SQF Food Safety Audit Edition 9
Western Foods - Pure Nature Foods

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
31895 | 157829

AUDIT RATING
88
Good

DECISION DATE
07/11/2022

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
06/19/2023

AUDIT DATES
05/31/2022 - 06/02/2022

EXPIRATION DATE
09/02/2023

ISSUE DATE
07/11/2022

Facility & Scope

Western Foods (44789)
Pure Nature Foods
700 Santa Anita Drive
Suite A
Woodland, CA 95776
United States

Food Sector Categories:
13. Bakery and Snack Food Processing

Products:
Extruded RTE snacks

Scope of Certification:
13. Bakery and Snack Food Processing: Manufacturing of Extruded RTE snacks

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: Shafaee, Amir (207702)
Technical Reviewer: Poziombka, Hagan (10211)

Hours Spent on Site: 20
Hours of ICT Activities: 0
Hours Spent Writing Report: 8

Non-Conforming

2.2.3 Records (Mandatory)

Records Control Procedure, SOP-99-00-2.2.2.1 & 2.2.3.1 to 2.2.3.3 Corp., version 6, dated 3/17/2021, outlines a Records Retention Schedule detailing the records will be maintained for a minimum of 5 years. The records are updated and maintained by SQFP. Records are readily accessible, retrievable, securely stored electronically and as hard copies. Records were observed to be signed and dated by those completing the work. Minor: Several documents such as magnet checks, Packaging Parameter Record Sheet, and CCP logs are not monitored based on the stated time frame in the program.

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: MINOR

EVIDENCE: Several documents such as magnet checks, Packaging Parameter Record Sheet, and CCP logs are not monitored based on the stated time frame in the program.

ROOT CAUSE: Investigating and talking with our associates we determined that the allowable + or – time frame for checks was not effectively communicated to all operators, some of whom are newer in their role and were not aware of the importance of completing all checks within the specified time frame. The + or – time frame was also not documented clearly on all the forms, some of which say “approximately every hour” instead of a specified time frame which doesn’t correctly convey the importance of checking within a specified time frame.

CAPA Form for 2.2.3.2.pdf

CORRECTIVE ACTION: A Good Documentation Practices refresher was conducted on 06/23/2022 with an emphasis on ensuring that all checks are conducted and documented within the time frame listed. All of the forms that are critical to the food safety system were prioritized to make sure they list the specified time frame required by the HACCP plan, and the training included specified instruction about these forms and check. A review of all documentation forms used to record process checks is being conducted to ensure that they all state the required time frame within which the tasks must be performed including the + or – time frame. A training was also completed with the Production Supervisors and the QA Specialists to ensure they understand that they need to be checking that checks were completed in the required time frame when they are reviewing the documentation after the shift.

Good Documentation Practices... 23-2022.pptx

Training Sign In sheet fo... Refresher Trainin

Training Form for Supervisors and QA

VERIFICATION OF CLOSEOUT: The CAPA and supporting training document meet the requirement. A.S.

COMPLETION DATE: 06/23/2022 **CLOSEOUT DATE:** 06/27/2022

2.3.4 Approved Supplier Program (Mandatory)

The site has a written supplier approval policy, SOP.53-00 -2.3.4, version 3, dated 5/23/2021, which has been implemented and covers the procedures for selecting, evaluating, approving, and monitoring suppliers of raw materials, ingredients, and packaging materials. 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 dated 1/17/2022 is maintained of all current approved suppliers, which was reviewed during the audit and found to be acceptable. The register also contained emergency/backup supplier including contact information. Raw materials: Spicy Vegan Nacho Seasoning, Sunflower Oil, Red Lentil Semolina, 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. Supplier audits are based on risk; audits were on file for approved suppliers of ingredients/components: Spicy Vegan Nacho Seasoning, Sunflower Oil, Red Lentil Semolina. Minor: Supplier approval was not basedon risk.

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: MINOR

EVIDENCE: Supplier approval was not basedon risk.

ROOT CAUSE: Supplier Approval was based on the review of supplier documentation and a hazard analysis of the ingredient however a supplier specific risk assessment was never documented.

CAPA Form for 2.3.4.6.pdf

CORRECTIVE ACTION: The Supplier Approval Program SOP has been updated with requirements for a supplier risk assessment to be conducted annually, as well as instructions on how to conduct the supplier risk assessment. In addition, a new Supplier Risk Assessment form has been created in order to document Supplier Risk Assessments. A copy of the updated procedure and an example of a new risk assessment form are attached as evidence. A column on the Supplier Approval Log has been added to include the Supplier Risk Assessment Completion date, to help verify that the risk assessment has been conducted before the supplier is approved and ensure that it is reviewed annually and updated as needed.

Updated Supplier Approval... 2.3.4.6.pdf

Example Supplier Risk Assessm... 2.3.4.6.pd

VERIFICATION OF CLOSEOUT: The updated CAPA and supporting documents meet the requirement. A.S.

COMPLETION DATE: 06/24/2022 **CLOSEOUT DATE:** 06/27/2022

2.4.3 Food Safety Plan (Mandatory)

The two Food Safety Plans have been developed, implemented and maintained by the site based on 12-steps identified in the Codex Alimentarius Commission HACCP guideline and per FSMA requirements, the facility has converted HACCP to included the Preventive Controls. The plans are maintained by company's server. A multi-disciplinary Food Safety Team has been identified and trained, with documentation found in HACCP Programs. The team are representing different department such as maintenance, QA, warehouse, production, etc. The Plan includes include 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 food safety team has analyzed all hazards reasonably likely to occur including physical, chemical and microbiological hazards for each process step, ingredient and packaging. Control measures are in place to eliminate or reduce the food safety risk to acceptable levels. HACCP 1: Snack: Critical Control Points have been identified as CCP 1: Oven/ dryer (250-400 F for 3-5 min depending on product) - CCP2: metal detector (1.5mm Fe, 1.5 mm NFe, 2.0 mm SS) start, every hour ±10min, at the end. Preventive Control have been identified as PC: Supply Chain (Annual), PC: Cleaning and Sanitizing (every cleaning), PC: Allergen control. HACCP 2: Bulk Snack: Critical Control Points have been identified as CCP1: CCP1: Extruder (150 to 185C) at start, hourly ±10 min, at end. CCP2: metal detector (1.5mm Fe, 1.5 mm NFe, 2.0 mm SS) start, every hour ±10min, at the end. Preventive Control have been identified as PC: Supply Chain (Annual), PC: Cleaning and Sanitizing (every cleaning), PC: Allergen control. These are monitored and verified in the Food Safety plans. Any deviations found in monitoring of established control limits are documented and investigated, with proper disposal of involved products. The plans are 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 4/28/2022. Minor: The validation of the CCP1 oven/dryer is incomplete.

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 validation of the CCP1 oven/dryer is incomplete

ROOT CAUSE: The validation of the Oven/dryer CCP was attempted with a surrogate organism at the same time as the study was conducted on the extruder temperature, however a sufficient log reduction was not achieved at the time on the oven. The team conducted a time & temperature study for internal product temperature to reach the required level for killing Salmonella, however this study did not include data to show the length of time the temperature was achieved in the product nor did it include a full temperature mapping of the oven to check for variation.

CAPA Form for 2.4.3.11.pdf

CORRECTIVE ACTION: The HACCP team met to discuss the validation of the Oven/Dryer CCP1, and determined that since the Extruder Temperature is already a validated pathogen reduction step, and is already a CCP for other products made at the PNF facility using the same production process based on some Customer's requests, it makes more sense to make the Extruder Temperature check the CCP #1 for all products and HACCP plans. The HACCP team performed a risk analysis and determined that since this is already effective for one of the extruded snack products, the risk for changing the CCP is low. A training was conducted with all the operators on the updated to the process CCPs on 06/23/2022, and all the HACCP plan documentation has been updated. A copy of the training sign in sheets, and the HACCP Team meeting minutes have been attached as evidence.

HACCP Meeting Docume... 2.4.3.11.pdf

Training Sign In sheet fo... Refresher Trainin

Good Documentation Practices... 23-2022.pptx

VERIFICATION OF CLOSEOUT: The CAPA and supporting documents for CCP meet the requirement. A.S.

COMPLETION DATE: 06/22/2022 **CLOSEOUT DATE:** 06/27/2022

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 SOP-99-99- 2.4.6.1, version 4, dated 1/31/2020. All analyses are conducted to nationally recognized standards or by an equivalent validated method. On site laboratory personnel conducting product sampling and/or environmental testing participate in annual proficiency testing, the last of which was conducted on 11/3/2021. N/A: The facility does not have an on-site chemical or microbiological laboratory that may pose a risk to product safety. (Sections 2.4.4.3 -2.4.4.4). Product evaluation and analytical testing records were reviewed during the audit and found to be conducted per procedures. Minor: There is no documentation that sampling, and testing are representative of the process batch.

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: MINOR

EVIDENCE: There is no documentation that sampling, and testing are representative of the process batch.

ROOT CAUSE: The SQF Practitioner did not realize that how the plant ensures that sampling and testing are representative of the batch needed to be documented.

CAPA Form for 2.4.4.1.pdf

CORRECTIVE ACTION: The product sampling, inspection and analysis SOP has been updated to include details on how PNF ensures that sampling is representative of the batch. A copy of the updated SOP will be attached as evidence.

Updated Product Sampling Inspection

VERIFICATION OF CLOSEOUT: The updated CAPA and updated SOP meet the requirement. A.S.

COMPLETION DATE: 06/24/2022 **CLOSEOUT DATE:** 06/27/2022

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 SOP-01-99-2.5.4 Corp., version 5, dated 3/18/2021. The Internal Audit Program is maintained by SQFP. 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 meetings. This was last completed on 5/13/2022. Internal auditor training records were reviewed for SQFP. Facility and equipment inspections are conducted daily to ensure Good Manufacturing Practices are followed. Records of internal audits were reviewed from 5/6/2022 to 5/2/2022 to 5/13/2022. Objective evidence was observed to be included in records of internal audits. Minor: The current staff conduction internal audit id not independent of the function being audited. Minor: Program states daily inspection and production supervisor needs to review this but neither being done.

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: MINOR

EVIDENCE: The current staff conduction internal audit id not independent of the function being audited.

ROOT CAUSE: Only two people were trained to perform internal audits, the SQF Practitioner, and the Back-up, and due to business needs the SQF Practitioner was performing all the internal audits.

CAPA Form for 2.5.4.2.pdf

CORRECTIVE ACTION: In order ensure that the QA Department is not auditing QA Functions, the SQF Practitioner will schedule the audits of QA functions to be led by the back-up SQF Practitioner/Plant Manager and/or a trained designee from a different department independent from QA. The Internal Audit Schedule for the next year with the lead internal auditor listed in attached as evidence.

Updated CAPA Form for 2.5.4.2.pdf

FO-52-00-2.5.4. INTERNAL AUDIT

VERIFICATION OF CLOSEOUT: The CAPA and supporting document meet the requirement. A.S.

COMPLETION DATE: 06/28/2022 **CLOSEOUT DATE:** 07/07/2022

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: MINOR

EVIDENCE: Program states daily inspection and production supervisor needs to review this but neither being done.

ROOT CAUSE: The QA Associates are supposed to perform an Internal GMP inspection on each of their shifts daily, and then review it with the production supervisor for their shift and the supervisor sign off on it. The QA associates say that sometimes they can't find the production supervisor at the end of their shift and they sometimes just turn the audit report in to the QA manager's box before they go home without waiting for the supervisor to sign in. The QA Associates also said that sometimes they don't have time to complete the internal GMP Audit on their shift because they are helping out with cleaning or production when the production team is short handed. The QA manager has not always held the QA associates accountable when they haven't had time to complete a daily GMP audit on their shift and make sure the production supervisor to review and sing off on the results as long as at least one Daily GMP audit was being completed each production day. Also due to the 24 hour production day, sometimes the date is the same on two audits from the same shift because one audit was conducted in the am hours at the end of the shift, and the next production day it was conducted in the pm hours of the same day so it looks like two audits were completed on the same day, but one was not completed the next day. This could be fixed by including the time the audit was performed to show that is was actually 2 different production days.

CAPA Form for 2.5.4.3.pdf

CORRECTIVE ACTION: The Daily GMP Audit form has been updated to include a space for the time completed to help identify when and on what shift the inspection is being completed. All QA associates and the Production supervisors are receiving documented training on the updated form, and the importance of completing it every shift and making sure that the supervisors review and sign the Daily GMP audits daily. The Dayshift QA personnel were trained 06/20/2022 (The training documentation is attached.) The supervisors and night shift QA will be trained 06/21/2022.

SKM_C45822062015530.pdf

Corrective Action 2.5.4.3 Supervis... shift QA trai

VERIFICATION OF CLOSEOUT: The updated CAPA and supporting documents meet the requirement. A.S.

COMPLETION DATE: 06/21/2022 **CLOSEOUT DATE:** 06/27/2022

11.1.1 Premises Location and Approval

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 State of California Public Health Department for their ongoing operations. Minor: No risk assessment conducted for the site environment.

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: MINOR

EVIDENCE: No risk assessment conducted for the site environment.

ROOT CAUSE: The risk assessment for site location was never properly documented, and this deficiency was not identified in internal audits.

CORRECTIVE ACTION: The HACCP team conducted a new site location risk assessment to take in consideration all of the surrounding buildings and land use and how they might impact the plant. The HACCP meeting notes and the completed risk assessment are attached as evidence.

VERIFICATION OF CLOSEOUT: The CAPA and update risk assessment meet the requirement. A.S.

COMPLETION DATE: 06/22/2022 **CLOSEOUT DATE:** 06/27/2022

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 GMP training. 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 Work Order log. Maintenance personnel are trained in good manufacturing practices and food safety. This was reviewed during the audit and found to be complete. Minor: The communication between maintenance and production for cleaning and QA for verification is not completed on the "Maintenance Clean Up Form".

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: MINOR

EVIDENCE: The communication between maintenance and production for cleaning and QA for verification is not completed on the "Maintenance Clean Up Form"

ROOT CAUSE: The communication and visual inspections for after maintenance clean up and sanitation were being communicated verbally but were not always properly documented. Our maintenance is handled by our parent company's maintenance team, and often communication has been handled by phone, and proper documentation has not always been properly enforced.

CAPA Form for 11.2.2.3.pdf

CORRECTIVE ACTION: The maintenance clean-up form has been updated to have sections for the initials of the associate who cleans the equipment after maintenance is complete, and the initials of the QA associate who performs the visual inspection to verify. Maintenance associates, the production supervisors, and the night shift QA associate have all been trained on the updates to this form and the training forms along with the updated form have been attached as evidence. The dayshift QA associate has been scheduled off for the rest of the week due to production needs, so she will be trained the day that she is called back in to work 6/27.

Corrective Action 11.2.2.3 Maintenance

VERIFICATION OF CLOSEOUT: The provided CAPA and supporting documents meet the requirement. A.S.

COMPLETION DATE: 06/21/2022 **CLOSEOUT DATE:** 06/27/2022

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. 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. Additional racks are set to be installed soon. Minor: There were signs of cobweb along the walls of the warehouse.

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: MINOR

EVIDENCE: There were signs of cobweb along the walls of the warehouse

ROOT CAUSE: The cleaning of cobwebs along the walls in the warehouse was never explicitly listed on the cleaning schedule or documentation, and the janitor missed a few of them in her weekly cleaning activities of the warehouse.

CAPA Form for 11.6.3.1.pdf

CORRECTIVE ACTION: The Weekly Sanitation Checklist has been updated to include checking for and cleaning any cobwebs from the warehouse walls and corners. The janitor is being trained to complete this procedure as part of her weekly cleaning. The training documentation and the updated form are attached as evidence.

Training Sign In Sheet and U... 11.6.3.1 and 11.

VERIFICATION OF CLOSEOUT: The provided CAPA and updated SOP meet the requirement. A.S.

COMPLETION DATE: 06/24/2022 **CLOSEOUT DATE:** 06/27/2022

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Any hazardous chemicals were observed to be properly stored and labeled and did not appear to present a hazard to personnel or food products. A current register of chemicals in the facility, part of the chemical inventory list, was available. Chemical storage areas were observed to be locked, adequately ventilated, and have appropriate signage. No pesticides are stored at site. 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. Daily supplies of chemicals were properly stored. All stored chemicals have current SDS information on file at the facility. Training for employees, operators, 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 In-Fact (chlorinated cleaner), Gleem (Soap), SB Peracetic acid F.

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: Based on the chemical labels on the containers, there were two un-compatible chemicals staged next to each other on the same secondary containment container.

ROOT CAUSE: Plant management understood the chemical to be neutral from the supplier and the information given on the chemical, and did not realize that the supplier had added the precautionary statement to the label. In addition no clear designated organization had been established in the chemical storage cage to make sure that all associates know to keep certain chemicals on separate spill containment pallets.

CAPA Form for 11.6.4.2.pdf

CORRECTIVE ACTION: We brought the chemical supplier representative in on 06/13/22 to help us verify that the correct labels and SDS sheets are being used. The chemical in question (Gleem Dishsoap) is a neutral chemical, however it does have a very small quantity of acid in it which is why the label states not to mix with bleach as a precautionary statement. The chemical cage has been reorganized to separate all alkaline, neutral, and acidic chemicals from each other so that they are not on the same spill containment pallets. Signs have been made and posted in the chemical cage to show where each chemical is to be stored to make sure that incompatible chemicals are not accidentally placed next to each other on the same spill containment pallet again. A picture of the new organization and signs are attached. Only QA and management have access to the combination code to get inside the chemical cage.

VERIFICATION OF CLOSEOUT: The updated CAPA and program meet the requirement. A.S.

COMPLETION DATE: 06/20/2022 **CLOSEOUT DATE:** 06/27/2022

11.7.3 Control of Foreign Matter Contamination

Policy PRP-99-00-11.7.3 version 4, dated 7/29/2021 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. The glass register is current as of 4/19/2022. 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 4/19/2022 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, PO-99-00-11.7.5.4/11.7.7 version 3, dated 6/30/2021, 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 Associate, 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. Minor: There were cleaning tools that had broken/damaged handles in the processing area which were held by tape together. Minor: There is no program in place to monitor gaskets, rubber or any materials that can wear or deteriorate over time.

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: MINOR

EVIDENCE: There were cleaning tools that had broken/damaged handles in the processing area which were held by tape together.

ROOT CAUSE: Employees are aware that if a cleaning tool needs to be replaced, repaired, or need additional cleaning tools that they should let their supervisor know, however we didn't have an established inspection program for the cleaning tools, and we didn't train employees not to use tape on the cleaning tools. Investigation showed that the tape on some of the cleaning tools observed was because the employees wanted better grip on the cleaning tool handles rather than because the tool handle was broken.

CAPA Form for 11.7.3.3.pdf

CORRECTIVE ACTION: A weekly inspection of cleaning tools has been added to the weekly sanitation checklist, and a training was conducted for the Janitor on how to inspect cleaning tool for tape and and any broken parts. Any tools that are unsuitable for use will be removed from use to be either repaired or replaced. A copy of the updated form, and the training documentation are attached for evidence.

Training Sign In Sheet and U... 11.6.3.1 and 11.

VERIFICATION OF CLOSEOUT: The provided CAPA and supporting documents meet the requirement. A.S.

COMPLETION DATE: 06/24/2022 **CLOSEOUT DATE:** 06/27/2022

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: MINOR

EVIDENCE: There is no program in place to monitor gaskets, rubber or any materials that can wear or deteriorate over time.

ROOT CAUSE: The operators are trained to perform a visual inspection as part of their start-up procedure. They are checking for equipment readiness, cleanliness, and wear and tear. They communicate any findings to the supervisor, however this was never explicitly documented on the forms, other than as equipment readiness on the pre-op forms.

CAPA Form for 11.7.3.9.pdf

CORRECTIVE ACTION: A complete process walk was performed to identify all gaskets, rubber, and materials that can wear in the process. These items were added to a newly implemented weekly audit for Gaskets, Rubber, and Materials that can wear. A training was conducted with the QA associates who will be performing this check weekly to check the condition of these materials and notify management so that they can determine if materials need to be replaced or identify if food safety is as risk. A copy of the first inspection performed and the training sign-in sheet for the inspection are attached as evidence.

Training Sign In Sheet and Gas... Materials that

VERIFICATION OF CLOSEOUT: The updated CAPA and supporting document meet the requirement. A.S.

COMPLETION DATE: 06/23/2022 **CLOSEOUT DATE:** 06/27/2022

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Kristen Bailey
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** kbailey@purenaturefoodsco.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Bruce Navarro: Plant Manager, Kristen Bailey: QA Manager/SQFP, Amir Shafaee: SQF Lead Auditor
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** This audit was an announced audit for SQF Food Safety for Food Manufacturing Edition 9.0. Pure Nature Foods Inc. is a privately own company and manufacturer of extruded RTE snacks. The facility is located in a commercial area of Woodland, CA and has approximately 43 employees working 24 hrs. a day Monday-Friday. The facility is about 60,000 sqft with processing of about 15,000 sqft. There are no cooler or freezer at site. The company is in business since 2017 and they are at this location since 2017. The company does not utilize a third-party storage.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Bruce Navarro: Plant Manager, Kristen Bailey: QA Manager/SQFP, Amir Shafaee: SQF Lead Auditor
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Issue certificate once deficiencies are rectified in allotted time.

Section Responses

2.1.1 Management Responsibility (Mandatory)

Management Responsibilities - document# SOP-01-00-2.1.1 & 2.1.2. Corp., version 5, dated 3/17/2021 - outlines the commitment to supply safe food, establish and maintain food safety culture, and continually improve food safety system. It signed by CEO, Plant Manager, and QA Manager on 5/4/2021. A copy of policy is posted in main employee break room and in languages spoken in the facility. It details the Management reporting process and role of the SQF Practitioner. There is an organizational chart which is dated 4.29.2022. It was observed to be up to date and accurate to the current reporting structure of the company. Job descriptions for key personnel were reviewed for QA Manager, Plant Manager, VP Operations and appeared to be adequate and includes the backup person for each department including SQFP. The QA Manager 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 SCS Global/International HACCP Alliance dated 10/29/2015, PCQI cert dated 8/5/2016, SQF cert dated 4/12/2016, Internal Audit cert date 5/13/2016. Plant Manager 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 SCS Global/International HACCP Alliance dated 8/4/2015, PCQI cert dated 8/5/2016, SQF cert dated 10/25/2019, Internal Audit cert date 5/15/20. 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. No blackout periods exist.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2 Management Review (Mandatory)

The entire SQF System is reviewed annually by the site's Food Safety Team with the last review documented and completed on 5/24/2022. 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 Meeting, on any matters that impact the site's SQF System. Monthly meetings from March-May 2022 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 Complaint policy, SOP-31-99.2.1.3.1 to 2.1.3.3 Corp., version 4, dated 3/17/2022, outlines the methods and responsibilities for handling food safety customer, commercial, and authority complaints and has been implemented. The investigation of complaints is handled by SQFP, with corrective actions and records kept of each complaint and resolution. Records of complaints were reviewed for 22-001 open seal, 22-003 flavor and 22-004 seal issue and showed that investigation and corrective actions of the complaints had been put into place. Trending graphs of complaints for the time period Jan-May 2022 were also reviewed.

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)

Food Safety Management system - SOP-01-00-2.1.1, version 4, dated 4/28/2022 - It summarizes the organization's food safety policies and methods to meet the requirements of the current SQF standard and maintained by SQFP. The organizational chart is current with the scope and listing of the products of interest. Procedures to validate justifiable changes to the food safety plan, PRP, GMP, regulatory, specification (raw & finished), and others are present. It is made available to all relevant staff by means of training.

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)

Document Control - SOP-99-00-2.2.2.1 & 2.2.3.1 to 2.2.3.3 Corp. - outlines on how each department specific programs and policies are to be identified, monitored, and maintained. Documents are stored digitally or filing cabinet and controlled by the SQF practitioner. All employees have authorized access to hard copies. An electronic document register is located Company uses an electronic storage and document sharing program for accessibility.

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

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

Records Control Procedure, SOP-99-00-2.2.2.1 & 2.2.3.1 to 2.2.3.3 Corp., version 6, dated 3/17/2021, outlines a Records Retention Schedule detailing the records will be maintained for a minimum of 5 years. The records are updated and maintained by SQFP. Records are readily accessible, retrievable, securely stored electronically and as hard copies. Records were observed to be signed and dated by those completing the work. Minor: Several documents such as magnet checks, Packaging Parameter Record Sheet, and CCP logs are not monitored based on the stated time frame in the program.

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: MINOR

EVIDENCE: Several documents such as magnet checks, Packaging Parameter Record Sheet, and CCP logs are not monitored based on the stated time frame in the program.

ROOT CAUSE: Investigating and talking with our associates we determined that the allowable + or – time frame for checks was not effectively communicated to all operators, some of whom are newer in their role and were not aware of the importance of completing all checks within the specified time frame. The + or – time frame was also not documented clearly on all the forms, some of which say “approximately every hour” instead of a specified time frame which doesn’t correctly convey the importance of checking within a specified time frame.

CAPA Form for 2.2.3.2.pdf

CORRECTIVE ACTION: A Good Documentation Practices refresher was conducted on 06/23/2022 with an emphasis on ensuring that all checks are conducted and documented within the time frame listed. All of the forms that are critical to the food safety system were prioritized to make sure they list the specified time frame required by the HACCP plan, and the training included specified instruction about these forms and check. A review of all documentation forms used to record process checks is being conducted to ensure that they all state the required time frame within which the tasks must be performed including the + or – time frame. A training was also completed with the Production Supervisors and the QA Specialists to ensure they understand that they need to be checking that checks were completed in the required time frame when they are reviewing the documentation after the shift.

Good Documentation Practices... 23-2022.pptx

Training Sign In sheet fo... Refresher Trainin

Training Form for Supervisors and QA

VERIFICATION OF CLOSEOUT: The CAPA and supporting training document meet the requirement. A.S.

COMPLETION DATE: 06/23/2022 **CLOSEOUT DATE:** 06/27/2022

2.3.1 Specification, Formulation and Realization

The policy defining the methods and responsibilities for designing and developing new product formulations and converting product concepts to commercial realization, called SOP-31-99-2.3.1, version 5, dated 6/1/2021, has been implemented. Procedures conducted at the facility include checking formulations and processes with production trials, shelf-life trials, and product testing. Shelf-life trials are conducted to establish "best by" dates, handling & storage requirements, and microbiological criteria. The food safety plan is validated and verified for each new product and process by risk-based analysis. This review includes changes to distribution and ingredients. The facility maintains records of all steps of the product development cycle including process development, shelf-life trials and facility trials. The records for development of new product Bulk Snack were reviewed and found to contain shelf life, product requirement, etc.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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 SOP-53-00-2.3.4, version 3, dated 5/23/2021. Specifications for raw materials, packaging, ingredients, additives, chemicals and processing aids have been documented. Specifications, 3rd party audit, and LOG/LOC for Spicy Vegan Nacho Seasoning, Sunflower Oil, and Red Lentil Semolina were reviewed and found to be current. Raw materials are required to COA at point of receiving. 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 approved supplier program. Product labels are approved by labels are approved by customers but verified at site bg QA manager, 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. A list of current contract service providers is maintained Food Safety Binder, and found to include providers of services including Phenix Equipment, Advanced IPM, Sillier, Calibration Plus. Finished product specifications are current, documented, and approved by the site and its customers. Specifications include chemical limits, physical limits, composition, labeling and packaging requirements. Finished product specifications 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 an annual basis with that last documented review taking place on 4/30/2022.

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. (Sections 2.3.3.1 – 2.3.3.4)

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 third party S&D.

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, SOP.53-00 -2.3.4, version 3, dated 5/23/2021, which has been implemented and covers the procedures for selecting, evaluating, approving, and monitoring suppliers of raw materials, ingredients, and packaging materials. 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 dated 1/17/2022 is maintained of all current approved suppliers, which was reviewed during the audit and found to be acceptable. The register also contained emergency/backup supplier including contact information. Raw materials: Spicy Vegan Nacho Seasoning, Sunflower Oil, Red Lentil Semolina, 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. Supplier audits are based on risk; audits were on file for approved suppliers of ingredients/components: Spicy Vegan Nacho Seasoning, Sunflower Oil, Red Lentil Semolina. Minor: Supplier approval was not basedon risk.

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: MINOR

EVIDENCE: Supplier approval was not basedon risk.

ROOT CAUSE: Supplier Approval was based on the review of supplier documentation and a hazard analysis of the ingredient however a supplier specific risk assessment was never documented.

CAPA Form for 2.3.4.6.pdf

CORRECTIVE ACTION: The Supplier Approval Program SOP has been updated with requirements for a supplier risk assessment to be conducted annually, as well as instructions on how to conduct the supplier risk assessment. In addition, a new Supplier Risk Assessment form has been created in order to document Supplier Risk Assessments. A copy of the updated procedure and an example of a new risk assessment form are attached as evidence. A column on the Supplier Approval Log has been added to include the Supplier Risk Assessment Completion date, to help verify that the risk assessment has been conducted before the supplier is approved and ensure that it is reviewed annually and updated as needed.

Updated Supplier Approval... 2.3.4.6.pdf

Example Supplier Risk Assessm... 2.3.4.6.pd

VERIFICATION OF CLOSEOUT: The updated CAPA and supporting documents meet the requirement. A.S.

COMPLETION DATE: 06/24/2022 **CLOSEOUT DATE:** 06/27/2022

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 per policy P0-52-00-2.4.1 dated 9/20/2021. Regulatory compliance for this operation includes FSMA food safety requirements, allergen content, nutritional labeling, etc. The site keeps updated about changes in relevant legislation, technical developments and industry codes of practice in their specific industry, by means of trade association, web sites, etc. The site has a written provision that the certification body, and SQFI will be notified within 24 hours if a food safety event requiring public notification occurs. Facility is register with FDA. Reg.# XXXXx42992, expire 12/31/2022, and reviewed State of California, Department of Health, Processed Food Registration, Reg# 98582 expire 2/6/2023 and State of California, Department of Health, Organic Processed Food Registration, Reg# 98582 expire 2/6/2023.

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 in food safety binder.

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)

The two Food Safety Plans have been developed, implemented and maintained by the site based on 12-steps identified in the Codex Alimentarius Commission HACCP guideline and per FSMA requirements, the facility has converted HACCP to included the Preventive Controls. The plans are maintained by company's server. A multi-disciplinary Food Safety Team has been identified and trained, with documentation found in HACCP Programs. The team are representing different department such as maintenance, QA, warehouse, production, etc. The Plan includes include 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 food safety team has analyzed all hazards reasonably likely to occur including physical, chemical and microbiological hazards for each process step, ingredient and packaging. Control measures are in place to eliminate or reduce the food safety risk to acceptable levels. HACCP 1: Snack: Critical Control Points have been identified as CCP 1: Oven/ dryer (250-400 F for 3-5 min depending on product) - CCP2: metal detector (1.5mm Fe, 1.5 mm NFe, 2.0 mm SS) start, every hour ±10min, at the end. Preventive Control have been identified as PC: Supply Chain (Annual), PC: Cleaning and Sanitizing (every cleaning), PC: Allergen control. HACCP 2: Bulk Snack: Critical Control Points have been identified as CCP1: CCP1: Extruder (150 to 185C) at start, hourly ±10 min, at end. CCP2: metal detector (1.5mm Fe, 1.5 mm NFe, 2.0 mm SS) start, every hour ±10min, at the end. Preventive Control have been identified as PC: Supply Chain (Annual), PC: Cleaning and Sanitizing (every cleaning), PC: Allergen control. These are monitored and verified in the Food Safety plans. Any deviations found in monitoring of established control limits are documented and investigated, with proper disposal of involved products. The plans are 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 4/28/2022. Minor: The validation of the CCP1 oven/dryer is incomplete.

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 validation of the CCP1 oven/dryer is incomplete

ROOT CAUSE: The validation of the Oven/dryer CCP was attempted with a surrogate organism at the same time as the study was conducted on the extruder temperature, however a sufficient log reduction was not achieved at the time on the oven. The team conducted a time & temperature study for internal product temperature to reach the required level for killing Salmonella, however this study did not include data to show the length of time the temperature was achieved in the product nor did it include a full temperature mapping of the oven to check for variation.

CAPA Form for 2.4.3.11.pdf

CORRECTIVE ACTION: The HACCP team met to discuss the validation of the Oven/Dryer CCP1, and determined that since the Extruder Temperature is already a validated pathogen reduction step, and is already a CCP for other products made at the PNF facility using the same production process based on some Customer's requests, it makes more sense to make the Extruder Temperature check the CCP #1 for all products and HACCP plans. The HACCP team performed a risk analysis and determined that since this is already effective for one of the extruded snack products, the risk for changing the CCP is low. A training was conducted with all the operators on the updated to the process CCPs on 06/23/2022, and all the HACCP plan documentation has been updated. A copy of the training sign in sheets, and the HACCP Team meeting minutes have been attached as evidence.

HACCP Meeting Docume... 2.4.3.11.pdf

Training Sign In sheet fo... Refresher Trainin

Good Documentation Practices... 23-2022.pptx

VERIFICATION OF CLOSEOUT: The CAPA and supporting documents for CCP meet the requirement. A.S.

COMPLETION DATE: 06/22/2022 **CLOSEOUT DATE:** 06/27/2022

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 SOP-99-99- 2.4.6.1, version 4, dated 1/31/2020. All analyses are conducted to nationally recognized standards or by an equivalent validated method. On site laboratory personnel conducting product sampling and/or environmental testing participate in annual proficiency testing, the last of which was conducted on 11/3/2021. N/A: The facility does not have an on-site chemical or microbiological laboratory that may pose a risk to product safety. (Sections 2.4.4.3 -2.4.4.4). Product evaluation and analytical testing records were reviewed during the audit and found to be conducted per procedures. Minor: There is no documentation that sampling, and testing are representative of the process batch.

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: MINOR

EVIDENCE: There is no documentation that sampling, and testing are representative of the process batch.

ROOT CAUSE: The SQF Practitioner did not realize that how the plant ensures that sampling and testing are representative of the batch needed to be documented.

CAPA Form for 2.4.4.1.pdf

CORRECTIVE ACTION: The product sampling, inspection and analysis SOP has been updated to include details on how PNF ensures that sampling is representative of the batch. A copy of the updated SOP will be attached as evidence.

Updated Product Sampling Inspection

VERIFICATION OF CLOSEOUT: The updated CAPA and updated SOP meet the requirement. A.S.

COMPLETION DATE: 06/24/2022 **CLOSEOUT DATE:** 06/27/2022

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

RESPONSE: COMPLIANT

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

RESPONSE: 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 SOP-99-99-2.4.6, version 2, dated 2/1/2018, which were found to be properly implemented in the facility. Methods to segregate, identify, handle and dispose of product include tagging and segregation, and were observed to minimize any inadvertent use. Nonconforming products or equipment is identified, segregated or disposed of, with records maintained by SQFP. This was observed during the audit by a review of the Hold Log for items: PNF 315 and PNF 304. Relevant staff is aware of the site's Hold policy, as evidenced by interviews with production associates.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.6 Product Rework

The site’s policy for reworking product has been documented, SOP- 51-99-2.4.6, version 4, dated 5/13/2019, and implemented. Reworked product will be clearly identified, traceable, inspected and analyzed before release. Facility has not yet rework any product in the last 24 months. The program is in place in the case that facility need to rework any product.

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: COMPLIANT

2.4.7 Product Release (Mandatory)

All products are approved and released per SOP-52-99-2.4.8.1, version 4, dated 5/19/2021. 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 and countries of use. Facility release products are released per Pre-Shipment release review requirement. This includes product evaluations, pre-op inspection, Preventive Controls, Packaging Log, Label Verification, etc. The facility utilizes a positive release method based on microbiological testing per customer requirement. Reviewed "Product Release Verification Form" for 5/27/2022.

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 PRP-52-00-2.4.8, version 7, dated 2/24/2022. This program is the responsibility of SQFP. The sampling and testing program includes 4 samples for listeria spp. and 4 samples for Salmonella for each of zone 2, 3, and 4 on a monthly basis. Records reviewed 4/29/2022 show that corrective actions were taken when unsatisfactory trends were found.

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: COMPLIANT

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 SOP-52-99-2.5.1 & 2.5.2 Corp., version 7, dated 3/18/2021 The entire SQF system is validated by section throughout the year by the SQF Practitioner. The frequency and methods used to validate and verify food safety fundamentals, critical limits, and other food safety controls identified in food safety plans are documented. Critical food safety limits are re-validated at least annually. Records of all verifications of effectiveness and validations are maintained by the SQFP.

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 SOP-52-99-2.5.1 & 2.5.2 Corp., version 7, dated 3/18/2021. The site has established a verification schedule, dated 1/10/2020, outlining the verification frequency and responsibilities for each verification activity. The schedule is maintained by the SQFP. Records of verification of monitoring activities including Metal detector and Packaging were reviewed.

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 SOP-52-99-2.5.5, version 1, dated 9/20/2016. 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. Reviewed F0-52-99-2.5.3.1.Corp. Corrective and Preventive Action log. Records of investigations and corrective actions were reviewed. These were found to have reviews, investigations, corrective and preventative actions and resolutions documented.

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 SOP-01-99-2.5.4 Corp., version 5, dated 3/18/2021. The Internal Audit Program is maintained by SQFP. 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 meetings. This was last completed on 5/13/2022. Internal auditor training records were reviewed for SQFP. Facility and equipment inspections are conducted daily to ensure Good Manufacturing Practices are followed. Records of internal audits were reviewed from 5/6/2022 to 5/2/2022 to 5/13/2022. Objective evidence was observed to be included in records of internal audits. Minor: The current staff conduction internal audit id not independent of the function being audited. Minor: Program states daily inspection and production supervisor needs to review this but neither being done.

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: MINOR

EVIDENCE: The current staff conduction internal audit id not independent of the function being audited.

ROOT CAUSE: Only two people were trained to perform internal audits, the SQF Practitioner, and the Back-up, and due to business needs the SQF Practitioner was performing all the internal audits.

CAPA Form for 2.5.4.2.pdf

CORRECTIVE ACTION: In order ensure that the QA Department is not auditing QA Functions, the SQF Practitioner will schedule the audits of QA functions to be led by the back-up SQF Practitioner/Plant Manager and/or a trained designee from a different department independent from QA. The Internal Audit Schedule for the next year with the lead internal auditor listed in attached as evidence.

Updated CAPA Form for 2.5.4.2.pdf

FO-52-00-2.5.4. INTERNAL AUDIT

VERIFICATION OF CLOSEOUT: The CAPA and supporting document meet the requirement. A.S.

COMPLETION DATE: 06/28/2022 **CLOSEOUT DATE:** 07/07/2022

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: MINOR

EVIDENCE: Program states daily inspection and production supervisor needs to review this but neither being done.

ROOT CAUSE: The QA Associates are supposed to perform an Internal GMP inspection on each of their shifts daily, and then review it with the production supervisor for their shift and the supervisor sign off on it. The QA associates say that sometimes they can't find the production supervisor at the end of their shift and they sometimes just turn the audit report in to the QA manager's box before they go home without waiting for the supervisor to sign in. The QA Associates also said that sometimes they don't have time to complete the internal GMP Audit on their shift because they are helping out with cleaning or production when the production team is short handed. The QA manager has not always held the QA associates accountable when they haven't had time to complete a daily GMP audit on their shift and make sure the production supervisor to review and sing off on the results as long as at least one Daily GMP audit was being completed each production day. Also due to the 24 hour production day, sometimes the date is the same on two audits from the same shift because one audit was conducted in the am hours at the end of the shift, and the next production day it was conducted in the pm hours of the same day so it looks like two audits were completed on the same day, but one was not completed the next day. This could be fixed by including the time the audit was performed to show that is was actually 2 different production days.

CAPA Form for 2.5.4.3.pdf

CORRECTIVE ACTION: The Daily GMP Audit form has been updated to include a space for the time completed to help identify when and on what shift the inspection is being completed. All QA associates and the Production supervisors are receiving documented training on the updated form, and the importance of completing it every shift and making sure that the supervisors review and sign the Daily GMP audits daily. The Dayshift QA personnel were trained 06/20/2022 (The training documentation is attached.) The supervisors and night shift QA will be trained 06/21/2022.

SKM_C45822062015530.pdf

Corrective Action 2.5.4.3 Supervis... shift QA trai

VERIFICATION OF CLOSEOUT: The updated CAPA and supporting documents meet the requirement. A.S.

COMPLETION DATE: 06/21/2022 **CLOSEOUT DATE:** 06/27/2022

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 SOP-99-99-2.6.1 & 2.6.2, version 3, dated 6/9/2021. 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 warehouse associate. Product identification records were reviewed during the audit and demonstrated the products were properly identified throughout the process. Products are identified as example: JJJYS: 03141 =D Julian date one digit for year , S shift of production + facility location and Packing line.

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 SOP-99-99-2.6.1 & 2.6.2, version 3, dated 6/9/2021. 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 SOP-01-99-2.6.3 version 7, dated 9/20/2021 A recall team has been designated and is led by President. 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 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 at least twice a year, 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 during audit for Vegan Nacho - spicy vegan Nacho cheese Seasoning on 6/1/2022. 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. Reviewed mock recall for finished good completed on 5/25/2022.

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 SOP-01-99-2.6.4, version 9, dated 4/18/2022. The Plan has been implemented and addresses serious disaster threats to the extended interruption of the business. President has oversight of the Plan and a Crisis Management team has been identified and trained as evidenced by SOP training done on 7/23/2021. 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. A test of the plan was conducted on 7/23/21 involving a disaster scenario of earthquake that affected the food safety of the site's products. Records are maintained in food safety binder, including follow-up corrective actions of this review and annual test of the Crisis Management Plan. The program also require SQFI and CB notification in case of actual disaster.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

The site has conducted a food defense threat assessment, dated 6/9/2021, 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, SOP-01-99-2.7.1, version 4, dated 6/9/2021, 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, SQFP, 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 training. The threat assessment and prevention plan is required to be reviewed at least annually with the last review documented on 6/9/2021. The Food Defense Plan was last tested and challenged on 5/24/2022 with records reviewed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.2 Food Fraud (Mandatory)

The site has conducted a Food Fraud Vulnerability Assessment, dated 5/23/2022, 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 5/23/2022, to address the control of the identified food fraud vulnerabilities. Instructions have been provided to all relevant staff by means of training. The Vulnerability Assessment and Mitigation Plan were last reviewed by SQFP.

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 PRP-52-99-2.81, version 3, dated 5/26/2021 and is the responsibility of QA Manager. Allergens of concern in this operation were observed to be dairy. 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 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 validated cleaning method 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 to control the accuracy of finished product labels, including labels of allergenic products. This was observed to be implemented on the plant floor. Reviewed allergen validation testing for dairy on 9/26/2022.

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 SQFP. The effectiveness of the facility's training program was evidenced by interviews with plant employees production and QA associates.

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 PRP-99-00 -2.9.corp., version 5, dated 3/5/2021, 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 General HACCP and GMP and interviews with production associates, 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 and Spanish, the languages 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

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 State of California Public Health Department for their ongoing operations. Minor: No risk assessment conducted for the site environment.

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: MINOR

EVIDENCE: No risk assessment conducted for the site environment.

ROOT CAUSE: The risk assessment for site location was never properly documented, and this deficiency was not identified in internal audits.

CAPA Form for 11.1.1.1.pdf

CORRECTIVE ACTION: The HACCP team conducted a new site location risk assessment to take in consideration all of the surrounding buildings and land use and how they might impact the plant. The HACCP meeting notes and the completed risk assessment are attached as evidence.

HACCP Meeting Documen... Assessmer

VERIFICATION OF CLOSEOUT: The CAPA and update risk assessment meet the requirement. A.S.

COMPLETION DATE: 06/22/2022 **CLOSEOUT DATE:** 06/27/2022

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. Waste trap systems are located at back of warehouse, which is away from food handling areas. 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. N/A: The facility does not have overhead pipes carrying sanitary waste or wastewater. (Section 11.1.2.6). 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 covered wood, which are easily cleaned and prevent product contamination. There are no drop ceilings at site. 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.

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: COMPLIANT

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: NOT APPLICABLE

EVIDENCE: N/A: The facility does not have overhead pipes carrying sanitary waste or wastewater.

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

Suitable area is provided for inspection and quality control activities, that are suitable for the examination and testing of the product. The area has easy access to hand washing; appropriate waste handling; and is kept clean.

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: COMPLIANT

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 and heat extraction were observed to be adequate above oven/dryer operations and other heat-generating operations so that no condensation was noted. Facility has positive air with G4 dust filtration.

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: COMPLIANT

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 Extruder were reviewed and found to be complete. Purchasing procedures for equipment are documented in P0-99-00- 11.2.9 version 3, dated 5/24/2022 and were seen to be appropriately implemented. Equipment and utensils, including tables, conveyors, 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, within the warehouse, 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. 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 weekly basis. Exterior inspection records were reviewed from 5/20/2022 and 5/27/2022. 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, PR P-99-00-11.2.10, dated 8/14/2017, 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 Record. Failures of plant and equipment are documented in non-conforming log and are reviewed by maintenance manager 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. The food grade lubricants were noted to be properly labeled and stored separately in Food Grade Lube Storage. 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 GMP training. 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 Work Order log. Maintenance personnel are trained in good manufacturing practices and food safety. This was reviewed during the audit and found to be complete. Minor: The communication between maintenance and production for cleaning and QA for verification is not completed on the "Maintenance Clean Up Form".

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: MINOR

EVIDENCE: The communication between maintenance and production for cleaning and QA for verification is not completed on the "Maintenance Clean Up Form"

ROOT CAUSE: The communication and visual inspections for after maintenance clean up and sanitation were being communicated verbally but were not always properly documented. Our maintenance is handled by our parent company's maintenance team, and often communication has been handled by phone, and proper documentation has not always been properly enforced.

CAPA Form for 11.2.2.3.pdf

CORRECTIVE ACTION: The maintenance clean-up form has been updated to have sections for the initials of the associate who cleans the equipment after maintenance is complete, and the initials of the QA associate who performs the visual inspection to verify. Maintenance associates, the production supervisors, and the night shift QA associate have all been trained on the updates to this form and the training forms along with the updated form have been attached as evidence. The dayshift QA associate has been scheduled off for the rest of the week due to production needs, so she will be trained the day that she is called back in to work 6/27.

Corrective Action 11.2.2.3 Maintenance

VERIFICATION OF CLOSEOUT: The provided CAPA and supporting documents meet the requirement. A.S.

COMPLETION DATE: 06/21/2022 **CLOSEOUT DATE:** 06/27/2022

11.2.3 Calibration

A policy, PRP-52-00-11.2.11, dated 7/2/2018 , 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 this program Inspection and testing equipment is protected from damage or unauthorized use. The facility has developed a calibration schedule for all devices listed. This documentation is located in F0-52-00-11-2.10. The frequency of calibrations is based on the manufacturer's recommendations or customer requirements. A review of the calibration records for Metal detector done 6/7/2021 by Wavesure, Scales done by North State Scale on 5/26/2021, Magnet by Phenix Equipment on 11/16/2021 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, PRP-52-00-11.2.12 version 4, dated 5/9/2019 and was observed to be effectively implemented. No pest activity was identified or noted during tours, that presented a risk for product contamination and corrective action and record keeping procedures are in place should this occur. 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 through training. The trending of the pest activity frequency is documented in pest control binder. A Pest Contractor has been contracted for pest prevention and an updated scope of service defines the methods of pest prevention, the frequency of interior, twice a month, and exterior, twice a month, inspections, and targeted pests. A current site map, dated 12/4/2020 is accurate showing the location of 14 external and 51 internal devices. A list of chemicals used by the Pest Contractor is found in pest control binder and includes SDS information. A pesticide application log gives details and dates of all chemical usage. Auditor reviewed State of California Department of Consumer Affairs, Structural Pest Control board, Reg# PR 1865, dated 7/11/1990. PCO who is the Commercial Pesticide Applicator, Certificate 55178, Expire 6/30/2023 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. N/A: No Pesticide kept at site. (Section 11.2.4.5). 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: NOT APPLICABLE

EVIDENCE: N/A: No Pesticide kept at site

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

RESPONSE: COMPLIANT

11.2.5 Cleaning and Sanitation

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, In-fact (Chlorinated) and SB Peracetic acid F, 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 by auto dilutor. 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, form F0-51-00-11-2-13 Production, for month of May 2022 were reviewed and had proper corrective actions documented as required. A verification schedule, documented in ATP swab, 5/28/2022, 5/27/2022, 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 April to May 2022 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 2/4/2022.

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: N/A: 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. Facility has medical screening program in place.

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; however, the facility does not have high risk areas. 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 production associate and QA associate 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

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 GMP policy and implemented. Jewelry and other loose objects are prohibited in food processing and handling areas. Employees were observed to comply with the jewelry policy during the audit tours. Plain bands are allowed by the facility's policy. Prescribed Medical Alert bracelets are allowed by policy when approved by management.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.4 Visitors

A policy defining visitor and contractor requirements, found in GMP 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 GMP Policy. N/A: Change rooms are not required at this facility. (Section 11.3.5.2). N/A: There are no high-risk areas of the facility. (Section 11.3.5.3). 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. An interview with the SQFP and Plant manager, 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. N/A: There are no outside eating areas provided. (Section 11.3.5.10). Signs reminding employees to wash their hands before returning to work were observed at the exit to lunchrooms. 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:** NOT APPLICABLE **EVIDENCE:** N/A: Change rooms are not required at this facility.
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:** NOT APPLICABLE **EVIDENCE:** N/A: There are no high-risk areas of the facility.
11.3.5.4	Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, food contact zones, food, and packaging storage areas. **RESPONSE:** COMPLIANT
11.3.5.5	Where required, a sufficient number of showers shall be provided for use by staff. **RESPONSE:** COMPLIANT
11.3.5.6	Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and vi. Kept clean and tidy. Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas. **RESPONSE:** COMPLIANT
11.3.5.7	Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations. **RESPONSE:** COMPLIANT
11.3.5.8	Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.3. **RESPONSE:** COMPLIANT
11.3.5.9	Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests. **RESPONSE:** COMPLIANT
11.3.5.10	Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for the introduction of contamination, including pests to the site. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A: There are no outside eating areas provided.

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 or spitting in the facility. Smoking is prohibited in all areas of the site. 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 were conducted in designated areas that were well lit and appropriately equipped for that purpose and personnel conducting sensory evaluations are trained and maintain high hygienic standards.

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: COMPLIANT

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. It was determined that there was adequate hot and cold water for cleaning and processing. A documented contingency plan, PRP-99-11.5 version 3, dated 6/10/2021, 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 4/16/2022. N/A: Non-potable water is not used at this site. (Section 11.5.1.5). N/A: Water is not stored on site. (Section 11.5.1.6).

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: N/A: 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: N/A: Water is not stored on site.

11.5.2 Water Treatment

N/A: Water is not required to be treated at the facility. (Sections 11.5.2.1-11.5.2.3)

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: N/A: 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: N/A: 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: N/A: 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 is set at a minimum frequency of once a year The last potability test was conducted on 4/14/2022 for Coliform.

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: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.4 Ice Supply

N/A: Ice is not used at the facility. (Sections 11.5.4.1 - 11.5.4.3)

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: N/A: 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: N/A: 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: N/A: Ice is not used at the facility.

11.5.5 Air and Other Gasses

Compressed air or other gases, nitrogen, coming in contact with food or food contact surfaces are checked periodically for cleanliness and food safety hazards. Compressed air or other gas systems are regularly maintained and monitored. The frequency of analysis was documented in and determined to be tested on a on annual basis. Records were reviewed for APC, E.coli, Coliform, Yeast, and Mold on 5/5/2022.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.1 Receipt, Storage and Handling of Goods

The site has implemented effective documented storage plan(s) for the storage of raw materials, ingredients, packaging, equipment and chemicals. The Good Warehouse Practices, was reviewed during the audit and found to be acceptable. Stock rotation, based on FIFO and/or FEFO has been implemented by the site to ensure that all materials, including rework, are used within their designated shelf-life. This stock rotation program is documented in this program. N/A: Temporary or overflow conditions are not used by the site. (Section 11.6.1.5). N/A: The site has not used alternate storage or temporary control measures over the timeframe being audited. (Section 11.6.1.6).

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: N/A: 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: N/A: 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

N/A: Cold storage is not required. All products are stored at ambient temperatures. (Sections 11.6.2.1 – 11.6.2.4)

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: N/A: Cold storage is not required. All products are stored at ambient temperatures.

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: N/A: Cold storage is not required. All products are stored at ambient temperatures.

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: N/A: Cold storage is not required. All products are stored at ambient temperatures.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: Cold storage is not required. All products are stored at ambient temperatures.

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

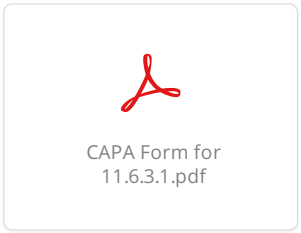
Storage areas for raw materials, packaging and finished goods were observed to be located away from any wet areas. The product is protected from contamination, deterioration and pest harborage. Racking is designed and constructed from impervious materials and located so storage areas can be cleaned and inspected. Additional racks are set to be installed soon. Minor: There were signs of cobweb along the walls of the warehouse.

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: MINOR

EVIDENCE: There were signs of cobweb along the walls of the warehouse

ROOT CAUSE: The cleaning of cobwebs along the walls in the warehouse was never explicitly listed on the cleaning schedule or documentation, and the janitor missed a few of them in her weekly cleaning activities of the warehouse.



CORRECTIVE ACTION: The Weekly Sanitation Checklist has been updated to include checking for and cleaning any cobwebs from the warehouse walls and corners. The janitor is being trained to complete this procedure as part of her weekly cleaning. The training documentation and the updated form are attached as evidence.

VERIFICATION OF CLOSEOUT: The provided CAPA and updated SOP meet the requirement. A.S.

COMPLETION DATE: 06/24/2022 **CLOSEOUT DATE:** 06/27/2022

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

Any hazardous chemicals were observed to be properly stored and labeled and did not appear to present a hazard to personnel or food products. A current register of chemicals in the facility, part of the chemical inventory list, was available. Chemical storage areas were observed to be locked, adequately ventilated, and have appropriate signage. No pesticides are stored at site. 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. Daily supplies of chemicals were properly stored. All stored chemicals have current SDS information on file at the facility. Training for employees, operators, 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 In-Fact (chlorinated cleaner), Gleem (Soap), SB Peracetic acid F.

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: Based on the chemical labels on the containers, there were two un-compatible chemicals staged next to each other on the same secondary containment container.

ROOT CAUSE: Plant management understood the chemical to be neutral from the supplier and the information given on the chemical, and did not realize that the supplier had added the precautionary statement to the label. In addition no clear designated organization had been established in the chemical storage cage to make sure that all associates know to keep certain chemicals on separate spill containment pallets.

CAPA Form for 11.6.4.2.pdf

CORRECTIVE ACTION: We brought the chemical supplier representative in on 06/13/22 to help us verify that the correct labels and SDS sheets are being used. The chemical in question (Gleem Dishsoap) is a neutral chemical, however it does have a very small quantity of acid in it which is why the label states not to mix with bleach as a precautionary statement. The chemical cage has been reorganized to separate all alkaline, neutral, and acidic chemicals from each other so that they are not on the same spill containment pallets. Signs have been made and posted in the chemical cage to show where each chemical is to be stored to make sure that incompatible chemicals are not accidentally placed next to each other on the same spill containment pallet again. A picture of the new organization and signs are attached. Only QA and management have access to the combination code to get inside the chemical cage.

VERIFICATION OF CLOSEOUT: The updated CAPA and program meet the requirement. A.S.

COMPLETION DATE: 06/20/2022 **CLOSEOUT DATE:** 06/27/2022

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 PRP-53-99-11.6.6.9 version 3, dated 6/10/2021. 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 March 2022, April 2022, and May 2022. Trailers and vehicles used for transport were observed to be properly secured from tampering by a seal or other device. N/A: The site's products are not required to be refrigerated. (Sections 11.6.5.5 - 11.6.5.6). N/A: No refrigerated items are received by the site. (Section 11.6.5.7). It was observed that unloading practices are designed to prevent product contamination.

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: N/A: 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: N/A: 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: N/A: 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

N/A: The site does not produce high risk products. (Sections 11.7.1.1 – 11.7.1.5)

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The site does not produce high risk products.

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: N/A: The site does not produce high risk products.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The site does not produce high risk products.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The site does not produce high risk products.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A: The site does not produce high risk products.

11.7.2 Thawing of Food

N/A: The facility does not require thawing of any product. (Sections 11.7.2.1 - 11.7.2.3)

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: N/A: 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: N/A: 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: N/A: The facility does not require thawing of any product.

11.7.3 Control of Foreign Matter Contamination

Policy PRP-99-00-11.7.3 version 4, dated 7/29/2021 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. The glass register is current as of 4/19/2022. 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 4/19/2022 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, PO-99-00-11.7.5.4/11.7.7 version 3, dated 6/30/2021, 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 Associate, 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. Minor: There were cleaning tools that had broken/damaged handles in the processing area which were held by tape together. Minor: There is no program in place to monitor gaskets, rubber or any materials that can wear or deteriorate over time.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: There were cleaning tools that had broken/damaged handles in the processing area which were held by tape together.

ROOT CAUSE: Employees are aware that if a cleaning tool needs to be replaced, repaired, or need additional cleaning tools that they should let their supervisor know, however we didn't have an established inspection program for the cleaning tools, and we didn't train employees not to use tape on the cleaning tools. Investigation showed that the tape on some of the cleaning tools observed was because the employees wanted better grip on the cleaning tool handles rather than because the tool handle was broken.

CAPA Form for 11.7.3.3.pdf

CORRECTIVE ACTION: A weekly inspection of cleaning tools has been added to the weekly sanitation checklist, and a training was conducted for the Janitor on how to inspect cleaning tool for tape and and any broken parts. Any tools that are unsuitable for use will be removed from use to be either repaired or replaced. A copy of the updated form, and the training documentation are attached for evidence.

Training Sign In Sheet and U... 11.6.3.1 and 11.

VERIFICATION OF CLOSEOUT: The provided CAPA and supporting documents meet the requirement. A.S.

COMPLETION DATE: 06/24/2022 **CLOSEOUT DATE:** 06/27/2022

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: MINOR

EVIDENCE: There is no program in place to monitor gaskets, rubber or any materials that can wear or deteriorate over time.

ROOT CAUSE: The operators are trained to perform a visual inspection as part of their start-up procedure. They are checking for equipment readiness, cleanliness, and wear and tear. They communicate any findings to the supervisor, however this was never explicitly documented on the forms, other than as equipment readiness on the pre-op forms.

CAPA Form for 11.7.3.9.pdf

CORRECTIVE ACTION: A complete process walk was performed to identify all gaskets, rubber, and materials that can wear in the process. These items were added to a newly implemented weekly audit for Gaskets, Rubber, and Materials that can wear. A training was conducted with the QA associates who will be performing this check weekly to check the condition of these materials and notify management so that they can determine if materials need to be replaced or identify if food safety is as risk. A copy of the first inspection performed and the training sign-in sheet for the inspection are attached as evidence.

Training Sign In Sheet and Gas... Materials that

VERIFICATION OF CLOSEOUT: The updated CAPA and supporting document meet the requirement. A.S.

COMPLETION DATE: 06/23/2022 **CLOSEOUT DATE:** 06/27/2022

11.7.4 Detection of Foreign Objects

The policy, SOP-51-98-2.4.3.metal Detector Monitoring Procedure, version 3, dated 10/14/2020, defining the methods and responsibilities for the use of foreign material detection has been documented and implemented. The devices used in the facility include metal detectors. Metal detectors are routinely monitored and verified by operations personnel. Demonstration and documentation of the devices were observed during the audit tours. Interviews with employees QA associates responsible for the monitoring indicated they were knowledgeable and understood what to do if the devices failed when tested with known samples. metal detectors were observed to reject defective product physically and isolate product. Records reviewed F0-51-98 -2.4.3.CCP#2 for April-May 2022 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

The policy, PRP-99-00-11.8.1, version 5, dated 6/10/2021, defines the methods and responsibilities for handling dry, wet and liquid waste has been documented and implemented. Waste was observed to be removed on a scheduled basis and is documented on 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, part of this program, 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.

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