SQF Food Safety Audit Edition 9
The Organic Snack Company - The Organic Snack Company

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
63394 | 143497

AUDIT RATING
88
Good

DECISION DATE
10/15/2021

AUDIT TYPE
INITIAL CERTIFICATION

RECERTIFICATION DATE
09/21/2022

AUDIT DATES
09/20/2021 - 09/21/2021

EXPIRATION DATE
12/05/2022

ISSUE DATE
10/15/2021

Facility & Scope

The Organic Snack Company (63940)
The Organic Snack Company
14 Commerce Ct
Bedford, PA 15522
United States

Food Sector Categories:
13. Bakery and Snack Food Processing

Products:
Granola Bars

Scope of Certification:
Manufacturing of Various Flavors of Granola Bars

Certification Body & Audit Team

SCS Global Services
2000 Powell St.
Suite 600
Emeryville, CA 94608
United States

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

CB#: CB-1-SCS
Accreditation Body: ANSI
Accreditation Number: 0821

Lead Auditor: Shelton, Brian (206241)
Technical Reviewer: Camparone, Anthony (133636)

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

Non-Conforming

2.1.1 Management Responsibility (Mandatory)

The site has a food safety policy statement, called Management Responsibility Policy, that senior management has implemented. It is signed by a senior manager, QA and Regulatory, CEO, Plant Operations Manager, QA Manager, SQFP. The Policy statement covers a commitment to supply safe food, establish and maintain and food safety culture, establish and continually improve the food safety management system, and comply with all customer and regulatory requirements. The Policy is communicated to the facility's staff by way of Clipboards in production, online training, and is in languages used in the site. Senior management has developed the following food safety objectives Safe Products, No Recalls, KPIs (service related, complaints, micro, packaging, foreign material). These have been effectively communicated to all relevant staff by Training, Posters, Bulletin Boards. Performance of defined food safety objectives is reviewed during internal audits, onsite verification of safety objectives by relevant staff. Plant staff is required to report food safety issues to management, as evidenced by policy food safety management manual, trainings, and interviews with 4 employees in production area. An organizational chart, dated 2/21/21, outlines the structure of staff having responsibility for food safety as well as backups for key personnel. Job descriptions for key personnel were reviewed for QA Manager, Production Supervisor and Batching employee and appeared to be adequate. It was observed through interviews and observations that site management has provided adequate resources through staffing the meet defined food safety objectives. Mark Thaler is the designated primary SQF Practitioner, is a full-time employee of the facility and has a HACCP food safety training course, as evidenced by a certificate from FSPCA, dated 12/10/20. Mark Thaler is the designated substitute SQF Practitioner, is a full-time employee of the facility and has a HACCP food safety training course, as evidenced by a certificate from FSPCA, dated 10/20/20. The SQF Practitioner is responsible for the development, implementation, and maintenance of the SQF System. Senior site management has processes in place to demonstrate continuous improvement and to ensure the integrity of the food safety systems when there are organizational or personnel changes. Minor: There was no signed management policy posted in a prominent location or any other location in the facility.

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: MINOR

EVIDENCE: There was no signed management policy posted in a prominent location or any other location in the facility.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity arose from a lack of understanding about the requirements of 2.1.1.1. Management was under the impression that the food safety statements contained in the employee handbook (which is posted throughout the site) were sufficient to satisfy this requirement. The clarity gained during the audit is sufficient to prevent this from happening again.

CORRECTIVE ACTION: A signed management policy addressing the commitment of site management to supply safe food, establish and maintain a food safety culture within the site, establish and continually improve the site's food safety management system, and to comply with customer and regulatory requirements to supply safe food has been posted in the following locations in the facility: Employee Break Room Hallway Bulletin Board Fulfillment Bulletin Board Pictures will be uploaded into Repositrak to show the posted document as well as a copy of the document.


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IMG_2984.pdf


IMG_2983.pdf


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Corrective Action Report - CA #1 2021.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

2.4.3 Food Safety Plan (Mandatory)

A Food Safety Plan has been developed, implemented, and maintained by the site. It is kept on file in the office and maintained by PCQI/SQFP. The Food Safety Plan has been prepared in accordance with the 12 steps identified in the Codex Alimentarius Commission HACCP guidelines. A multi-disciplinary Food Safety Team has been identified and trained, with documentation found in Food Safety Plan (PCQI/HACCP Leader). The Plan includes a list of all products in the scope of the certification, a complete product description, intended product use (including vulnerable populations) and flow diagrams for each process including all input and output steps in the process. The process flow has been verified by the site per walkthrough with HACCP team and signed on 9/19/21 by the PCQI. The food safety team has analyzed all hazards reasonably likely to occur including physical, chemical, and microbiological hazards for each process step, ingredient and packaging. Preventive Controls/CCPs have been identified as Supply Chain (C/L: Supplier approval by visual review for each lot by PCQI or designee), Sanitation (C/L: Pathogen contamination cannot be present by visual inspection of the PCQI or designee each production day) Foreign Material (C/L: metal detection present and operating checked every hour by visual examination the detector is detecting metal) Allergens (CL: Allergens are not present by visual inspection or allergen testing weekly by QA or designee). Any deviations found in monitoring of established control limits are documented and investigated, with proper disposal of involved products. The plan is verified as part of the SQF System and reviewed annually or when changes occur, by the food safety team with the last review date on 9/19/21 FDA regulatory requirements for the site also require a Preventive Control food safety plan, which was observed to be implemented. Minor: The site has two CCPs for Allergens and Metal Detection that do not list a measurable or quantitative limits that define acceptable limits from non-acceptable limits. The critical limits for allergens are listed as “Not present or detectable above trigger level.” Allersnap swabs are used and have varying degrees of detectable limits based on the target allergen, those specific limits are not mentioned in the Critical Limits. The Critical Limits for metal detection are “metal detection is present and operating." Site is using 1.2mm Fe, 1.5mm nFe, and 2.0mm 304 Stainless Steel. The specific Critical Limits are not listed in the food safety plan.

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: MINOR

EVIDENCE: The site has two CCPs for Allergens and Metal Detection that do not list a measurable or quantitative limits that define acceptable limits from non-acceptable limits. The critical limits for allergens are listed as “Not present or detectable above trigger level.” Allersnap swabs are used and have varying degrees of detectable limits based on the target allergen, those specific limits are not mentioned in the Critical Limits. The Critical Limits for metal detection are “metal detection is present and operating." Site is using 1.2mm Fe, 1.5mm nFe, and 2.0mm 304 Stainless Steel. The specific Critical Limits are not listed in the food safety plan.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity was an oversight on the part of our food safety team. Because the AllerSnap swabs are an “off the shelf” solution and our metal detector test samples were provided by the manufacturer, we did not specifically add these values to the relevant documents. These are all pieces of information readily available in our reference materials, but were not added to the above controlled documents Future internal audits will serve to prevent issues like this from arising in the future.

CORRECTIVE ACTION: The critical limits for each individual allergen covered by the AllerSnap swabs have been added to our Allergen procedure. The size of our metal detector samples have been added to our metal detector work instruction. Both of these categories of information have also been added to our food safety plan to flag them as critical limits.

Corrective Action Report - CA #2 2021.pdf

Food Safety Plan The Organic Sn... 100621.doc

PRO.QA.COR.009.B Allergen ... 100621.pdf

WOR.QUA.BES.001.B Metal Detector

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/08/2021 **CLOSEOUT DATE:** 10/14/2021

2.4.4 Product Sampling, Inspection and Analysis

The site's procedures and criteria for sampling, inspecting, and analyzing raw materials, work-in-progress and finished product have been documented and implemented in Core Manufacturing Processes All analyses are conducted to nationally recognized standards or by an equivalent validated method. An onsite chemical (Gluten Testing) laboratory, whose operation has potential to pose a product safety risk, is located separately from any food handling/processing areas. A sign indicates the laboratory is limited to only authorized personnel. The hazardous waste generated is properly disposed. Retention samples were observed to be kept for the shelf-life of the product and maintained in laboratory and warehouse. Product evaluation and testing records were reviewed for product inspection from 7/5/1, 7/19/21, and 7/282/21, reviewed Gluten testing from 7/1/21, 8/5/21, and 9/11/21 during the audit and found to be conducted per procedures. Minor: The site is conducting gluten testing to support its Gluten Free claim on some products. The lab technician running the test does not have any proficiency testing for 2021.

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: MINOR

EVIDENCE: The site is conducting gluten testing to support its Gluten Free claim on some products. The lab technician running the test does not have any proficiency testing for 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity was caused by 2 issues. First, our gluten test supplier, Romer Labs, offers annual proficiency testing to all customers that purchase their product. Although we purchased Romer tests, we were left off of the announcement email for annual proficiency testing. This has been rectified so that we will receive the communications about periodic proficiency testing offerings. The second issue was a general misunderstanding (due to this being our first audit) that certain tasks had to be accomplished prior to the food safety program being certified by SQF. We were under the impression that testing needed to begin once the underlying policies and programs supporting it had been approved. Mr. Shelton corrected that misconception during the audit and a similar mistake will not happen in the future.

CORRECTIVE ACTION: On 10-5-21 our Director of Quality Assurance performed the Qualitative Gluten Allergen Proficiency Testing Panel from Emport LLC. Results of proficiency testing were received 10-6-21 and our Director of QA is proficient. Our Director of QA has also reached out to our current gluten testing vendor to ensure that we are not left off of future announcements regarding proficiency testing offerings.

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Corrective Action Report - CA #3 2021.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/08/2021 **CLOSEOUT DATE:** 10/14/2021

2.4.5 Non-conforming Materials and Product

The site has written procedures for withholding non-conforming products, raw materials, work-in-progress, ingredients, packaging and equipment in document Product Hold and Dispositions dated 6/28/21, which were found to be implemented in the facility and the responsibility of the QA Manager. This was observed during the audit by a review of the Hold Log for items: Sesame Seeds and Almonds (See 2.4.5.1). Relevant staff is aware of the site's Hold policy, as evidenced by interviews with Shipping personnel and QA Manager. Minor: There is a pallet sitting in the cooler that contains items on hold due to damage at receiving. However, there were no hold tags on the pallet, nor is there a marked hold location where the pallet is stored. The company is unable to show that the product could not be used inadvertently in production. The following items were observed without hold tags despite the items being on the hold log: Sesame Seeds (Damaged when received), Almonds Damaged when received (Damaged when received), Crispy rice damaged when received (Damaged when received), Raisins (Damaged when received).

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: MINOR

EVIDENCE: There is a pallet sitting in the cooler that contains items on hold due to damage at receiving. However, there were no hold tags on the pallet, nor is there a marked hold location where the pallet is stored. The company is unable to show that the product could not be used inadvertently in production. The following items were observed without hold tags despite the items being on the hold log: Sesame Seeds (Damaged when received), Almonds Damaged when received (Damaged when received), Crispy rice damaged when received (Damaged when received), Raisins (Damaged when received).

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity was caused by practices that arose from working with a small team. As there are only two warehouse employees it was easy to keep everyone on the same page as to what could be used and what could not be. This mindset is not how we will scale successfully and we need to be careful to identify similar issues before they lead to bad habits.

CORRECTIVE ACTION: Hold tags were placed on the relevant items in the cooler. Please see the attached photographs.

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Corrective Action Report - CA #4 2021.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

2.4.8 Environmental Monitoring

The site has implemented a risk-based environmental monitoring program, which is described in the document called Environmental Monitoring dated 6/15/21. This program is the responsibility of QA Manager. The sampling and testing program includes Product sampling zones 1 – 4 for Listeria and Salmonella are once per month for Zone 1 (10 swabs), Zone 2 (30 Swabs). Minor: The site is swabbing monthly for Listeria and Salmonella for its Environmental Monitoring program. However, test results could not be provided for July 2021 and August 2021.

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: MINOR

EVIDENCE: The site is swabbing monthly for Listeria and Salmonella for its Environmental Monitoring program. However, test results could not be provided for July 2021 and August 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity was caused by the delayed start to our environmental testing program due to confusion on the part of Eurofins as to the number of tests we wanted to conduct, the frequency, and our location in relation to their pickup roots. There was also a mistaken belief that our environmental testing program had to be approved by SQF prior to implementing the accompanying testing.

CORRECTIVE ACTION: Our testing program has been fully implemented. Our September test requests are submitted for our 30 Salmonella samples and 10 Listeria samples. QA and Eurofins are now on the same page as to the timing and delivery method of environmental samples. Our results were "not detected" across the board. We will continue utilizing this methodology monthly moving forward.

Corrective Action Report - CA #5 2... 2.pd

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AR-21-QP-088730-01[2021102195811].pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

2.6.4 Crisis Management Planning

The site's written Crisis Management Plan is found in document Crisis Management Planning Policy. The Plan has been implemented and addresses serious disaster threats to the extended interruption of the business. COO has oversight of the Plan and a Crisis Management team has been identified and trained as evidenced by employee interviews and classroom training/testing. The Plan includes responses to a business interruption, isolating and identifying affected product and a current crisis alert list. The Crisis Management Plan includes internal/external communications and sources of legal and expert advice. Minor: The site could not produce any documentation to show the Crisis Management plan had been tested for 2021.

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: MINOR

EVIDENCE: The site could not produce any documentation to show the Crisis Management plan had been tested for 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformance was caused by the mistaken belief that we did not need to have a mock-crisis exercise until our crisis management plan was approved during the audit. As this was our first audit, this will not happen again.

CORRECTIVE ACTION: We ran a mock-crisis exercise on 10/4/21. Under our scenario a blizzard knocked out power and water at our facility for several days and the team had to walk through our crisis management procedure in navigating our response. All emergency contact numbers were also verified during the mock-crisis. The mock exercise was a success and led to a helpful discussion as to what numbers needed to be on our contact list, and how to handle such a scenario (i.e. a water test would be required prior to start up due to the lines being stagnant for so long). Please see the attached Crisis Management Scenario Evaluation.

Corrective Action Report - CA #6 2021.pdf

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VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

2.7.1 Food Defense Plan (Mandatory)

The site has conducted a food defense threat assessment, dated 8/16/21 that identifies potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident. The site has a Food Defense Plan, Food Defense Plan, based on the threat assessment in which the methods, responsibilities, and criteria for preventing deliberate food adulteration have been documented and implemented. A food defense protocol includes the name of the senior manager responsible for food defense, COO, CEO, and CPO methods to allow access to the site only for authorized personnel, designated access points, the secured storage of materials, and hazardous chemicals and the control of access to contractors and visitors. Instructions have been provided to all relevant staff by means of in house training. The threat assessment and prevention plan is required to be reviewed at least annually with the last review documented on 8/16/21. Minor: The site could not produce any documentation to show the Food Defense plan had been tested for 2021.

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: MINOR

EVIDENCE: The site could not produce any documentation to show the Food Defense plan had been tested for 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformance was caused by the mistaken belief that we did not need to have a mock-food defense crisis exercise plan until our food defense plan was approved during the audit. As this was our first audit, this will not happen again.

CORRECTIVE ACTION: We ran a mock-food defense crisis exercise on 10/4/21. Under our scenario, a disgruntled employee attempted to adulterate an ingredient. The team had to walk through our food defense plan in navigating our response. All emergency contact numbers were also verified during the mock attack. The exercise was a success and led to a helpful conversation about building security and when certain people should have access to the building. Access fob settings were changed so that employees can only enter the facility with their fobs an hour before and an hour after their shifts. Please see the attached Food Defense Scenario Evaluation.

Corrective Action Report - CA #7 2021.pdf

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VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

11.3.3 Clothing and Personal Effects

A policy, based on a documented risk assessment, found in GMPs defines the site's clothing requirements and been implemented. Clothing including shoes are required to be clean at the commencement of the shift and changed or replaced if excessively soiled. Disposable gloves and aprons are to be changed when soiled or damaged. Employees were observed to comply with the clothing requirements of the facility. Protective clothing was observed to be manufactured from materials that will not pose a risk to food safety. A policy defining jewelry use has been written in the GMP Policy and implemented. Several employees were observed wearing earrings, a nose ring, and necklaces in the production room containing exposed products. The current risk assessment does not support the decision that wearing earrings and necklaces in production would not pose a risk to food safety.

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: MINOR

EVIDENCE: Several employees were observed wearing earrings, a nose ring, and necklaces in the production room containing exposed products. The current risk assessment does not support the decision that wearing earrings and necklaces in production would not pose a risk to food safety.

ROOT CAUSE: ROOT CAUSE ANALYSIS: Our GMPs at the time of audit were based off of the CFR for GMPs. The language from the CFR prohibited "non-secured" jewelry. We interpreted that to mean that earrings with certain types of backs and necklaces did not pose a food safety risk as they were secured and therefore unlikely to fall off. Via our conversations with Mr. Shelton and internally as a food safety team, we determined the risks posed by allowing even "secured" jewelry were greater than the benefits of letting employees wear such items.

CORRECTIVE ACTION: All jewelry, aside from stoneless wedding bands, have been banned in production. Our GMPs and Employee Handbook have been updated to reflect this and this has been communicated to our production team.

Corrective Action Report - CA #8 2... 2.pd

Employee Handbook - Tram ... 10.6.2021).pdf

PRO.QUA.COR.007.B Good Manufacturing

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

11.5.3 Water Quality

Water used in processing, cleaning or handwashing is monitored periodically for potability by the site.. Samples from inside the facility are sent to an outside lab for analysis. Based on risk, the site's testing frequency policy is set at a minimum frequency of annually. Minor: The site did not have potable water test results for its annual water testing due in 2021.

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 did not have potable water test results for its annual water testing due in 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This non-conformance was caused by a mistake made on the part of QA. The colisure tests that were needed to conduct the testing arrived prior to our audit, but we did not realize that an incubator was needed to conduct the tests. The incubator was ordered but did not arrive until after the audit. Now that we have the proper equipment, testing of our water will not be an issue.

CORRECTIVE ACTION: Potable water testing was conducted on 10-6-21. The results of these tests are attached.

Total Coliform Sample Tem... Gluten Testing T

Corrective Action Report - CA #9 2021.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/08/2021 **CLOSEOUT DATE:** 10/14/2021

11.5.5 Air and Other Gasses

Compressed air or other gas systems are regularly maintained. Filters are located at the point of use and are of the appropriate micron size to effectively filter the air or gas before contacting food or food contact surfaces. Minor: The site is using compressed air as a rejection device that directly touches open product. That rejected product is sent to a work in process bin and re-used in the same lot on the same production day. At the time of the audit no testing was available for the compressed air. The facility also produces nitrogen gas for some products. The nitrogen is used to flush the bags prior to sealing in the packaging area. The site did not have testing during the audit to show the nitrogen would not present a risk to food safety.

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: MINOR

EVIDENCE: The site is using compressed air as a rejection device that directly touches open product. That rejected product is sent to a work in process bin and re-used in the same lot on the same production day. At the time of the audit no testing was available for the compressed air. The facility also produces nitrogen gas for some products. The nitrogen is used to flush the bags prior to sealing in the packaging area. The site did not have testing during the audit to show the nitrogen would not present a risk to food safety.

ROOT CAUSE: ROOT CAUSE ANALYSIS: Our air testing kit was delayed from the sender, preventing us from conducting these tests prior to our audit. As this was our first audit, we have now learned to order these test kits with ample time ahead of our renewal and this issue will not happen again.

CORRECTIVE ACTION: Compressed air samples and nitrogen samples were collected on 9-30 and were sent to an outside lab for analysis. Results were obtained on 10-8-21& 10-11-21 and the samples were found to be acceptable with regard to pathogens and the air was dry, oil free, and water free. A plan has been put in place by QA to ensure that this testing is conducted on at least an annual basis.

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2021-09-30_Air Check - Trace An..pdf

2021-09-30_69590_21-30322DS.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/11/2021 **CLOSEOUT DATE:** 10/14/2021

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

A current register of chemicals in the facility, dated 6/28/21, was available. Chemical storage areas were observed to be locked, adequately ventilated, and have appropriate signage. Pesticides are stored separately from cleaning chemicals. Chemical storage areas were observed to be locked and had instructions on handling hazardous chemicals, an up-to-date inventory of all chemicals, available first aid and spill containment equipment. All stored chemicals have current SDS information on file at the facility. Training for employees, Production employee, who handle hazardous chemicals and toxic substances were observed to have training records available. SDS and the label declaration and/or documented approval for the chemical's intended use were reviewed for Tough on Grease, NABC Acid Cleaner and Haynes Lubri-Film. Minor: A green can of CRC food grade penetrating oil was observed to be stored in the production toolbox with caulking. The caulking was not food grade and should have been segregated from food grade oil.

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: MINOR

EVIDENCE: A green can of CRC food grade penetrating oil was observed to be stored in the production toolbox with caulking. The caulking was not food grade and should have been segregated from food grade oil.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This was an oversight by maintenance - the food grade caulk was not returned to its proper home. A sign in sign out form system is being implemented with all maintenance techs.

CORRECTIVE ACTION: The caulking was removed from the drawer and returned to the proper location with the other non-food grade caulks (maintenance office). The food grade penetrating oil is now the only chemical in that drawer. A conversation was had with maintenance about the importance of segregating food grade and non-food grade chemicals. Please see attached picture.

Corrective Action Report - C... 2021.pd

IMG_2995.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

11.7.3 Control of Foreign Matter Contamination

Metal Detector/Checkweigher Policies 11/9/20 defines the methods and responsibilities to prevent foreign material contamination. The policy's implementation was demonstrated by pre-operational inspections and regularly scheduled maintenance inspections, that are conducted and documented for the condition of equipment and any potential contaminants. A glass register has been documented with glass, brittle plastic and ceramic sources included in all areas of the plant (See 11.7.3.2). The glass register is current as of 9/9/21. Periodic inspections with documentation are made of these areas to ensure breakage has not occurred, and items are not missing or moved. The last inspection conducted on 9/14/21 was reviewed and found to be completed as scheduled. The site's policy requires that any product affected by foreign material contamination be isolated, inspected, reworked or disposed of. The glass policy requires that a thorough cleanup and inspection (including of cleaning equipment and footwear) occur if a glass breakage were to occur. A responsible person, QA Manager and SQFP, is required to inspect the affected area before the restarting of production. Wood pallets were clean and in good condition, and the facility has a policy prohibiting and/or controlling wooden utensils in processing/food handling areas. The site has documented a knife policy, and knives are controlled, cleaned and required to be in good condition. Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate are inspected at Weekly. Records from 9/9/21 were reviewed. Minor: The site is missing a brittle plastic alarm for metal detection rejects, buttons on line 1 for control panel, paper towel and soap dispensers, exit signs above entry way in production, and a Plexi-Glass type material on the flow wrapper on the glass and plastic register. All these observed items are located in production room.

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: MINOR

EVIDENCE: The site is missing a brittle plastic alarm for metal detection rejects, buttons on line 1 for control panel, paper towel and soap dispensers, exit signs above entry way in production, and a Plexi-Glass type material on the flow wrapper on the glass and plastic register. All these observed items are located in production room.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This was a result of being too close to this process. SInce day 1 we have had specific plastic items that need to be checked (i.e. mixer paddles) at the start of each day. However through familiarity we have overlooked many of the more mundane items (paper towel dispensers). We will now monitor every piece of equipment that enters production to ensure that our log is up to date in the future.

CORRECTIVE ACTION: We have created a Brittle Plastics / Glass Register and Inspection Form that accounts for all of the above items and all other Brittle Plastics / Glass in the production room. The list was compiled by the CEO, CPO, and Director of QA all conducting independent walkthroughs of production and combining the lists. This list has been incorporated into our daily set up checks and periodic management walkthroughs.

Corrective Action Report - C... 2021.pd

Plastic Inspection Checklist .docx

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Mark Thaler
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** mark@organicsnackco.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Mark Thaler: CEO/SQFP, Matt Blair, PCQI, Mackenzie Blair: Controller, Shanzie Taylor: QA Manager, Bryan Armentrout; Consultant, Brian Shelton; Lead Auditor
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** This is a new facility which opened in March of 2020. The hours of operation are 8 a.m. to 4 p.m., seven days per week with one shift. The building is 20,000 Sq Ft with one processing room, dry storage, maintenance shop, shipping area, and offices. The building is located in a rural area airport business park. There are planned future equipment and line expansions.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Mark Thaler: CEO/SQFP, Matt Blair, PCQI, Mackenzie Blair: Controller, Shanzie Taylor: QA Manager, Bryan Armentrout; Consultant, Brian Shelton; Lead Auditor
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Approve pending Corrective Action completion

Section Responses

2.1.1 Management Responsibility (Mandatory)

The site has a food safety policy statement, called Management Responsibility Policy, that senior management has implemented. It is signed by a senior manager, QA and Regulatory, CEO, Plant Operations Manager, QA Manager, SQFP. The Policy statement covers a commitment to supply safe food, establish and maintain and food safety culture, establish and continually improve the food safety management system, and comply with all customer and regulatory requirements. The Policy is communicated to the facility's staff by way of Clipboards in production, online training, and is in languages used in the site. Senior management has developed the following food safety objectives Safe Products, No Recalls, KPIs (service related, complaints, micro, packaging, foreign material). These have been effectively communicated to all relevant staff by Training, Posters, Bulletin Boards. Performance of defined food safety objectives is reviewed during internal audits, onsite verification of safety objectives by relevant staff. Plant staff is required to report food safety issues to management, as evidenced by policy food safety management manual, trainings, and interviews with 4 employees in production area. An organizational chart, dated 2/21/21, outlines the structure of staff having responsibility for food safety as well as backups for key personnel. Job descriptions for key personnel were reviewed for QA Manager, Production Supervisor and Batching employee and appeared to be adequate. It was observed through interviews and observations that site management has provided adequate resources through staffing the meet defined food safety objectives. Mark Thaler is the designated primary SQF Practitioner, is a full-time employee of the facility and has a HACCP food safety training course, as evidenced by a certificate from FSPCA, dated 12/10/20. Mark Thaler is the designated substitute SQF Practitioner, is a full-time employee of the facility and has a HACCP food safety training course, as evidenced by a certificate from FSPCA, dated 10/20/20. The SQF Practitioner is responsible for the development, implementation, and maintenance of the SQF System. Senior site management has processes in place to demonstrate continuous improvement and to ensure the integrity of the food safety systems when there are organizational or personnel changes. Minor: There was no signed management policy posted in a prominent location or any other location in the facility.

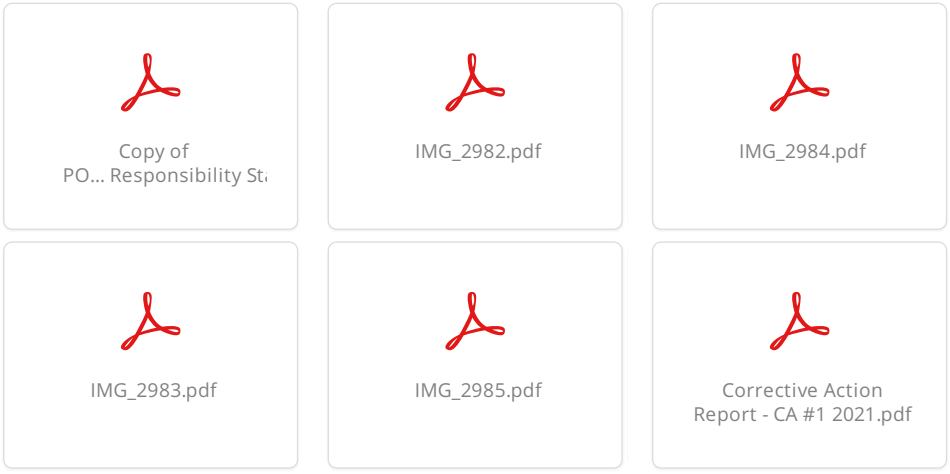
2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to: i. Supply safe food; ii.Establish and maintain a food safety culture within the site; iii. Establish and continually improve the site's food safety management 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: MINOR

EVIDENCE: There was no signed management policy posted in a prominent location or any other location in the facility.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity arose from a lack of understanding about the requirements of 2.1.1.1. Management was under the impression that the food safety statements contained in the employee handbook (which is posted throughout the site) were sufficient to satisfy this requirement. The clarity gained during the audit is sufficient to prevent this from happening again.

CORRECTIVE ACTION: A signed management policy addressing the commitment of site management to supply safe food, establish and maintain a food safety culture within the site, establish and continually improve the site's food safety management system, and to comply with customer and regulatory requirements to supply safe food has been posted in the following locations in the facility: Employee Break Room Hallway Bulletin Board Fulfillment Bulletin Board Pictures will be uploaded into Repositrak to show the posted document as well as a copy of the document.



VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

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 SQF System is reviewed annually by the site's Plant Management Team and SQFP with the last review documented and completed on 9/13/21. The review includes changes to the food safety management system documentation (policies, procedures, specifications, and food safety plans); food safety culture performance; food safety objectives and performance; corrective and preventive actions and trends related to internal audits, external audits, customer complaints, verification and validation activities; hazard and risk management system; and follow up actions from previous management review. The SQF Practitioner has updated senior site management on a monthly basis, by means of management meetings, on any matters that impact the site's SQF System. Monthly meetings from 9/13/21, 8/31/21, and 7/12/21 were reviewed and appeared to be adequate.

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's written Complaint policy is found in the document 1/21/21 It defines the methods and responsibilities for handling food safety customer, commercial, and authority complaints and has been implemented. The investigation of complaints is handled by QA Manager, with corrective actions and records kept of each complaint and resolution. Records of complaints were reviewed for Complaint for mold on open packaging, Fibrous twigs in peanut butter bar, and Missing one box of bars on an order and showed that investigation and corrective actions of the complaints had been put into place. Trending graphs of complaints for January 2021 to September 2021 were also reviewed and found to be acceptable.

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)

A food safety manual has been developed and is maintained in hard copy and electronic form called Food Safety Manual. It is dated 1/5/21 and maintained by QA Manager. The food safety manual contains the scope of the certification, a list of products in the scope, the organizational chart and food safety policies, programs and procedures that make up the site's SQF System. It is made available to all relevant staff by means of hard copies when requested or electronic storage.

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 has implemented its policy called 8/31/20, defining the methods and responsibilities for document control. All staff have access to current requirements and instructions by means of Training and employee handbooks.

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 has implemented its policy for verifying, maintaining, and retaining records found in the document called Records Policy 8/31/20. Records were observed to be readily accessible, legibly filled out, securely stored to prevent damage, and have documented retention times. Records are retained for 5 years in onsite.

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

N/A: Product Development is not carried out at this site.

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: NOT APPLICABLE

EVIDENCE: N/A: Product Development is not carried out at this site.

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: NOT APPLICABLE

EVIDENCE: N/A: Product Development is not carried out at this site.

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: NOT APPLICABLE

EVIDENCE: N/A: Product Development is not carried out at this site.

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: NOT APPLICABLE

EVIDENCE: N/A: Product Development is not carried out at this site.

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: NOT APPLICABLE

EVIDENCE: N/A: Product Development is not carried out at this site.

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: NOT APPLICABLE

EVIDENCE: N/A: Product Development is not carried out at this site.

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

A policy defining the methods and responsibilities for developing, managing, and approving raw material, finished product, and packaging specifications has been documented and implemented in Specification Approval Policy dated 2/3/21. Specifications for raw materials, packaging, ingredients, additives, chemicals and processing aids have been documented. Specifications for Organic Peanut Butter, Organic Flax Seed, and FCS Film were reviewed and found to be current. Raw and packaging materials are verified to ensure product safety, regulatory requirements and fit for purpose requirements are met. These are done by means COA (Peanut Butter – 7/22/21), Certificate of Conformance from packaging supplier, Flax Seed (12/10/20). Approved suppliers are required to notify the site of changes in product composition that could have an impact of product formulations. This is documented in Specification Approval Policy 2/3/21. Food contact packaging, Certificate of Conformance and SDS, has a certificate of conformance from Fortis Solutions Group, indicating that it does not present a risk of chemical migration to food products. Product labels are approved by PCQI, who is qualified to ensure they are accurate and meet regulatory requirements. Descriptions of services provided by all contract service providers having an impact on food safety are documented in Approved Services Policy. A list of current contract service providers is maintained in electronic file and found to include providers of services including Orkin (Pest Control), Haynes Services (Food Safe Grease), Knisley (Glycol) and Cintas (Uniforms). Contract arrangements for Orkin and Knisley were reviewed during the audit and found to be satisfactory. Finished product specifications are current, documented, and approved by the site and its customers. Specifications include microbiological limits, chemical limits, physical limits, composition, labeling and packaging requirements, and storage requirements. Finished product specifications Organic Peanut Butter, Organic Flax Seed and FCS Film were reviewed during the audit and contained the required information. Specifications for raw materials, packaging materials, chemicals, processing aids, contract services, and finished products are reviewed on annually basis with that last documented review taking place on 9/2/21.

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 use contract manufacturers.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The site does not use contract manufacturers.

2.3.3.2 The site shall establish a method to determine the food safety risk level of contract manufactured product and shall document the risk. The site shall 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

EVIDENCE: N/A: The site does not use contract manufacturers.

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

EVIDENCE: N/A: The site does not use contract manufacturers.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The site does not use contract manufacturers.

2.3.4 Approved Supplier Program (Mandatory)

The site has a written supplier approval policy, Specification Approval Policy dated 2/4/21, which has been implemented and covers the procedures for selecting, evaluating, approving, and monitoring suppliers of raw materials, ingredients, and packaging materials. Approved supplier performance and status is reviewed using continuous monitoring at receiving and Label and quality checks at receiving. The policy includes a review of the specifications of products, the supplier's food safety controls, procedures for granting and monitoring approved suppliers, the level of risk of products to the site and details of requirements for Certificate of Conformance, Certificates of Analysis and testing. A register is maintained of all current approved suppliers, which was reviewed during the audit and found to be acceptable. Raw materials: Organic Peanut Butter, Organic Flax Seed and FCS Film were verified to have come from suppliers on the Approved Supplier List and documented reviewed to confirm risk level and monitoring details. The procedures for emergency use of non-approved suppliers have been documented. Per the supplier approval policy, incoming materials from sister sites are subject to the same specifications and supplier approval requirements. Supplier audits are based on risk; audits were on file for approved suppliers of ingredients/components: Organic Peanut Butter (SQF Audit), Organic Flax Seed (SQF Audit) and FCS Film.

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

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

2.4.1 Food Legislation (Mandatory)

The site has ensured that products delivered to its customers comply with regulatory requirements in the country of use. Regulatory compliance for this operation includes keeping up to date on changing regulations from FDA, adding notifications form FDA into the Crisis Management System, and Food Recall Reporter. The site keeps updated about changes in relevant legislation, technical developments and industry codes of practice in their specific industry, by means of FDA updates. The site has a written provision that SCS Global Services, the certification body, and SQFI will be notified within 24 hours 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)

The property, buildings and equipment are located, constructed and designed to ensure food is manufactured in a safe, hygienic environment. The site has written and implemented those Good Manufacturing Practices applicable to the scope of this certification. These food safety pre-requisite programs are found electronic and hard copy.

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: COMPLIANT

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)

A Food Safety Plan has been developed, implemented, and maintained by the site. It is kept on file in the office and maintained by PCQI/SQFP. The Food Safety Plan has been prepared in accordance with the 12 steps identified in the Codex Alimentarius Commission HACCP guidelines. A multi-disciplinary Food Safety Team has been identified and trained, with documentation found in Food Safety Plan (PCQI/HACCP Leader). The Plan includes a list of all products in the scope of the certification, a complete product description, intended product use (including vulnerable populations) and flow diagrams for each process including all input and output steps in the process. The process flow has been verified by the site per walkthrough with HACCP team and signed on 9/19/21 by the PCQI. The food safety team has analyzed all hazards reasonably likely to occur including physical, chemical, and microbiological hazards for each process step, ingredient and packaging. Preventive Controls/CCPs have been identified as Supply Chain (C/L: Supplier approval by visual review for each lot by PCQI or designee), Sanitation (C/L: Pathogen contamination cannot be present by visual inspection of the PCQI or designee each production day) Foreign Material (C/L: metal detection present and operating checked every hour by visual examination the detector is detecting metal) Allergens (CL: Allergens are not present by visual inspection or allergen testing weekly by QA or designee). Any deviations found in monitoring of established control limits are documented and investigated, with proper disposal of involved products. The plan is verified as part of the SQF System and reviewed annually or when changes occur, by the food safety team with the last review date on 9/19/21 FDA regulatory requirements for the site also require a Preventive Control food safety plan, which was observed to be implemented. Minor: The site has two CCPs for Allergens and Metal Detection that do not list a measurable or quantitative limits that define acceptable limits from non-acceptable limits. The critical limits for allergens are listed as “Not present or detectable above trigger level.” Allersnap swabs are used and have varying degrees of detectable limits based on the target allergen, those specific limits are not mentioned in the Critical Limits. The Critical Limits for metal detection are “metal detection is present and operating." Site is using 1.2mm Fe, 1.5mm nFe, and 2.0mm 304 Stainless Steel. The specific Critical Limits are not listed in the food safety plan.

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: MINOR

EVIDENCE: The site has two CCPs for Allergens and Metal Detection that do not list a measurable or quantitative limits that define acceptable limits from non-acceptable limits. The critical limits for allergens are listed as “Not present or detectable above trigger level.” Allersnap swabs are used and have varying degrees of detectable limits based on the target allergen, those specific limits are not mentioned in the Critical Limits. The Critical Limits for metal detection are “metal detection is present and operating." Site is using 1.2mm Fe, 1.5mm nFe, and 2.0mm 304 Stainless Steel. The specific Critical Limits are not listed in the food safety plan.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity was an oversight on the part of our food safety team. Because the AllerSnap swabs are an “off the shelf” solution and our metal detector test samples were provided by the manufacturer, we did not specifically add these values to the relevant documents. These are all pieces of information readily available in our reference materials, but were not added to the above controlled documents Future internal audits will serve to prevent issues like this from arising in the future.

CORRECTIVE ACTION: The critical limits for each individual allergen covered by the AllerSnap swabs have been added to our Allergen procedure. The size of our metal detector samples have been added to our metal detector work instruction. Both of these categories of information have also been added to our food safety plan to flag them as critical limits.

Corrective Action Report - CA #2 2021.pdf

Food Safety Plan The Organic Sn... 100621.doc

PRO.QA.COR.009.B Allergen ... 100621.pdf

WOR.QUA.BES.001.B Metal Detector

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/08/2021 **CLOSEOUT DATE:** 10/14/2021

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

The site's procedures and criteria for sampling, inspecting, and analyzing raw materials, work-in-progress and finished product have been documented and implemented in Core Manufacturing Processes All analyses are conducted to nationally recognized standards or by an equivalent validated method. An onsite chemical (Gluten Testing) laboratory, whose operation has potential to pose a product safety risk, is located separately from any food handling/processing areas. A sign indicates the laboratory is limited to only authorized personnel. The hazardous waste generated is properly disposed. Retention samples were observed to be kept for the shelf-life of the product and maintained in laboratory and warehouse. Product evaluation and testing records were reviewed for product inspection from 7/5/1, 7/19/21, and 7/282/21, reviewed Gluten testing from 7/1/21, 8/5/21, and 9/11/21 during the audit and found to be conducted per procedures. Minor: The site is conducting gluten testing to support its Gluten Free claim on some products. The lab technician running the test does not have any proficiency testing for 2021.

2.4.4.1 The methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in-progress, and finished product shall be documented and implemented. The methods applied shall ensure that inspections and analyses are completed at regular intervals as required and to agreed 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: MINOR

EVIDENCE: The site is conducting gluten testing to support its Gluten Free claim on some products. The lab technician running the test does not have any proficiency testing for 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity was caused by 2 issues. First, our gluten test supplier, Romer Labs, offers annual proficiency testing to all customers that purchase their product. Although we purchased Romer tests, we were left off of the announcement email for annual proficiency testing. This has been rectified so that we will receive the communications about periodic proficiency testing offerings. The second issue was a general misunderstanding (due to this being our first audit) that certain tasks had to be accomplished prior to the food safety program being certified by SQF. We were under the impression that testing needed to begin once the underlying policies and programs supporting it had been approved. Mr. Shelton corrected that misconception during the audit and a similar mistake will not happen in the future.

CORRECTIVE ACTION: On 10-5-21 our Director of Quality Assurance performed the Qualitative Gluten Allergen Proficiency Testing Panel from Emport LLC. Results of proficiency testing were received 10-6-21 and our Director of QA is proficient. Our Director of QA has also reached out to our current gluten testing vendor to ensure that we are not left off of future announcements regarding proficiency testing offerings.

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Corrective Action Report - CA #3 2021.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/08/2021 **CLOSEOUT DATE:** 10/14/2021

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: COMPLIANT

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

RESPONSE: COMPLIANT

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: COMPLIANT

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Materials and Product

The site has written procedures for withholding non-conforming products, raw materials, work-in-progress, ingredients, packaging and equipment in document Product Hold and Dispositions dated 6/28/21, which were found to be implemented in the facility and the responsibility of the QA Manager. This was observed during the audit by a review of the Hold Log for items: Sesame Seeds and Almonds (See 2.4.5.1). Relevant staff is aware of the site's Hold policy, as evidenced by interviews with Shipping personnel and QA Manager. Minor: There is a pallet sitting in the cooler that contains items on hold due to damage at receiving. However, there were no hold tags on the pallet, nor is there a marked hold location where the pallet is stored. The company is unable to show that the product could not be used inadvertently in production. The following items were observed without hold tags despite the items being on the hold log: Sesame Seeds (Damaged when received), Almonds Damaged when received (Damaged when received), Crispy rice damaged when received (Damaged when received), Raisins (Damaged when received).

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: MINOR

EVIDENCE: There is a pallet sitting in the cooler that contains items on hold due to damage at receiving. However, there were no hold tags on the pallet, nor is there a marked hold location where the pallet is stored. The company is unable to show that the product could not be used inadvertently in production. The following items were observed without hold tags despite the items being on the hold log: Sesame Seeds (Damaged when received), Almonds Damaged when received (Damaged when received), Crispy rice damaged when received (Damaged when received), Raisins (Damaged when received).

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity was caused by practices that arose from working with a small team. As there are only two warehouse employees it was easy to keep everyone on the same page as to what could be used and what could not be. This mindset is not how we will scale successfully and we need to be careful to identify similar issues before they lead to bad habits.

CORRECTIVE ACTION: Hold tags were placed on the relevant items in the cooler. Please see the attached photographs.

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IMG_2992.pdf

IMG_2990.pdf

IMG_2989.pdf

Corrective Action Report - CA #4 2021.pdf

VERIFICATION OF CLOSEOUT: Verified

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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: Product is not reworked, recouped or recycled.

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

EVIDENCE: N/A: Product is not reworked, recouped or recycled.

2.4.7 Product Release (Mandatory)

The site has written procedures, Product Release dated 6/28/21 implemented for releasing finished products. These release procedures include ensuring that all product inspections and analyses have been verified and documented by authorized personnel to show that all food safety controls have been met. The procedure also includes a requirement to confirm product labels comply with all regulatory requirements of the country of manufacture of use. A review of records for product releases for PBMC Bar, on 7/5/21, DCCA Bar on 7/19/21, and PBDCA Bar on 7/29/21 during the audit showed they had been conducted per procedures. The facility does not conduct any testing on products prior to shipping.

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 implemented a risk-based environmental monitoring program, which is described in the document called Environmental Monitoring dated 6/15/21. This program is the responsibility of QA Manager. The sampling and testing program includes Product sampling zones 1 – 4 for Listeria and Salmonella are once per month for Zone 1 (10 swabs), Zone 2 (30 Swabs). Minor: The site is swabbing monthly for Listeria and Salmonella for its Environmental Monitoring program. However, test results could not be provided for July 2021 and August 2021.

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: COMPLIANT

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: MINOR

EVIDENCE: The site is swabbing monthly for Listeria and Salmonella for its Environmental Monitoring program. However, test results could not be provided for July 2021 and August 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformity was caused by the delayed start to our environmental testing program due to confusion on the part of Eurofins as to the number of tests we wanted to conduct, the frequency, and our location in relation to their pickup roots. There was also a mistaken belief that our environmental testing program had to be approved by SQF prior to implementing the accompanying testing.

CORRECTIVE ACTION: Our testing program has been fully implemented. Our September test requests are submitted for our 30 Salmonella samples and 10 Listeria samples. QA and Eurofins are now on the same page as to the timing and delivery method of environmental samples. Our results were “not detected” across the board. We will continue utilizing this methodology monthly moving forward.

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VERIFICATION OF CLOSEOUT: Verified

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2.5.1 Validation and Effectiveness (Mandatory)

The methods, responsibilities and criteria for ensuring the effectiveness of all applicable elements of the SQF Program have been documented and implemented in Validation and Effectiveness. The methods applied confirm that each element has been deemed effective. Methods to ensure that procedure or process changes are still effective in controlling food safety are in place and documented in 6/28/21 Critical food safety limits are re-validated at least annually by third party validation for metal detector on 3/26/21. Records of all verifications of effectiveness and validations are maintained by the PCQI.

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

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

The methods, responsibilities and criteria for verifying monitoring of Good Manufacturing Practices, critical control points, and other food safety controls, and legality of certified products has been documented and implemented in Verifying. The site has established a verification schedule, dated 6/28/21, outlining the verification frequency and responsibilities for each verification activity. The schedule is found in Verification Activities and maintained by the SQFP manager. Records of verification of monitoring activities including Pest Control, Allergen Verification and GMPs were reviewed and found to be acceptable.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

The site's Corrective and Preventative Action program is written in Corrective and Preventative Action Policy dated 2/13/21. It describes the methods and responsibilities for investigating, resolving, and managing corrective actions. The identification of root causes and resolutions to deviations of critical control limits are documented. There were no Corrective Actions needed since the implementation of the SQF System in June 2021.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4 Internal Audits and Inspections (Mandatory)

The site's procedure for scheduling and conducting internal audits to assess the effectiveness of the SQF system has been documented and implemented per document Internal Audit Policy dated 7/6/21. The Internal Audit Program is maintained by CEO and QA Manager. All applicable SQF Code requirements, using the SQF checklist or a similar tool, are part of the internal audit program. Audit results are communicated to relevant management personal and staff responsible for implementing and verifying corrective and preventive actions by means of Corporate Management Meetings along with KPIs. This was last completed on 6/16/21. Personnel conducting audits have been properly trained and where practical, audit areas independent of their function. Internal auditor training records were reviewed for third party consultant. Facility and equipment inspections are conducted Daily to ensure Good Manufacturing Practices are followed. Records of internal audits were reviewed from 9/20/21 (GMP), 8/31/21 (GMP), and 7/29/21(GMP), Objective evidence was observed to be included in records of internal audits.

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: COMPLIANT

2.6.1 Product Identification (Mandatory)

A policy defining how products are identified from receipt through production and shipping has been documented in Product Identification. The site's identification system ensures all raw materials, ingredients, packaging materials, work-in-progress, process inputs and finished goods are clearly identified at all stages of their process. Items are marked at receipt by Logistics Coordinator. Product identification records were reviewed during the audit for Production receiving paperwork from 8/30/21, 8/19/21, 7/28/21, 7/13/21 and demonstrated the products were properly identified throughout the process. There were no changeovers forms available due to scheduling. Production runs one product a day per production matrix. There were no mid-production changeovers conducted during the audit. A per-operational inspection was observed on 9/21/21 during the audit. All procedures were observed to be acceptable.

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)

A policy defines the methods and responsibilities for tracing product to the customer (one up) and from vendors of raw materials and packaging (one back). This is written in Product Trace Policy. The effectiveness of the trace system is conducted at least annually, as part of the product withdrawal and recall program. Records of the receipt, use and dispatch of finished product are maintained.

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)

The site has a Recall Plan defining the methods and responsibilities for withdrawing and recalling product if necessary documented in Corporate Recall Decision Policy. A recall team has been designated and is led by Chief Production Officer The withdrawal policy includes the requirement to investigate a recall and determine the root cause of a recall/withdrawal with a corrective action. It also includes a communication plan to notify customers, consumers, regulatory authorities, and other essential bodies. This includes SQFI and SCS Global Services, the Certification Body, who must be notified within 24 hours in writing of any food safety event requiring public notification. Investigation into the root cause of any product recall, mock recall, or product withdrawal, with actions taken, was observed to be documented. Mock trace exercises are completed annually one step forward and one step back, to verify the effectiveness of the system. Records were reviewed of the recall plan and summaries of the trace exercises performed for DCM Bar and Cocoa Powder on 1/13/21 The mock trace exercise records reviewed showed the Product Withdrawal and Recall procedures were tested back one step and forward one step with acceptable accountability. Conducted onsite mock trace exercise for PBHF Bites produced on 8/24/21, (Lot: 8/24/22). There were 5,166 Bars produced. Reviewed Peanut butter lot # 7/22/21 received on 9/2/21. Hemp seed organic Lot: VATCN16920121LOGFS received on 6/24/21, Film Lot 6/15/21, and received on 6/15/21. All three components were successfully traced back to the supplier in 43 minutes. The site also successfully traced all finished products to the customer.

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 found in document Crisis Management Planning Policy. The Plan has been implemented and addresses serious disaster threats to the extended interruption of the business. COO has oversight of the Plan and a Crisis Management team has been identified and trained as evidenced by employee interviews and classroom training/testing. The Plan includes responses to a business interruption, isolating and identifying affected product and a current crisis alert list. The Crisis Management Plan includes internal/external communications and sources of legal and expert advice. Minor: The site could not produce any documentation to show the Crisis Management plan had been tested for 2021.

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: MINOR

EVIDENCE: The site could not produce any documentation to show the Crisis Management plan had been tested for 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformance was caused by the mistaken belief that we did not need to have a mock-crisis exercise until our crisis management plan was approved during the audit. As this was our first audit, this will not happen again.

CORRECTIVE ACTION: We ran a mock-crisis exercise on 10/4/21. Under our scenario a blizzard knocked out power and water at our facility for several days and the team had to walk through our crisis management procedure in navigating our response. All emergency contact numbers were also verified during the mock-crisis. The mock exercise was a success and led to a helpful discussion as to what numbers needed to be on our contact list, and how to handle such a scenario (i.e. a water test would be required prior to start up due to the lines being stagnant for so long). Please see the attached Crisis Management Scenario Evaluation.

Corrective Action Report - CA #6 2021.pdf

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VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

2.7.1 Food Defense Plan (Mandatory)

The site has conducted a food defense threat assessment, dated 8/16/21 that identifies potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident. The site has a Food Defense Plan, Food Defense Plan, based on the threat assessment in which the methods, responsibilities, and criteria for preventing deliberate food adulteration have been documented and implemented. A food defense protocol includes the name of the senior manager responsible for food defense, COO, CEO, and CPO methods to allow access to the site only for authorized personnel, designated access points, the secured storage of materials, and hazardous chemicals and the control of access to contractors and visitors. Instructions have been provided to all relevant staff by means of in house training. The threat assessment and prevention plan is required to be reviewed at least annually with the last review documented on 8/16/21. Minor: The site could not produce any documentation to show the Food Defense plan had been tested for 2021.

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

RESPONSE: COMPLIANT

2.7.1.2 A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum: i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident; ii. The name of the senior site management person responsible for food defense; iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points; iv. The methods implemented to protect sensitive processing points from intentional adulteration; v. The measures taken to ensure the secure receipt and storage of raw 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: MINOR

EVIDENCE: The site could not produce any documentation to show the Food Defense plan had been tested for 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This nonconformance was caused by the mistaken belief that we did not need to have a mock-food defense crisis exercise plan until our food defense plan was approved during the audit. As this was our first audit, this will not happen again.

CORRECTIVE ACTION: We ran a mock-food defense crisis exercise on 10/4/21. Under our scenario, a disgruntled employee attempted to adulterate an ingredient. The team had to walk through our food defense plan in navigating our response. All emergency contact numbers were also verified during the mock attack. The exercise was a success and led to a helpful conversation about building security and when certain people should have access to the building. Access fob settings were changed so that employees can only enter the facility with their fobs an hour before and an hour after their shifts. Please see the attached Food Defense Scenario Evaluation.

Corrective Action Report - CA #7 2021.pdf

BRN3C2AF4D96151_0000002329.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

2.7.2 Food Fraud (Mandatory)

The site has conducted a Food Fraud Vulnerability Assessment, dated 6/28/21, that includes the methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to substitution, finished product mislabeling, dilution, and counterfeiting. The site has developed a Food Fraud Mitigation Plan, dated 9/19/21, to address the control of the identified food fraud vulnerabilities. Instructions have been provided to all relevant staff by means of using online resources for recent outbreaks, supplier approval, and Food Safety Plan. The Vulnerability Assessment and Mitigation Plan were last reviewed on 9/19/21 by the COO.

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 Allergen Management Policy to control allergens and prevent contamination of other products is found in document Food Allergen Management and is the responsibility of PCQI, QA Manager, and CPO. Allergens of concern in this operation were observed to be Milk, Tree Nuts, Peanuts, Sesame. A risk analysis was observed to be in place for allergens including raw materials, ingredients and processing aids such as food grade lubricants. Workplace allergens from locations such as lunchrooms, locker rooms and vending machines were found to be part of the allergen program. Instructions, in class, testing, and online training have been provided to all relevant staff involved in handling allergenic product. The operation was found to have a product identification system that includes clear identification and labeling of products to meet regulatory requirements when made on production lines used for allergenic products. Proper procedures for cleaning of food contact surfaces, including periodic validation of cleaning methods by protein-specific testing, were found to be in place. Product changeovers where allergen cross contamination could occur use are scheduled in advance to preclude allergen changeovers during production, risk matrix, and allergen swabbing to eliminate the risk of cross contact. Allergenic products in storage were observed during the audit to be properly labeled and stored separately to prevent cross-contamination. The product trace system ensures the complete trace of allergenic ingredients, containing allergens. The site has procedures in place, found in document Preventive Control Policy to control the accuracy of finished product labels, including labels of allergenic products. This was observed to be implemented on the plant floor on Line 1.

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

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

2.9.1 Training Requirements

Appropriate training is provided for all plant personnel for all tasks to ensure the effective implementation of the SQF system. Training programs are the assigned responsibility of HR Manager and direct supervisor for each department and role of employee. The effectiveness of the facility's training program was evidenced by interviews with plant employees Shipping Personnel, Batching Employee, QA Technician, and Production Lead.

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)

The site has implemented a training program, entitled Training Program which covers the necessary competencies for plant personnel. This program requires training to be conducted in implementing HACCP, CCP Monitoring, Personal Hygiene, GMPs, Sampling and Test Methods, Environmental Monitoring, Allergen Management, and other tasks identified as critical to meeting the effective implementation of the SQF code. Periodic refresher training needs have been identified in the Training Program. From a review of refresher training records covering GMPs, Allergen, State Food Safety, Preventive Controls/HACCP, Pest Control, and interviews with Shipping personnel and packing line employee, it was evident the proper refresher training has been conducted to ensure food safety and the SQF system are maintained. Specific refresher training topics are covered on an annual basis. The training language and materials are in English (Indicate any other applicable languages), the language used in the operation and understood by all plant personnel. Training records reviewed included the participant name, skills description, description of training, date of training, trainer, and training verification.

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

An assessment, last reviewed on 8/26/21, confirms that local activities and the site environment does not have an adverse impact on product safety. The site's buildings, property and surroundings were observed during the audit to not pose a food safety risk to products. The site maintains the required approvals by relevant authorities, as evidenced by Pennsylvania Department of Agriculture, Organic Certified by Baystate Organic Certifiers, Gluten Free Certified by GFCO, Non-GMO certified by Non-GMO Project and FDA for their ongoing operations.

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

Floors are constructed of smooth and dense impact resistant material and properly graded for effective drainage of overflow or wastewater. Wastewater during the audit was observed to be properly discharged. Drains were observed to be located and constructed for ease of cleaning and inspection. Walls, ceilings, 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 properly designed and installed to prevent contamination and for ease of cleaning. A documented risk assessment dated 8/26/21, confirms that food contamination risks are mitigated. Doors, windows, and frames in product areas were observed to be properly constructed of materials with the same functional requirements as internal walls and partitions. The ceilings in all food processing and handling areas are constructed of FRP drop panels, which are easily cleaned and prevent product contamination. Drop ceilings were observed to allow for cleaning and inspection. Stairs, catwalks and platforms were observed during facility tours to be constructed and designed so that food contamination is avoided, and with no open grates above exposed product surfaces. There are no waste traps on site.

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: There are no waste traps on site.

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: COMPLIANT

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: COMPLIANT

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: COMPLIANT

11.1.3 Lightings and Light Fittings

Lighting was of the appropriate intensity for employees to carry out their tasks efficiently. All lighting is either covered or is shatter-proof.

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

Inspection/Quality Control areas are not required in this operation.

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

EVIDENCE: Inspection/Quality Control areas are not required in this operation.

11.1.5 Dust, Insect, and Pest Proofing

External windows, doors and other openings were observed during facility tours to be properly sealed to prevent any pest infestation or dust coming into the facility. External personnel doors were observed to be self-closing and sealed to prevent dust and pest ingress. All external doors and dock doors were sealed to prevent infestation. Electric insect devices, and interior and exterior rodent stations are located so the product is not at risk for contamination. Rodenticide bait is only used on the outside 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 available, where needed, in enclosed processing and food handling areas. Ventilation equipment was seen to be adequately cleaned, insect-proofed, and located to not pose a risk of contamination. Ventilation equipment was not used.

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: Ventilation equipment was not used.

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

Specifications for the former, tables, mixer, conveyors and paddles were reviewed and found to be complete. Purchasing procedures for equipment are documented in Supplier Approval and were seen to be appropriately implemented. Equipment and utensils, (including tables, packers, conveyors, tubs, bins and containers are designed, constructed and installed to meet regulatory requirements and prevent risks of contamination of the product. These items were found to be cleaned and stored properly after use to prevent cross contamination. Equipment storage rooms, clean room, were observed to be designed and constructed to allow for safe and hygienic storage. Equipment surfaces were observed to be smooth, impervious and free from cracks and crevices. Containers and bins are made of non-toxic materials and were labeled or color-coded, for appropriate use with either edible or non-edible materials. Forklifts and other vehicles in processing areas and storage areas were observed to not present a food hazard. Non-conforming equipment is identified, tagged, and/or segregated by means of quarantine. Records of non-conforming equipment are maintained.

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

Exterior inspections are required to be completed on a daily basis. Exterior inspection records were reviewed from 8/30/21, 8/19/21, 7/28/21, 7/13/21 and found to be acceptable. The grounds and surrounding areas were observed to minimize dust and be free of any waste, so pests are not attracted. Paths, roadways and dock areas were seen to be adequately and properly drained and well maintained, so they do not present a hazard. No pooling water was observed during exterior inspections. Walkways from the parking lot and other employee amenities were paved or effectively sealed.

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: COMPLIANT

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 has a program, Preventive Maintenance and Repair Policy, that defines the responsibilities for the maintenance and repair of all plant equipment and buildings. There is a schedule of planned Preventive Maintenance, and tasks are documented in PM Schedule. Failures of plant and equipment are documented in Preventive Maintenance and Repair Policy and are reviewed by Director of Maintenance on an weekly basis. Temporary repairs, if required, are appropriate, included in the cleaning program and have a plan for their removal. Machinery, conveyors and other equipment over or near food or food contact surfaces are lubricated with food grade materials. Paint is not used on food contact surfaces and any paint in processing areas was noted to be in good condition with no observed flaking.

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

Maintenance and engineering contractors on site are trained in the site’s food safety and hygiene procedures by means of training video upon entering site and being escorted while onsite. When repairs and maintenance are complete, maintenance personnel remove all tools and debris and notify a supervisor. Appropriate cleaning and pre-operational inspections are carried out before resumption of operations, documented in Post-Maintenance Record. Maintenance personnel are trained in good manufacturing practices and food safety. This was reviewed during the audit and found to be complete.

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

A policy, Calibration Policy dated 7/6/21, defines the methods and responsibilities for calibrating measuring, testing and inspection equipment, and has been implemented. Equipment is calibrated against national or international standards. A procedure to address the disposition of any affected product should inspection equipment be found to be out of calibration, written in Calibration Policy. Inspection and testing equipment is protected from damage or unauthorized use by password protection. The facility has developed a calibration schedule for all devices listed. This documentation is located in Calibration Log. The frequency of calibrations is based on the manufacturer's recommendations or customer requirements. A review of the calibration records for Metal Detector 1 and inline Metal Detector 2 on 3/26/21 confirms the schedule is being followed.

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: COMPLIANT

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

A pest prevention program that defines the methods, responsibilities, and maintenance has been documented, Pest Control Program (Orkin) and was observed to be effectively implemented. The methods uses to make staff aware of the bait control program and measures to take when they come into contact with a bait station were online and in person training. The trending of the pest activity frequency is documented in Service Agreement from 8/31/21. A Pest Contractor has been contracted for pest prevention and an updated scope of service, dated 8/31/21, defines the methods of pest prevention, the frequency of interior and exterior inspections, and targeted pests. A current site map dated 9/19/21 is accurate showing the location of 14 external and 25 internal devices. A list of chemicals used by the Pest Contractor is found in the pest control book and includes SDS information. A pesticide application log gives details and dates of all chemical usage. Licenses of the Pest Contractor, expiring on 9/30/21 from local authorities are current and indicate employees are trained and competent. Inspection activity reports are signed by a management representative after visits and were reviewed and found to be completed as scheduled. Any observations or issues noted by the Pest Contractor are addressed and documented by the site. No animals are allowed on-site in food handling or storage areas.

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: COMPLIANT

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

The site has a Cleaning and Sanitation Program that describes the methods and responsibilities for cleaning of processing equipment, the environment, storage areas, bathrooms and break rooms. Sanitation Standard Operating Procedures are written and include what is cleaned, chemical usage (concentrations, etc.), cleaning methods, frequency of cleaning, and who is responsible. Chemicals, Alkaline Degreaser 45642 and Alkaline Degreaser 50628, were observed to be included on a list of approved chemicals, labeled consistent with regulations and had SDS on hand. Cleaning materials are stored securely and properly labeled with SDS information available to all employees. Dispensed cleaning chemicals were properly stored and identified. Cleaning chemicals mixed on-site have concentration checks conducted by production supervisor and recorded in 3 Bay sink PPM document. There is a suitable area for cleaning containers, knives, cutting boards and other utensils that does not cause a food product contamination. Sanitation tasks and pre-operational inspections by qualified personnel are documented. Pre-operational inspections for 8/30/21, 8/19/21, 7/28/21, 7/13/21 were reviewed and had proper corrective actions documented as required. A verification schedule, documented in the Master Sanitation Schedule, includes the methods, frequencies and responsibilities for verifying the effectiveness of cleaning methods. A master sanitation plan includes all areas of the facility with frequencies and responsibilities for deep cleaning. A review of the plan for 8/30/21, 8/19/21, 7/28/21, 7/13/21 showed cleaning tasks were completed as scheduled. Sanitation personnel are properly trained in cleaning methods and the safe use of chemicals. The last chemical handling training was conducted 2/25/21. Clean-In-Place procedures are not carried out at the site.

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: COMPLIANT

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: Clean-In-Place procedures are not carried out at the site.

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

Employees are prohibited from working in food handling or open food storage areas who are suffering from, or who are or were carriers of, an infectious disease that may be passed through food. The site has documented measures to prevent contact of product materials with bodily fluids and respond appropriately to any bodily fluid spillage. The policy includes the prohibition of any food handling activity for persons with exposed cuts, sores or lesions and requires that minor cuts or abrasions be covered with a waterproof, metal detectable, colored bandage or dressing.

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

Handwashing was observed to be required upon entering food handling or processing areas, after toilet visits, after using a handkerchief, after smoking, eating, drinking, and after handling wash down hoses, cleaning materials, or contamination materials. 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. Soap in a fixed dispenser, paper towels and waste containers are available. Hands-free operated taps and hand sanitizers are available in the high-risk areas of the facility. Signs are posted reminding employees to wash their hands before returning to work. Signs are posted at hand wash stations and in bathrooms. Employees are required to wash hands when wearing gloves. Interviews conducted with batching employee, and QA technician during the audit demonstrated that employees understand the hand washing requirements. Employees were observed to wash their hands properly during the audit and to use proper glove procedures.

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: COMPLIANT

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

A policy, based on a documented risk assessment, found in GMPs defines the site's clothing requirements and been implemented. Clothing including shoes are required to be clean at the commencement of the shift and changed or replaced if excessively soiled. Disposable gloves and aprons are to be changed when soiled or damaged. Employees were observed to comply with the clothing requirements of the facility. Protective clothing was observed to be manufactured from materials that will not pose a risk to food safety. A policy defining jewelry use has been written in the GMP Policy and implemented. Several employees were observed wearing earrings, a nose ring, and necklaces in the production room containing exposed products. The current risk assessment does not support the decision that wearing earrings and necklaces in production would not pose a risk to food safety.

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: MINOR

EVIDENCE: Several employees were observed wearing earrings, a nose ring, and necklaces in the production room containing exposed products. The current risk assessment does not support the decision that wearing earrings and necklaces in production would not pose a risk to food safety.

ROOT CAUSE: ROOT CAUSE ANALYSIS: Our GMPs at the time of audit were based off of the CFR for GMPs. The language from the CFR prohibited “non-secured” jewelry. We interpreted that to mean that earrings with certain types of backs and necklaces did not pose a food safety risk as they were secured and therefore unlikely to fall off. Via our conversations with Mr. Shelton and internally as a food safety team, we determined the risks posed by allowing even “secured” jewelry were greater than the benefits of letting employees wear such items.

CORRECTIVE ACTION: All jewelry, aside from stoneless wedding bands, have been banned in production. Our GMPs and Employee Handbook have been updated to reflect this and this has been communicated to our production team.

Corrective Action Report - CA #8 2... 2.pd

Employee Handbook - Tram ... 10.6.2021).pdf

PRO.QUA.COR.007.B Good Manufacturing

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

11.3.4 Visitors

A policy defining visitor and contractor requirements, found in Visitor, Supplier, Auditor, and Contractor Facility Access Policy, has been documented and implemented. The policy requires that visitors be trained in hygiene and food safety requirements before entering food processing or handling areas, or that they be continually escorted while in those locations. The requirements for visitors in those areas include the proper use of access points, hand wash requirements, suitable protective clothing and footwear, removal of jewelry or other loose objects, and an absence of visible signs of illness.

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)

Employee bathrooms and break rooms were observed to be appropriately lit and ventilated and available for all personnel at the facility. Documented cleaning procedures are staff amenities are documented in 6/28/21. There are facilities for employees to change into and out of protective clothing. Provisions have been made for storage of street clothing and personal items and are separate from processing and storage areas. Change rooms are provided for employees working in high-risk areas. Restrooms and washrooms were observed to be separate from food processing and handling areas and accessed via a separate room or airlock. An area has been provided for the storage of outer garments and other items while using the facilities. Sanitary facilities were observed to be sufficient in number for all employees and were cleaned and maintained on a scheduled basis. Site drawings combined with onsite observations provided satisfactory evidence that sanitary drainage is separated from plant drainage and that it is disposed of in accordance with regulations. The sanitary facilities have hand wash sinks that comply with the requirements of the SQF Code. Lunchrooms that are properly separated from production are available, well lit, properly ventilated and are appropriately sized for the number of facility employees. Lunchrooms include hot and cold potable water, food storage areas, refrigerators with hand and utensil washing capabilities. Outside eating areas are properly maintained to prevent contamination and pest risks. Signs reminding employees to wash their hands before returning to work were observed at the exit to lunchrooms and in or adjacent to outside eating areas where applicable. Lunchrooms were observed to be clean and well-maintained during the audit tours.

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: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

Food handling procedures for all employees are documented and implemented. Personnel are required to access the processing areas through personnel doors only and doors were observed closed. False fingernails or fingernail polish, long nails, false or extended eyelashes are prohibited, and no violations were noted. Hair restraints were observed to be worn where the product is exposed. Ingredients were in appropriate, labeled containers and kept off the floor. The GMP policy prohibits smoking, eating, drinking (except for water under acceptable, controlled conditions) or spitting in the facility. Smoking is permitted only in designated areas. Employee interviews confirmed that employees are trained in good manufacturing practices and are knowledgeable of the requirements. The process flow was observed to be logical, with a continuous flow and designed to prevent cross contamination. It was observed during audit tours that the flow of employees is such that any cross contamination is minimal. Wash down hoses were observed to be properly stored on racks when not in use. Sensory evaluations are not conducted in the food handling/processing areas.

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: Sensory evaluations are not conducted in the food handling/processing areas.

11.5.1 Water Supply

Potable water is sourced for use in the facility for processing and cleaning the premises and equipment. Potable water is supplied from municipality (City of Bedford). It was determined that there was adequate hot and cold water for cleaning and processing. A documented contingency plan, water supply policy was in place should the water supply be contaminated. Back flow devices are installed on water lines. Back flow devices are tested annually, and the last test was conducted on 9/17/21. Water is not stored on site. Non-potable water is not used at this 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: Non-potable water is not used at this 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: Water is not stored on site.

11.5.2 Water Treatment

Water is not required to be treated at the facility.

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

EVIDENCE: Water is not required to be treated at the facility.

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

EVIDENCE: Water is not required to be treated at the facility.

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

EVIDENCE: Water is not required to be treated at the facility.

11.5.3 Water Quality

Water used in processing, cleaning or handwashing is monitored periodically for potability by the site.. Samples from inside the facility are sent to an outside lab for analysis. Based on risk, the site's testing frequency policy is set at a minimum frequency of annually. Minor: The site did not have potable water test results for its annual water testing due in 2021.

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 did not have potable water test results for its annual water testing due in 2021.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This non-conformance was caused by a mistake made on the part of QA. The colisure tests that were needed to conduct the testing arrived prior to our audit, but we did not realize that an incubator was needed to conduct the tests. The incubator was ordered but did not arrive until after the audit. Now that we have the proper equipment, testing of our water will not be an issue.

CORRECTIVE ACTION: Potable water testing was conducted on 10-6-21. The results of these tests are attached.

Total Coliform Sample Tem... Gluten Testing T

Corrective Action Report - CA #9 2021.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/08/2021 **CLOSEOUT DATE:** 10/14/2021

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

RESPONSE: COMPLIANT

11.5.4 Ice Supply

Ice is not used at the facility.

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

EVIDENCE: Ice is not used at the facility.

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

EVIDENCE: Ice is not used at the facility.

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

EVIDENCE: Ice is not used at the facility.

11.5.5 Air and Other Gasses

Compressed air or other gas systems are regularly maintained. Filters are located at the point of use and are of the appropriate micron size to effectively filter the air or gas before contacting food or food contact surfaces. Minor: The site is using compressed air as a rejection device that directly touches open product. That rejected product is sent to a work in process bin and re-used in the same lot on the same production day. At the time of the audit no testing was available for the compressed air. The facility also produces nitrogen gas for some products. The nitrogen is used to flush the bags prior to sealing in the packaging area. The site did not have testing during the audit to show the nitrogen would not present a risk to food safety.

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: MINOR

EVIDENCE: The site is using compressed air as a rejection device that directly touches open product. That rejected product is sent to a work in process bin and re-used in the same lot on the same production day. At the time of the audit no testing was available for the compressed air. The facility also produces nitrogen gas for some products. The nitrogen is used to flush the bags prior to sealing in the packaging area. The site did not have testing during the audit to show the nitrogen would not present a risk to food safety.

ROOT CAUSE: ROOT CAUSE ANALYSIS: Our air testing kit was delayed from the sender, preventing us from conducting these tests prior to our audit. As this was our first audit, we have now learned to order these test kits with ample time ahead of our renewal and this issue will not happen again.

CORRECTIVE ACTION: Compressed air samples and nitrogen samples were collected on 9-30 and were sent to an outside lab for analysis. Results were obtained on 10-8-21& 10-11-21 and the samples were found to be acceptable with regard to pathogens and the air was dry, oil free, and water free. A plan has been put in place by QA to ensure that this testing is conducted on at least an annual basis.

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2021-09-30_69590_21-30322DS.pdf

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/11/2021 **CLOSEOUT DATE:** 10/14/2021

11.6.1 Receipt, Storage and Handling of Goods

The site has implemented effective documented storage plan(s) for the storage of raw materials, ingredients, packaging, equipment and chemicals. The Freight Receiving and Storage, was reviewed during the audit and found to be acceptable. Stock rotation, based on FIFO has been implemented by the site to ensure that all materials, are used within their designated shelf-life. This stock rotation program is documented in Freight Receiving and Storage. Temporary or overflow conditions are not used by the site. The site has not used alternate storage or temporary control measures over the timeframe being audited.

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: Temporary or overflow conditions are not used by the site.

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 has not used alternate storage or temporary control measures over the timeframe being audited.

11.6.2 Cold Storage, Freezing and Chilling of Foods

Cold storage is not required.

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

EVIDENCE: Cold storage is not required.

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

EVIDENCE: Cold storage is not required.

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

EVIDENCE: Cold storage is not required.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Cold storage is not required.

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

Storage areas for raw materials, packaging and finished goods were observed to be located away from any wet areas, clean and well maintained. The product is protected from contamination, deterioration and pest harborage. Racking is designed and constructed from impervious materials and located so storage areas can be cleaned and inspected.

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

A current register of chemicals in the facility, dated 6/28/21, was available. Chemical storage areas were observed to be locked, adequately ventilated, and have appropriate signage. Pesticides are stored separately from cleaning chemicals. Chemical storage areas were observed to be locked and had instructions on handling hazardous chemicals, an up-to-date inventory of all chemicals, available first aid and spill containment equipment. All stored chemicals have current SDS information on file at the facility. Training for employees, Production employee, who handle hazardous chemicals and toxic substances were observed to have training records available. SDS and the label declaration and/or documented approval for the chemical's intended use were reviewed for Tough on Grease, NABC Acid Cleaner and Haynes Lubri-Film. Minor: A green can of CRC food grade penetrating oil was observed to be stored in the production toolbox with caulking. The caulking was not food grade and should have been segregated from food grade oil.

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: MINOR

EVIDENCE: A green can of CRC food grade penetrating oil was observed to be stored in the production toolbox with caulking. The caulking was not food grade and should have been segregated from food grade oil.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This was an oversight by maintenance - the food grade caulk was not returned to its proper home. A sign in sign out form system is being implemented with all maintenance techs.

CORRECTIVE ACTION: The caulking was removed from the drawer and returned to the proper location with the other non-food grade caulks (maintenance office). The food grade penetrating oil is now the only chemical in that drawer. A conversation was had with maintenance about the importance of segregating food grade and non-food grade chemicals. Please see attached picture.

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VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

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

A policy defining the practices for loading, unloading and storage of food products has been documented and implemented in Freight Receiving and Storage. It was observed during the audit tours that food is unloaded, stored and loaded under conditions that prevent cross contamination. The site's policy requires that all trailers be inspected for cleanliness, infestation, odors, damage, etc. before loading and that vehicles be secured from tampering by use of seal or other agreed method. Trailer inspections records were reviewed for 8/30/21, 8/19/21, 7/28/21, 7/13/21. Trailers and vehicles used for transport were observed to be properly secured from tampering by a locked (for LTL loads, sealed for full truck loads). The site's products are not required to be refrigerated. No refrigerated items are received by the site.

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

RESPONSE: COMPLIANT

11.6.5.2 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's products are not required to be refrigerated.

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's products are not required to be refrigerated.

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: No refrigerated items are received by the site.

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

The process of manufacturing high risk foods takes place under controlled conditions in a protected/segregated area. Personnel are dedicated to the high-risk function by using distinctive equipment and protective clothing with separate access points, and staff entering these areas change into clean clothing or don temporary protective outerwear. Employees working in the high-risk area were observed to follow high standards of personal hygiene with minimal risk to the controlled environment and product. The site has a risk assessment in place to precludes them from ambient air testing based on microbiological hazards in the products are minimal due to the low pH and water activity.

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: COMPLIANT

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

EVIDENCE: The site has a risk assessment in place to precludes them from ambient air testing based on microbiological hazards in the products are minimal due to the low pH and water activity.

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

RESPONSE: COMPLIANT

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: COMPLIANT

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: COMPLIANT

11.7.2 Thawing of Food

The facility does not require thawing of any 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

EVIDENCE: The facility does not require thawing of any product.

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

EVIDENCE: The facility does not require thawing of any product.

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

EVIDENCE: The facility does not require thawing of any product.

11.7.3 Control of Foreign Matter Contamination

Metal Detector/Checkweigher Policies 11/9/20 defines the methods and responsibilities to prevent foreign material contamination. The policy's implementation was demonstrated by pre-operational inspections and regularly scheduled maintenance inspections, that are conducted and documented for the condition of equipment and any potential contaminants. A glass register has been documented with glass, brittle plastic and ceramic sources included in all areas of the plant (See 11.7.3.2). The glass register is current as of 9/9/21. Periodic inspections with documentation are made of these areas to ensure breakage has not occurred, and items are not missing or moved. The last inspection conducted on 9/14/21 was reviewed and found to be completed as scheduled. The site's policy requires that any product affected by foreign material contamination be isolated, inspected, reworked or disposed of. The glass policy requires that a thorough cleanup and inspection (including of cleaning equipment and footwear) occur if a glass breakage were to occur. A responsible person, QA Manager and SQFP, is required to inspect the affected area before the restarting of production. Wood pallets were clean and in good condition, and the facility has a policy prohibiting and/or controlling wooden utensils in processing/food handling areas. The site has documented a knife policy, and knives are controlled, cleaned and required to be in good condition. Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate are inspected at Weekly. Records from 9/9/21 were reviewed. Minor: The site is missing a brittle plastic alarm for metal detection rejects, buttons on line 1 for control panel, paper towel and soap dispensers, exit signs above entry way in production, and a Plexi-Glass type material on the flow wrapper on the glass and plastic register. All these observed items are located in production room.

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: MINOR

EVIDENCE: The site is missing a brittle plastic alarm for metal detection rejects, buttons on line 1 for control panel, paper towel and soap dispensers, exit signs above entry way in production, and a Plexi-Glass type material on the flow wrapper on the glass and plastic register. All these observed items are located in production room.

ROOT CAUSE: ROOT CAUSE ANALYSIS: This was a result of being too close to this process. SInce day 1 we have had specific plastic items that need to be checked (i.e. mixer paddles) at the start of each day. However through familiarity we have overlooked many of the more mundane items (paper towel dispensers). We will now monitor every piece of equipment that enters production to ensure that our log is up to date in the future.

CORRECTIVE ACTION: We have created a Brittle Plastics / Glass Register and Inspection Form that accounts for all of the above items and all other Brittle Plastics / Glass in the production room. The list was compiled by the CEO, CPO, and Director of QA all conducting independent walkthroughs of production and combining the lists. This list has been incorporated into our daily set up checks and periodic management walkthroughs.

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Plastic Inspection Checklist .docx

VERIFICATION OF CLOSEOUT: Verified

COMPLETION DATE: 10/06/2021 **CLOSEOUT DATE:** 10/14/2021

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

A policy, Metal Detector/Checkweigher Policies 11/9/20, defining the methods and responsibilities for the use of foreign material detection and removal devices has been documented and implemented. The devices used in the facility are metal detection. Metal detectors are routinely monitored, validated and verified by operations personnel. Demonstration and documentation of the devices were observed during the audit tours. Interviews with employees QA Technician and QA Manager responsible for the monitoring indicated they were knowledgeable and understood what to do if the devices failed when tested with known samples. Devices were observed to reject defective product physically and isolate product. Records reviewed demonstrated the site was verifying the functioning of these devices, documenting any objects rejected or removed by them and implementing corrective actions.

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

A policy defining the methods and responsibilities for handling dry, wet and liquid waste has been documented and implemented, is found in Waste Disposal. Waste was observed to be removed on a scheduled basis and is documented on pre-operational inspections and internal audits conducted by the plant. Waste containers, hoppers, bins and storage areas on the interior and exterior of the facility were observed to be well-maintained and clean. Solid waste from processing was observed to be properly disposed of. Wastewater is discharged to plant drains and collected for disposal to the municipality's wastewater system. A documented procedure Warehouse receiving and production policy is in place to ensure controlled disposal of trademarked materials where required, including a review of any contracted disposal services. Inedible waste designated for animal feed is handled and stored so as not to pose a risk to the animal or to further processing. Reviewed records for film reconciliation from 9/8/21 and 9/10/21 which were observed to be acceptable.

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:** COMPLIANT
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