemicals have current SDS information on file at the facility. Company employees do not handle pesticides, herbicides or rodenticides Sanitation employees are trained inhouse by managers. All chemical containers were properly labeled. Empty containers that are used for sanitation chemicals are rinsed and returned to the supplier when they are emptied.

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be: i. Clearly labeled, identifying and matching the contents of their containers; ii. Included in a current register of all hazardous chemicals and toxic substances that are stored on-site; and iii. Supplemented with current Safety Data Sheets (SDS) made available to all staff.

RESPONSE: COMPLIANT

11.6.4.2 Storage of hazardous chemicals and toxic substances shall be: i. Located in an area with appropriate signage indicating that the area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii. Adequately ventilated; iv. Stored where intended and not comingled (e.g., food versus non-food grade); v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces. Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4.5 Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals,: i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use; ii. Be provided first aid equipment and personnel protective equipment (PPE); and iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements.

RESPONSE: COMPLIANT

11.6.4.6 The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are: i. Not reused; ii. Segregated and securely stored prior to collection; and iii. Disposed through an approved vendor.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

The site adheres to the directives in their Policy 11.6 which requires all trailers to be inspected for cleanliness, infestation, odors, damage before loading or unloading. All loads are staged on an enclosed dock prior to the trailer/truck being backed in and loaded. It was observed during the audit that loading practices do not unnecessarily expose products to detrimental conditions. The company ships the majority of the product they produce on their own trucks which are locked upon loading and noted on the BOL and the Shipping Log. The site does not arrange shipping for their products. All shipments are arranged by the customers as third party pick-ups. Shipping records from 4/22/22, 5/2/22, 5/14/22, 5/26/22 and 6/8/22 were reviewed doing the audit. At the point of loading and release of product, ownership and responsibility is transferred to the customer. At that point it is the responsibility of the customer to ensure that trailers are either locked or sealed. All secondary containers are sealed and all pallets are stretch wrapped prior to loading. It was observed during the audit tours that these loading practices do not expose products to detrimental conditions. Receiving records from 5/10/22, 6/3/22, 6/9/22, 6/27/22 and 7/1/22 were reviewed doing the audit. The receiving check sheets showed that trailer inspections were being performed, the BOL's were being checked against the order and seals/locks were being verified. Warehouse interviews revealed that employees are aware of the proper procedures and follow them. The site does not ship finished goods on refrigerated transports. The site does not receive ingredients on refrigerated transports. Unloading practices appeared to be designed to prevent product distress and contamination of product. Minor: Clause 11.6.5.1 calls for foods to be loaded, transported and unloaded under conditions suitable to prevent contamination. The loading doce at the site's warehouse at 500 E. Touhy Ave. had a trash container that was overflowing onto the dock which creates a pest problem.

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: MINOR

EVIDENCE: Clause 11.6.5.1 calls for foods to be loaded, transported and unloaded under conditions suitable to prevent contamination. The loading doce at the site's warehouse at 500 E. Touhy Ave. had a trash container that was overflowing onto the dock which creates a pest problem.

ROOT CAUSE: The root cause of this non-conformance was that there was not enough monitoring of the shared dock to ensure that the site was regularly inspected and maintained up to SQF standards.

CORRECTIVE ACTION: The corrective action for this non-conformance was to gather up and throw the trash away in the dumpster. The preventative action for this non-conformance was to add a shared dock inspection section to the internal audit checklist for the touhy ave location. I also spoke with our warehouse manager and the manager of the business that shares the dock with Nettie's Kitchen about ensuring that the trash is taken out in a timely manner moving forward.

11.6.5.1 corrective action training log.pdf

VERIFICATION OF CLOSEOUT: Training was reviewed and approved.

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

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

RESPONSE: COMPLIANT

11.6.5.3 Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.5.5 Refrigerated units shall maintain the product at the required temperature. The unit's temperature settings shall be set, checked, and recorded before loading, and the product temperature shall be recorded at regular intervals during loading, as applicable.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not ship finished goods on refrigerated transports.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not ship finished goods on refrigerated transports.

11.6.5.7 On arrival, prior to opening the doors, the food transport vehicle's refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently, and product temperatures shall be recorded at the start of unloading and regular intervals during unloading.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not receive ingredients on refrigerated transports.

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

RESPONSE: COMPLIANT

11.7.1 High-Risk Processes

N/A: This is not a high risk process.

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

RESPONSE: NOT APPLICABLE

11.7.1.2 Ambient air in high-risk areas shall be tested at least annually to confirm that it does not pose a risk to food safety.

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.7.1.4 Staff engaged in high-risk areas shall change into clean clothing and footwear or temporary protective outerwear when entering high-risk areas. Staff access points shall be located, designed, and equipped to enable staff to change into the distinctive protective clothing and practice a high standard of personal hygiene to prevent product contamination.

RESPONSE: NOT APPLICABLE

11.7.1.5 Product transfer points shall be located and designed, so they do not compromise high-risk segregation and minimize the risk of cross-contamination.

RESPONSE: NOT APPLICABLE

11.7.2 Thawing of Food

N/A: The site does not thaw product.

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.7.3 Control of Foreign Matter Contamination

The site follows the directives in their Policy 11.7.5 which details the methods and responsibilities for preventing foreign material contamination. The policy has been put in place and implemented. Materials are all received under LOG's and COA's from approved suppliers. Incoming materials are inspected upon arrival, they are inspected again during the batching process where materials are either dumped from combo bins or removed from boxes. Pre-operational inspections and regularly scheduled maintenance inspections are conducted and documented for the condition of equipment and any potential contaminants. Pre-operational inspections from 6/1/22, 6/13/22, 6/19/22 and 6/28/22 were reviewed during the audit. The supplier's policy prohibits the use of temporary fixes such as wire, string, rope or tape and none were observed during the audit tours. A glass register has been documented with glass, brittle plastic and ceramic sources included in all areas of the plant. Monthly inspections with documentation are made of these areas to ensure breakage has not occurred and items are not missing or moved. Monthly inspections along with Brittle Plastic/Glass for March, April, May and Juneof 2022 were reviewed and found to be completed as scheduled. Wood pallets were clean and in good condition. The facility has a policy prohibiting wooden utensils in processing/food handling areas and none were observed during the audit. The site has a documented knife policy in which knives are controlled, cleaned and required to be in good condition. Periodic maintenance inspections include looking for loose objects and potential contaminants from overheads. The site inspects belting during assembly.

11.7.3.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff. Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

11.7.3.2 Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation). Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition.

RESPONSE: COMPLIANT

11.7.3.3 Regular inspections of food handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.3.6 Wooden pallets and other wooden utensils used in food processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.3.9 Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3).

RESPONSE: COMPLIANT

11.7.4 Detection of Foreign Objects

The site does not have sieves screens or filters to remove foreign materials. The site does have a metal detectors on the packaging lines. The metal detectors are calibrated at the start of the shift with product prior to allowing the first package of product to be packed. The site challenges the unit on an hourly basis. The metal detector log from 6/1/22, 6/13/22, 6/19/22 and 6/28/22 were reviewed during the audit. The site test wand for metal is 1.0 mm FE, 2.0 mm Non Fe, and 2.5 mm SS. During the audit annual calibration certificates for the two metal detectors from 1/22/22 were reviewed. During the audit testing of the metal detectors was observed to be working properly. In the event that foreign material is found the affected product is put on hold per the site's Policy 2.4.5 (non-conforming product). Affected product is disposed of. If foreign material is found in raw materials the material is put on hold pending direction from the supplier.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.8.1 Waste Disposal

Per Policy 11.9.1: All solid waste, trash and inedible products are removed from production and storage areas throughout the day and disposed of it into a designated dumpster that is emptied weekly by a Contract Waste Removal Service. Liquid waste flows through the floor drains to the municipal sewage treatment facility. Waste was observed to be removed on a regular basis from the production areas and deposited in a dumpster. The effectiveness of the waste removal process is documented on pre-operational inspections and internal audits conducted by the plant. Waste containers, hoppers, bins and storage areas were observed to be well maintained and clean on the exterior of the facility. All trademarked material the site handles is for the company's that the site co-packs for. Disposal of trademarked materials is controlled by the customers. The site does not designate inedible waste designated for animal feed.

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

RESPONSE: COMPLIANT

11.8.1.2 Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.

RESPONSE: COMPLIANT

11.8.1.3 Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements.

RESPONSE: COMPLIANT

11.8.1.4 Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin.

RESPONSE: COMPLIANT

11.8.1.5	Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging. **RESPONSE:** COMPLIANT
11.8.1.6	Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance. **RESPONSE:** COMPLIANT
11.8.1.7	Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** The site does not designate inedible waste designated for animal feed.
11.8.1.8	Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards. **RESPONSE:** COMPLIANT
11.8.1.9	Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards. **RESPONSE:** COMPLIANT
11.8.1.10	Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports. **RESPONSE:** COMPLIANT