SQF Food Safety Audit Edition 8.1

Azteca Bakeries - Azteca Bakeries

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
9143 | 113251

AUDIT RATING
95
Good

DECISION DATE
07/21/2020

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
04/29/2021

AUDIT DATES
05/27/2020 - 05/28/2020

EXPIRATION DATE
07/13/2021

ISSUE DATE
07/22/2020

Facility & Scope

Azteca Bakeries (45048)
Azteca Bakeries
4317 n 43rd ave
phoenix, AZ 85031
United States

Food Sector Categories:
13. Bakery and Snack Food Processing

Products:
Frozen breads, pastries, cookie doughs, frozen baked goods, muffins

Scope of Certification:
Exclusions: None

Certification Body & Audit Team

AIBI Certification Services
1213 Bakers Way
PO Box 3999
Manhattan, KS 66502
United States

Email: GFSI@aibinternational.com

CB#: CB-1-AIBI
Accreditation Body: ANSI
Accreditation Number: 0835

Lead Auditor: Berry, Greg (122689)
Technical Reviewer: Mistry, Narendrakumar (120780)

Hours Auditing: 16
Hours Writing Report: 8

Non-Conforming

2.3.1 Product Development and Realization

1. The product commercialization process is described in the Product Development & Realization procedure. The process is initiated and administered by a process development team. The results of the process is documented & uploaded into SafeFood 360 document database. 2. The commercialization process includes the requirement for establishment and performance of the following: Product specifications Plant trials Food Safety HACCP program review Label review Shelf life trials 3. The facility applies shelf life ranging from 120 -180 days to products manufactured on site. Shelf life trials justifying the time frames have not been completed, therefore not provided for review during the audit. 4. The requirement to verify and validate new products against the food safety plan is included in the commercialization procedure. The results of the review are documented on the SafeFood 360 document database. 5. The results of the new product commercialization process are recorded on the SafeFood 360 document database. The document includes a listing of all the steps of the commercialization process and subsequent completion status. The following new products commercialized during the last year were provided for review: 03/31/20, Bollitos

2.3.1.3 Shelf life trials where necessary shall be conducted to establish and validate a product's: i. Handling and storage requirements including the establishment of "use by" or "best before dates"; ii. Microbiological criteria; and iii. Consumer preparation, storage and handling requirements.

RESPONSE: MINOR

EVIDENCE: The facility applies shelf life ranging from 120 -180 days to products manufactured on site. Shelf life trials justifying the time frames have not been completed, therefore not provided for review during the audit.

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: Product Development and Realization Program has been updated. Shelf life trial procedures have been updated. Validation testing for existing products will begin on 7-20-2020.

VERIFICATION OF CLOSEOUT: Product Development & Realization procedure with instruction for shelf life trial instruction provided for review.

COMPLETION DATE: 07/16/2020 **CLOSEOUT DATE:** 07/19/2020

2.4.3 Food Safety Plan (Mandatory)

1. The facility has a documented HACCP program that is written in conformance with the Codex Alimentarius HACCP program guidelines. The program was last reviewed and approved by the food safety team on 05/25/20. 2. The facility has implemented a HACCP plan which includes the manufacture of the following products: Frozen pastries, baked good, cookie dough, and muffins 3. The HACCP programs are authored and implemented by a team that includes the following staff: Director of operations SQF Practitioner QC Manager Production Manager Sanitation Manager Warehouse Manager Maintenance Manager Assistant SQF Practitioner 4. The scope of the food safety plans covers product processes from raw material receipt through finished product shipment. 5. - 6. There are documented descriptions (specifications) and intended use for products manufactured on site that include information such as ingredients, shelf life, storage & distribution, and intended customer. 7. Process flow diagrams have been completed for the manufacturing processes performed in the facility. The diagrams have been confirmed and signed by the food safety team on 05/25/20. 8. - 9. A documented hazard analysis for manufacturing and the storage and distribution facilities has been completed that includes likely physical, chemical, microbiological hazards from ingredient purchase to material receipt and product shipping. 10. In the hazard analyses controls have been identified for applicable process steps. Controls include sanitation, allergen, trace & recall, and supplier approval. 11. Based on results of the hazard analysis the facility has implemented the following controls: a. Biological hazard control (salmonella), product bake in oven, identified as "kill step" in the control column of the hazard analysis b. Physical hazard control, metal detection as a CCP at the finished product packaging step. 12. - 14. The monitoring, deviation, corrective action, and record keeping requirements for the metal detector CCP at packaging step are described in the HACCP program CCP monitoring table. However, review of the program noted that similar monitoring, deviation, corrective action, record keeping requirements, and supporting validation information have not also been documented for the product biological hazard (salmonella) oven bake "kill step". 15. - 16. The SQFP and the HACCP team are responsible for food safety plan administration and implementation. The program with associated implementation is to reviewed and verified annually, lastly completed on 05/25/20 17. Products manufactured on site are only subject to domestic distribution and thus only required to meet FSMA 21 CFR 117 requirements. The facility food safety plans are integrated into the HACCP program and management has designated the Director of operations as the site PCQI.

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

RESPONSE: MINOR

EVIDENCE: The monitoring, deviation, corrective action, and record keeping requirements for the metal detector CCP at packaging step are described in the HACCP program CCP monitoring table. However, review of the program noted that similar monitoring, deviation, corrective action, record keeping requirements, and supporting validation information have not also been documented for the product biological hazard (salmonella) oven bake "kill step".

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: HACCP Master Plan was updated to show critical limits of bake "kill" step, monitoring activities, records, corrective actions and verification.

VERIFICATION OF CLOSEOUT: HACCP program with CCP monitoring instruction with the control step referenced provided for review.

COMPLETION DATE: 07/16/2020 **CLOSEOUT DATE:** 07/19/2020

2.4.4 Approved Supplier Program (Mandatory)

1. The facility purchases raw materials & components from suppliers that have been evaluated by management. The following material suppliers were reviewed during the audit: Flour, Grain Craft Apple filling, Honeyville Packaging liner, Ace Packaging 2. It was indicated that the producer does not obtain or use materials from non approved suppliers. 3. The supplier approval process is defined in the Approved Supplier Program procedure. The Director of Operations & the SQFP are responsible for reviewing, approving, and monitoring suppliers. 4. Incoming materials are delivered in trailers that are either locked or sealed, then transferred into the warehouse area which are also secure and maintained under the site's security program. 5. A documented food fraud vulnerability assessment was completed for the site. The assessment includes a review of general adulteration vulnerabilities within the site and general mitigation controls. The controls identified and implemented include supplier approval and receipt of CoA with materials. However, the facility uses at least 30 different ingredients ranging from bulk flour, oils, to spices. Review of the vulnerability assessment noted that it includes evaluation of ingredients as a whole, yet does not address unique vulnerabilities for each or different categories of ingredients that are known to have different range of vulnerabilities to food fraud, as noted above, spices vs. bulk flour. 6. Incoming material validation is recorded at time of receipt in the Prims inventory management system by receiving personnel. 7. Raw materials, ingredients, and packaging materials are not received from other facilities under the same corporate ownership. 8. The approval process for ingredient and service suppliers includes an initial and annual review with the submission of the following information: Verification of food safety / HACCP program Specification sheet / CoA Allergen assessment Risk assessment 3rd party food safety certificate 9. Based on risk assessment, onsite audits of suppliers is not performed at this time. 10. Suppliers are listed in the SafeFood 360 Master Data Approved Supplier database worksheet. Review of the register and supplier document folders, found information to include the material supplied, supplier, and contact information adequately maintained for selected suppliers previously noted above.

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

RESPONSE: MINOR

EVIDENCE: A documented food fraud vulnerability assessment was completed for the site. The assessment includes a review of general adulteration vulnerabilities within the site and general mitigation controls. The controls identified and implemented include supplier approval and receipt of CoA with materials. However, the facility uses at least 30 different ingredients ranging from bulk flour, oils, to spices. Review of the vulnerability assessment noted that it includes evaluation of ingredients as a whole, yet does not address unique vulnerabilities for each or different categories of ingredients that are known to have different range of vulnerabilities to food fraud, as noted above, spices vs. bulk flour.

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: The Food Fraud Vulnerability Assessment was conducted using the SSAFE/PWC software tool. Unfortunately, we could not get the questionnaire from SSAFE and received no response. Records of review of this assessment for this audit year have been maintained. As corrective action for this minor, a vulnerability assessment has been created individually for each ingredient.

VERIFICATION OF CLOSEOUT: Ingredient food fraud vulnerability assessment provided for review.

COMPLETION DATE: 06/15/2020 **CLOSEOUT DATE:** 06/15/2020

11.6.1 Storage and Handling of Goods

1. The site storage plan is described in the following documents: Inventory Procedure Facility map The documents define the facility process flow, dedicated process areas and specific storage areas for both raw materials and finished product. 2. Stock rotation practices are described in the Product Identification procedure. Product and material rotation is per FIFO principles. The SQFP and shipping and receiving staff are responsible for program oversight and implementation. The facility utilizes Prism Inventory management software for stock rotation. The system has been coded to rotate materials based on receipt and shelf life date. 3. The facility handles raw material and finished products that have shelf life or expiration dates. Control of these materials is performed, as noted previously, through the inventory management software. Monthly inventory cycle counts are also performed in facility warehouses. Materials are reviewed for condition and remaining shelf life. However, comparison of documentation of four materials with shelf life dates noted the following discrepancies with two of the materials: a. Molasses Manufacturer shelf life = 6 months Manufacturing date = 03/16/20 Expiration date in Prism = 09/14/20, does not match manufacturer recommendation b. Eggs Manufacturer shelf life = 30 days Manufacturing date = 03/26/20 Expiration date in Prism = 04/29/20, does not match manufacturer recommendation 4. The warehouse area for material, packaging and product storage is adequate in space and organization to help facilitate effective material movement and area cleaning and inspection. 5 - 6. Alternate or temporary storage not designed for safe storage are not needed at this time as the facility has sufficient space for holding all materials and product.

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

RESPONSE: MINOR

EVIDENCE: The facility handles raw material and finished products that have shelf life or expiration dates. Control of these materials is performed, as noted previously, through the inventory management software. Monthly inventory cycle counts are also performed in facility warehouses. Materials are reviewed for condition and remaining shelf life. However, comparison of documentation of four materials with shelf life dates noted the following discrepancies with two of the materials: a. Molasses Manufacturer shelf life = 6 months Manufacturing date = 03/16/20 Expiration date in Prism = 09/14/20, does not match manufacturer recommendation b. Eggs Manufacturer shelf life = 30 days Manufacturing date = 03/26/20 Expiration date in Prism = 04/29/20, does not match manufacturer recommendation

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: As corrective action for this minor, all warehouse technicians involved with entering information into the PRIMS software have been re-trained by Warehouse Manager. Additionally, lot-code explanation information tool has been introduced which will allow the warehouse technicians to better-understand the lot codes for different ingredients and decipher accurate expiration dates.

VERIFICATION OF CLOSEOUT: Lot code book and staff training record provided for review.

COMPLETION DATE: 06/04/2020 **CLOSEOUT DATE:** 06/15/2020

11.6.2 Cold Storage, Freezing and Chilling of Foods

1., 2., 4. The producer is involved in the handling and storage of finished products in ambient storage and at 25F. The freezer is estimated to provide at least 100% capacity, it is organized and outfitted with calibrated thermometers within the room. The system temperatures are monitored daily and have automated alarming capability. The alarms are forwarded to the senior management. Review of recent temperature records for the coolers was provided review and found to meet required product storage specifications. 3. Discharge from the cooling and condensing units is generally adequately consolidated with drip pans and directed to piping and floor drains. However, Review of the walk-in freezer observed the following deficiencies: a. There was a significant buildup of ice & frost buildup was observed on the central condensing/cooling unit. The amount noted exceeded the footprint of the under unit drip pan, so that during defrost cycle the melting ice would drop on floor bypassing the drip pan. b. Observation, directly under the unit buildup of ice was noted on the floor. c. Additionally, observed significant buildup of ice and frost on the condenser return piping which did not have a drip pan directly underneath. 5. Loading and unloading docks are adequately organized and clean to help facilitate effective, controlled and organized material handling.

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

RESPONSE: MINOR

EVIDENCE: Discharge from the cooling and condensing units is generally adequately consolidated with drip pans and directed to piping and floor drains. However, Review of the walk-in freezer observed the following deficiencies: a. There was a significant buildup of ice & frost buildup was observed on the central condensing/cooling unit. The amount noted exceeded the footprint of the under unit drip pan, so that during defrost cycle the melting ice would drop on floor bypassing the drip pan. b. Observation, directly under the unit buildup of ice was noted on the floor. c. Additionally, observed significant buildup of ice and frost on the condenser return piping which did not have a drip pan directly underneath.

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: As corrective action for this minor, Maintenance Dept. has increased the frequency of Preventive Maintenance (PM) on the area in question to once every three weeks. The frequency of defrost cycle has been increased from 4 times a day to 6 times a day. Additionally, the duration for defrost cycle has been increased from 30mins to 40mins. The condensate-return piping has been re-insulated to prevent the frost build-up on the piping.

VERIFICATION OF CLOSEOUT: Work order and pictures of completed work provided for review.

COMPLETION DATE: 06/15/2020 **CLOSEOUT DATE:** 06/15/2020

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Annie Bajwa
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** sqf@aztecabakeries.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Greg Berry: SQF Auditor, Richard Jacob: Warehouse Manager, Evelyn Crospa: Sanitation Supervisor, Cody Yamamato: CFO, Ben Lopez: VP Operations, Cecilia Conejo: Assistant SQF Practitioner, Minerva Lopez: HR Manager, Felix Lopez: Owner, Jim White: SQF consultant, Allen Herman: Director of Bakery Operations, Keith Wartchow: Maintenance Manager, Annie Bajwe: SQF Practitioner, Mariel Moreno: QC Manager
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 was an announced SQF Food Safety Code annual re-certification audit of a FSC 13 producer of Frozen breads, pastries, cookie doughs, frozen baked goods, & muffin products for food service customers. The operation established and in this location since approximately 1992 is in a commercial area surrounded by an asphalt road way, commercial buildings, and open space. The facility consists of one building totaling approximately 31,000 sq. ft. in size. The production and warehousing spaces are outfitted with mixers, formers, ovens and semi automated and manual packaging lines. The operation is managed by approximately 100 full time staff working 2 shifts 5 days per week. The facility has implemented one HACCP plan that includes the manufacturing of frozen breads, pastries, cookie doughs, frozen baked goods, and muffin products. All representative processing activities were observed during the audit.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Greg Berry: SQF Auditor, Evelyn Crospa: Sanitation Supervisor, Ben Lopez: VP Operations, Cecilia Conejo: Assistant SQF Practitioner, Minerva Lopez: HR Manager, Jim White: SQF consultant, Allen Herman: Director of Bakery Operations, Annie Bajwe: SQF Practitioner, Mariel Moreno: QC Manager, Hunter Higgins: Production Manager
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Based on the auditor's observations, the facility is recommended for continued certification upon adequate closure of the noted non-conformances.

Section Responses

2.1.1 Food Safety Policy (Mandatory)

1. - 2. The facility mission and food safety and quality goals are described in the Management Policy Statement. The document was signed by the senior management on 03/27/20. The policy written in English & Spanish includes the following company goals: Production of safe and quality food Meeting customer expectations Continual improvement Regulatory compliance The methods to attain the goals include focus on continuous improvement, and employee training and involvement. The statement is included in the food safety management system and communicated to staff during training and via poster located adjacent to the staff.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2 Management Responsibility (Mandatory)

1. The facility reporting structure identifying those who have responsibility for food safety is displayed on the facility organizational chart. The document was last updated on 03/26/20. Staff are made of aware of the reporting structure during staff training. Staff reporting includes the following: CEO VP of Operations Director of Bakery Operations SQF Practitioner Plant Manager Sanitation 2. There is a documented staff training program described in section 2.9 of this report that includes provisions for communication of food safety & quality principles to staff to help ensure that they are aware of how to operate in this type of facility. Supervisory staff have also been identified and tasked with oversight responsibilities to help ensure that the food safety practices are implemented. 3. Based on review of the organizational chart, the facility is adequately staffed with a director of bakery, production manager, SQFP, and production and warehousing workers to help support the implementation of the operation's SQF food safety program. 4. Senior management have designated an SQF Practitioner (SQFP) for the site. The responsibilities are documented in the Management Responsibilities and the same name job description document. Responsibilities include oversight and management of the SQF and food safety programs. 5. The site SQFP, A. Bajwe has been tasked with oversight & implementation of this facility's SQF program. She has completed the following training: Basic HACCP training, dated 01/09/20 PCQI, dated 02/07/20 Based on interview and observation, the SQFP is adequately equipped and understands the SQF program requirements for successful implementation. 6. There is a documented staff training program described in section 2.9 of this report that includes provisions for communication of food safety principles to help ensure that staff are aware of how to operate in this type of facility. The training curriculum includes topics such as SQF, GMP, food safety, and skill based training. 7. Based on review of current training records and interview of selected supervisors and personnel involved in production and warehousing activities during the audit, it was confirmed that staff are adequately trained and aware of the responsibilities for the communication of food safety related issues to supervisors and managers. 8. There are documented job descriptions for operational and food safety positions in the facility listed on the Azteca Bakeries organizational chart. Descriptions include duties, qualifications, and prerequisites. The following jobs were reviewed: CEO VP of Operations Director of Bakery Operations SQF Practitioner Plant Manager Sanitation The Assistant SQF Practitioner & QC Manager have been identified as the backups to the SQFP. 9. The management review process is used to identify areas for continuous improvement in the facility. Methods include review of nonconformances and corrective actions. The following examples of continuous improvement were provided for review during the audit: Developed new maintenance manager position Replacement of mixer Implementation of new record keeping sheet for batch mixing sheet Upgraded Preoperation Inspection sheet 10. Senior management has designated a director of manufacturing, warehouse manager, and other department supervisors with authority for decision making and adequate backup coverage to help support continued operation in the event of organizational disruption. 11. The facility does not currently have black out periods within the unannounced audit window. However, staff are aware of the requirement to communicate these non-work days or black out periods to the SQF certification body.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2.4	Senior site management shall designate an SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF System, including good manufacturing practices outlined in 2.4.2, and the food safety plan outlined in 2.4.3. ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System. **RESPONSE:** COMPLIANT
2.1.2.5	The SQF practitioner shall: i. Be employed by the site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code for Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification. **RESPONSE:** COMPLIANT
2.1.2.6	Senior site management shall ensure the training needs of the site are resourced, implemented and meet the requirements outlined in system elements 2.9, and that site personnel have met the required competencies to carry out those functions affecting the legality and safety of food products. **RESPONSE:** COMPLIANT
2.1.2.7	Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements of the SQF Food Safety Code for Manufacturing, and are informed of their responsibility to report food safety problems to personnel with authority to initiate action. **RESPONSE:** COMPLIANT
2.1.2.8	Job descriptions for those responsible for food safety shall be documented and include a provision to cover for the absence of key personnel. **RESPONSE:** COMPLIANT
2.1.2.9	Senior site management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement. **RESPONSE:** COMPLIANT
2.1.2.10	Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities. **RESPONSE:** COMPLIANT
2.1.2.11	Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed upon unannounced audit. **RESPONSE:** COMPLIANT

2.1.3 Management Review (Mandatory)

1. The requirement for periodic management review of the SQF system is described in the Management Review section of the Facility Policy document. The activity is overseen by the SQFP and is recorded on the Meeting Minutes Review form. The activity is to include an annual review of the following programs: Policy manual Internal audits Complaints Non conformances Corrective actions The last management review, dated 05/04/20, and recorded on the Training Sheet and Internal Audit worksheet was provided for review. 2. The requirement that the SQFP update senior site management on the status of the SQF systems is described n the Management Review section of the Facility Policy document. The SQFP updates senior management during weekly management review meetings. The activity is recorded on the Weekly Management review form. Meetings for the first half of 2020 were provided for review during the audit. 3. The SQFP job description indicates that the SQFP is responsible for oversight and management of program changes. The change management process is described in the Management Review procedure. 4. The aforementioned management review activity completed on 05/04/20 was provided for review during the audit.

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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.4 Complaint Management (Mandatory)

1. The methods for investigating and resolving customer complaints are described in the Complaint Management procedure. Complaints are received by the Sales manager, records the event on the SafeFood 360 Complaint log then forwards to the appropriate department. Complaints are then evaluated, investigated for root cause, corrective action established, and customer notified. The complaint documentation includes information such as product, lot code, complaint, customer, receipt date, root cause, corrective action, and resolution. 2. The SQFP and Food Safety team are responsible for performing a annually trend analysis of complaints. The last analysis was completed on 05/20/20 during the last management review meeting. Review of the analysis found a total of 10 complaints categorized as follows: Packaging, 2 Quality, 8 Food safety, 0 3. Review of selected complaint records found complaints to be adequately investigated with root cause and appropriate corrective actions implemented. 4. Written records of complaints are maintained on site on the SafeFood 360 Complaint log. Review of the following records found complaints to be adequately documented and maintained. 10/08/19, bigote, foul order / sour taste, recipe modification 02/15/20, empanada, product open at seam, product over dusting, prechilling of product, operator training 01/21/20 01/21/20, cookies, white spots on product, equipment setup, operator retraining

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.5 Crisis Management Planning

1. - 2. The response to potential adverse threats to business and the ability to supply safe quality food is described in the Crisis Management Planning Program policy. The document includes the establishment of a response team, responsibilities, team lead - owner, communications, contacts, methods for business continuity, and the evaluation & management of potentially affected materials. 3. - 4. The requirement that the crisis management plan be reviewed, tested, and verified at least annually is included in the Crisis Management Planning Program. Review of program records noted that the review, test, and verification of the program was completed 02/28/20. The activity was a simulated power outage and was documented on a Crisis Management event form.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

1. There is a documented food safety management system compiled in the digital SafeFood 360 document database. The system is comprehensive and indexed correlating with the SQF food safety system programs including information such as facility policies and procedures, pre-requisite programs, HACCP programs, policy statement, organizational chart, scope of certification and products manufactured. The system is maintained by the SQF practitioner and documents are made available to staff upon request. 2. The Food Safety Management policy, Management Commitment statement, and the Document Control Program includes SQFP responsibility for oversight and management of program changes. The documents also include responsibility for the maintenance of the SQF System and the verification and validation of changes to the food safety plan. Review of selected documentation and records during the audit found the SQFP actively involved in the establishment, review and validation of system procedures and documentation. The reason and justification for document or program changes are recorded in the digital SafeFood 360 document database.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

1. Document control practices and the management of procedures, policies, forms, and other controlled documents are described in the Document Control & Record keeping procedure. The SQFP is responsible for program oversight. Selected procedures and documents were found to be adequately approved and managed during the audit. 2. SOPs, forms, and policies are listed on the SafeFood 360 document database. The program includes information such as document title, location, revision #, and approval. The register is current with the selected SOPs and documents reviewed during the audit found listed therein. 3. Production and quality documents are securely stored in the Production department and SQFP offices. In addition, some original documentation is scanned digitally, stored on a company server locally. The digital documents are backed up daily off site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.2.3 Documents shall be safely stored and readily accessible.

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

1. Process monitoring methods are described on production batch record forms and in the HACCP / Food Safety Plan. Record retention requirements are defined in the Document Control & Record Keeping procedure. The document indicates that records are to be held on site for at least two years. 2. Production batch records include documentation such as the following: PRIMs production software database Production workorder Production Report Pre-Operation Daily Checklist mixer, line, packaging Ingredient / Batch Temperature Information Sheet Sample Retention Form Raw Product Weight Check Sheet Code Date Verification Shipping & receiving documents Review of sample records found documentation to be recorded and approved in a timely manner utilizing good documentation practices. The following production batch and records were reviewed during the audit: item 4210 , concha, lot 050237 08/04/20, date 04/06/20 item 40401, cookies, lot 045707 10420, date 04/07/20 item 74470, mantecadas, lot 61745 10420, date 04/07/20 3. Production and quality documents are securely stored in the Production department and SQFP offices. In addition, some original documentation is scanned digitally, stored on a company server locally. The digital documents are backed up daily off site. All requested documentation was supplied in a timely manner during the audit.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.1 Product Development and Realization

1. The product commercialization process is described in the Product Development & Realization procedure. The process is initiated and administered by a process development team. The results of the process is documented & uploaded into SafeFood 360 document database. 2. The commercialization process includes the requirement for establishment and performance of the following: Product specifications Plant trials Food Safety HACCP program review Label review Shelf life trials 3. The facility applies shelf life ranging from 120 -180 days to products manufactured on site. Shelf life trials justifying the time frames have not been completed, therefore not provided for review during the audit. 4. The requirement to verify and validate new products against the food safety plan is included in the commercialization procedure. The results of the review are documented on the SafeFood 360 document database. 5. The results of the new product commercialization process are recorded on the SafeFood 360 document database. The document includes a listing of all the steps of the commercialization process and subsequent completion status. The following new products commercialized during the last year were provided for review: 03/31/20, Bollitos

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.1.3 Shelf life trials where necessary shall be conducted to establish and validate a product's: i. Handling and storage requirements including the establishment of "use by" or "best before dates"; ii. Microbiological criteria; and iii. Consumer preparation, storage and handling requirements.

RESPONSE: MINOR

EVIDENCE: The facility applies shelf life ranging from 120 -180 days to products manufactured on site. Shelf life trials justifying the time frames have not been completed, therefore not provided for review during the audit.

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: Product Development and Realization Program has been updated. Shelf life trial procedures have been updated. Validation testing for existing products will begin on 7-20-2020.

VERIFICATION OF CLOSEOUT: Product Development & Realization procedure with instruction for shelf life trial instruction provided for review.

COMPLETION DATE: 07/16/2020 **CLOSEOUT DATE:** 07/19/2020

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

RESPONSE: COMPLIANT

2.3.1.5 Records of all product design, process development, shelf life trials and approvals shall be maintained.

RESPONSE: COMPLIANT

2.3.2 Raw and Packaging Materials

1. There are documented specifications for incoming ingredients and packaging materials. The specifications are provided by the supplier and include information such as material description, chemical, physical, and microbiological limits, storage and packaging requirements. The Director of operations is responsible for specification approval which is documented in the SafeFood360 database. The following specifications were reviewed during the audit: Flour, Grain Craft Apple filling, Honeyville Packaging, liner Packaging, boxes 2. As part of the Supplier Approval process, the producer requires suppliers to provide legislation compliance documentation in the form of LOG, specification, Kosher, and, Organic certification for raw materials and packaging. Sample compliance documentation was provided for the materials referenced above. 3. The methods and responsibility for developing raw material, ingredient, and packaging specifications are described in the Approved Supplier program procedure. The SQFP is responsible for program oversight and administration. 4. Validation of raw materials is performed by inspection and comparison of materials with associated CoA by warehouse and QC receiving personnel. The results of the inspections are recorded in the Prims & SafeFood 360 inventory control software. 5. Packaging validation is performed through the supplier provision of compliance documentation such as LoG or CoC. Supporting records for the materials referenced above were provided for review during the audit. 6. Products are packaged in bulk, destined for food service and not retail sale. Product labels were found to be complete and compliant, including information such as product identification, net contents, lot number, and manufacturing information. Labels are subject to review and approval by Sales manager & SQFP. 7. Materials, components and packaging are recorded on the SafeFood 360 Master data - products and materials register. The register includes information such as the name of material, item code, storage, and shelf life information. Review of the document found it to be current and complete with the materials referenced above found included therein.

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

RESPONSE: COMPLIANT

2.3.2.2 All raw and packaging materials and ingredients shall comply with the relevant legislation in the country of manufacture and country of destination, if known.

RESPONSE: COMPLIANT

2.3.2.3 The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented.

RESPONSE: COMPLIANT

2.3.2.4 Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, certificate of analysis, or sampling and testing.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.2.7 A register of raw and packaging material specifications and labels shall be maintained and kept current.

RESPONSE: COMPLIANT

2.3.3 Contract Service Providers

1. The producer utilizes the following contract service providers: Pest control Lab Calibration Service specifications are defined in the Contract Services policy which includes the requirements for the approval and monitoring of the providers. 2. The service providers are listed in the SafeFood 360 Master Data module. The documentation includes information such as the name of the provider, address, service description, frequency, and training & licensing requirements. The register is current with the type providers referenced above found therein.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.4 Contract Manufacturers

1. The facility does not use contract manufacturers.

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

RESPONSE: NOT APPLICABLE

2.3.4.2 The site shall: i. Verify compliance with the SQF Food Safety Code for Manufacturing and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the site or other third-party agency to confirm compliance to the SQF Food Safety Code for Manufacturing and agreed arrangements; and ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

2.3.5 Finished Product Specifications

1. The specifications for products manufactured on site are documented on Product Descriptions that include information such as product characteristics, ingredients, nutrition, packaging requirements. Management and customer approval of specifications is recorded in the SafeFood 360 database. The following finished product specifications were reviewed during the audit: item 4210 , concha item 40401, cookies item 74470, mantecadas 2. A listing of finished products is documented in the Product Register Table. Review of the documents found them to include information such as product description, expiration period, and item number. The register was current and complete containing the products manufactured in the facility.

2.3.5.1 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include: i. Microbiological and chemical limits; and ii. Labeling and packaging requirements.

RESPONSE: COMPLIANT

2.3.5.2 A register of finished product specifications shall be maintained.

RESPONSE: COMPLIANT

2.4.1 Food Legislation (Mandatory)

1. - 2. The products under review are only subject to local distribution. The requirement for compliance to regulations is described in the Food Legislation Compliance Program. This document indicates the SQFP and senior management are responsible for ensuring compliance. Compliance is implemented through receipt of materials and products from suppliers who conform to regulations and operating the facility in accordance with established regulations. Products manufactured on site are only subject to domestic distribution and thus only required to meet FSMA 21 CFR 117 requirements. The facility food safety plans are integrated into the HACCP program and management has designated the Director of operations as the site PCQI. Based on observation and interview with the senior management there is adequate understanding of the requirements for maintaining regulatory compliance. Methods for staying up to date with current legislation and industry practices include membership and communications with AIBI, FDA, USDA, and SQFI. 3. The responsibility and requirement to notify SQFI and the certification body in the event of a reportable event is described in the Food Legislation Compliance Program procedure. It was indicated that there have not been any reportable events for the 2019/20 year to date.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

1. The pre-requisite programs used to support the food safety / HACCP programs are documented in the food safety management system. A partial list of the programs implemented in the facility include the following: Sanitation GMP Policy Pest control Customer complaints Traceability & product recall Allergen control Supplier approval Training 2. Based on observation, the facility is designed, constructed, and adequately maintained to help provide areas free from potential adverse impact on food safety or quality. All of the previously mentioned module 2 & 11 pre-requisite programs with sufficient staff have been implemented. No programs have been exempted or excluded.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

1. The facility has a documented HACCP program that is written in conformance with the Codex Alimentarius HACCP program guidelines. The program was last reviewed and approved by the food safety team on 05/25/20. 2. The facility has implemented a HACCP plan which includes the manufacture of the following products: Frozen pastries, baked good, cookie dough, and muffins 3. The HACCP programs are authored and implemented by a team that includes the following staff: Director of operations SQF Practitioner QC Manager Production Manager Sanitation Manager Warehouse Manager Maintenance Manager Assistant SQF Practitioner 4. The scope of the food safety plans covers product processes from raw material receipt through finished product shipment. 5. - 6. There are documented descriptions (specifications) and intended use for products manufactured on site that include information such as ingredients, shelf life, storage & distribution, and intended customer. 7. Process flow diagrams have been completed for the manufacturing processes performed in the facility. The diagrams have been confirmed and signed by the food safety team on 05/25/20. 8. - 9. A documented hazard analysis for manufacturing and the storage and distribution facilities has been completed that includes likely physical, chemical, microbiological hazards from ingredient purchase to material receipt and product shipping. 10. In the hazard analyses controls have been identified for applicable process steps. Controls include sanitation, allergen, trace & recall, and supplier approval. 11. Based on results of the hazard analysis the facility has implemented the following controls: a. Biological hazard control (salmonella), product bake in oven, identified as "kill step" in the control column of the hazard analysis b. Physical hazard control, metal detection as a CCP at the finished product packaging step. 12. - 14. The monitoring, deviation, corrective action, and record keeping requirements for the metal detector CCP at packaging step are described in the HACCP program CCP monitoring table. However, review of the program noted that similar monitoring, deviation, corrective action, record keeping requirements, and supporting validation information have not also been documented for the product biological hazard (salmonella) oven bake "kill step". 15. - 16. The SQFP and the HACCP team are responsible for food safety plan administration and implementation. The program with associated implementation is to reviewed and verified annually, lastly completed on 05/25/20 17. Products manufactured on site are only subject to domestic distribution and thus only required to meet FSMA 21 CFR 117 requirements. The facility food safety plans are integrated into the HACCP program and management has designated the Director of operations as the site PCQI.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.8	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs. **RESPONSE:** COMPLIANT
2.4.3.9	The food safety team shall conduct a hazard analysis for every identified hazard to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT
2.4.3.10	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure. **RESPONSE:** COMPLIANT
2.4.3.11	Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e. a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure. **RESPONSE:** COMPLIANT
2.4.3.12	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard (s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1). **RESPONSE:** MINOR **EVIDENCE:** The monitoring, deviation, corrective action, and record keeping requirements for the metal detector CCP at packaging step are described in the HACCP program CCP monitoring table. However, review of the program noted that similar monitoring, deviation, corrective action, record keeping requirements, and supporting validation information have not also been documented for the product biological hazard (salmonella) oven bake "kill step". **ROOT CAUSE:** Not Applicable **CORRECTIVE ACTION:** HACCP Master Plan was updated to show critical limits of bake "kill" step, monitoring activities, records, corrective actions and verification. **VERIFICATION OF CLOSEOUT:** HACCP program with CCP monitoring instruction with the control step referenced provided for review. **COMPLETION DATE:** 07/16/2020 **CLOSEOUT DATE:** 07/19/2020
2.4.3.13	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT
2.4.3.14	The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure. **RESPONSE:** COMPLIANT
2.4.3.15	The documented and approved food safety plan (s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs or other changes affecting product safety occur. **RESPONSE:** COMPLIANT
2.4.3.16	Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5). **RESPONSE:** COMPLIANT

2.4.3.17	Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements. **RESPONSE:** COMPLIANT

2.4.4 Approved Supplier Program (Mandatory)

1. The facility purchases raw materials & components from suppliers that have been evaluated by management. The following material suppliers were reviewed during the audit: Flour, Grain Craft Apple filling, Honeyville Packaging liner, Ace Packaging 2. It was indicated that the producer does not obtain or use materials from non approved suppliers. 3. The supplier approval process is defined in the Approved Supplier Program procedure. The Director of Operations & the SQFP are responsible for reviewing, approving, and monitoring suppliers. 4. Incoming materials are delivered in trailers that are either locked or sealed, then transferred into the warehouse area which are also secure and maintained under the site's security program. 5. A documented food fraud vulnerability assessment was completed for the site. The assessment includes a review of general adulteration vulnerabilities within the site and general mitigation controls. The controls identified and implemented include supplier approval and receipt of CoA with materials. However, the facility uses at least 30 different ingredients ranging from bulk flour, oils, to spices. Review of the vulnerability assessment noted that it includes evaluation of ingredients as a whole, yet does not address unique vulnerabilities for each or different categories of ingredients that are known to have different range of vulnerabilities to food fraud, as noted above, spices vs. bulk flour. 6. Incoming material validation is recorded at time of receipt in the Prims inventory management system by receiving personnel. 7. Raw materials, ingredients, and packaging materials are not received from other facilities under the same corporate ownership. 8. The approval process for ingredient and service suppliers includes an initial and annual review with the submission of the following information: Verification of food safety / HACCP program Specification sheet / CoA Allergen assessment Risk assessment 3rd party food safety certificate 9. Based on risk assessment, onsite audits of suppliers is not performed at this time. 10. Suppliers are listed in the SafeFood 360 Master Data Approved Supplier database worksheet. Review of the register and supplier document folders, found information to include the material supplied, supplier, and contact information adequately maintained for selected suppliers previously noted above.

2.4.4.1	Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification (refer to 2.3.2) and be supplied by an approved supplier. **RESPONSE:** COMPLIANT
2.4.4.2	The receipt of raw materials, ingredients, and packaging materials received from non-approved suppliers shall be acceptable only in an emergency situation, and provided they are inspected or analyzed before use. **RESPONSE:** COMPLIANT
2.4.4.3	The responsibility and procedure for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented. **RESPONSE:** COMPLIANT
2.4.4.4	The site's food defense plan (refer to 2.7.1.1) shall include measures to secure incoming materials and ingredients and protect them from deliberate act of sabotage or terrorist-like incidents. **RESPONSE:** COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: A documented food fraud vulnerability assessment was completed for the site. The assessment includes a review of general adulteration vulnerabilities within the site and general mitigation controls. The controls identified and implemented include supplier approval and receipt of CoA with materials. However, the facility uses at least 30 different ingredients ranging from bulk flour, oils, to spices. Review of the vulnerability assessment noted that it includes evaluation of ingredients as a whole, yet does not address unique vulnerabilities for each or different categories of ingredients that are known to have different range of vulnerabilities to food fraud, as noted above, spices vs. bulk flour.

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: The Food Fraud Vulnerability Assessment was conducted using the SSAFE/PWC software tool. Unfortunately, we could not get the questionnaire from SSAFE and received no response. Records of review of this assessment for this audit year have been maintained. As corrective action for this minor, a vulnerability assessment has been created individually for each ingredient.

VERIFICATION OF CLOSEOUT: Ingredient food fraud vulnerability assessment provided for review.

COMPLETION DATE: 06/15/2020 **CLOSEOUT DATE:** 06/15/2020

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.5 Non-conforming Product or Equipment

1. The management of non conforming (NC) materials and equipment is described in the Non-Conformance Product or Equipment procedure. The document includes SQFP oversight, steps for the identification, handling, and documenting such events. 2. Non-conforming events are documented SafeFood 360 software database. The following records were provided for review and noted to be adequately maintained: 04/16/20, mold in filling, sent complaint to supplier, rejected and disposed 04/29/20, metal in product, metal from equipment pipe threads, product disposed 04/20/20, WIP product, blood in product, operator error, equipment cleaned and product disposed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.6 Product Rework

1. The facility performs rework related to the recoup and repackaging of product related to quality issues. The methods and responsibilities are described in the Product Rework Program procedure. The QC and production staff are responsible for program implementation. 2. Rework activities are documented on the following: Monthly Rework in / out use sheet Daily Rework Used Log & Production Remain Form The following rework records were provided and found to be adequately maintained during the audit: 04/17/20, concha 04/07/20, cookie 04/29/20, cookie

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

RESPONSE: COMPLIANT

2.4.6.2 Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

2.4.7 Product Release (Mandatory)

1. The product release program with responsibilities and methods is described in the Product Release procedure. The release is to be performed after product packaging is complete by department managers and the Director of Operations. 2. Product release is recorded in the SafeFood 360 software database - Finished Product Baked Register. The following records of release were provided for review and found to be adequately maintained: item 4210 , concha, lot 050237 08/04/20, date 04/06/20 item 40401, cookies, lot 045707 10420, date 04/07/20 item 74470, mantecadas, lot 61745 10420, date 04/07/20

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

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release shall be maintained.

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

1. - 2. The facility has implemented a basic risk based environmental monitoring program. The program requirements are described in the following documents: Environmental Monitoring Production Equipment Cleaning Validation & Verification The QA department is responsible for program implementation. 3. The monitoring program includes instruction for annual surface sampling of zones 1 & 2 for Salmonella and E.coli in production and support areas. The program also includes corrective action instruction for out of specification limits. 4. Sampling and trending results for the previous year were provided for review and noted to be adequately maintained. No out of specification results were noted during the review.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

1. The responsibility for food safety and pre-requisite program verification and validation is described in the following documents: Validation & Effectiveness procedure Verification Schedule table The SQFP is responsible for program oversight and implementation. The validations are documented on the internal audit checklist. 2. Written records of validation activities are maintained. The following program validations were provided for review: Sanitation, annual Allergen control, annual Supplier management

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

RESPONSE: COMPLIANT

2.5.1.2 Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

1. The schedule for verification activities is described in the Verification Schedule table. The table includes information such as the program to be reviewed, as well as information such as what and when to review. Based on the following records reviewed, verification and validation activities are being performed per schedule. 2. The verification of food safety plan and prerequisite programs is described in the following documents: Validation & Effectiveness procedure Verification Schedule table The SQFP and area managers are responsible for program oversight and scheduling of program activities. The documents include instruction, frequency and responsibility for performing verification. 3. Written records of verification activities are maintained on-site. The following selected verification activities were provided and found to be current and adequately maintained: Sanitation, MSS supervisory review Preop Inspection, supervisory review Pest Control, plant manager review Metal detector, SQFP review

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

1. The management of corrective actions (CAs) generated from inspections, complaints, and audits, is described in the Corrective & Preventative Actions procedure. The SQFP and Director of operations is responsible for program oversight, verification, and the management of corrective action records. CAs are recorded in the SafeFood 360 document database. The database includes information such as the finding, root cause, corrective action, responsibility, date, and resolution date. 2. The producer maintains written CA records on site. Review of the following CA records found deficiencies to be adequately investigated, resolved and documentation maintained: 10/08/19, bigote, foul order / sour taste, recipe modification 02/15/20, empanada, product open at seam, product over dusting, prechilling of product, operator training 01/21/20 01/21/20, cookies, white spots on product, equipment setup, operator retraining

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4 Product Sampling, Inspection and Analysis

1. Basic material & product testing is performed on site. The sampling and testing is described in the following procedures: Quality Control Program / Product Sampling, Inspection, and Analysis Specific control and testing programs also support testing. QC and production operators are responsible for implementing product testing. 2. QC technicians are trained on testing annually to help confirm ability to attain accurate results. 3. ISO 17025 certified testing labs, Food Safety Net Services & IAS labs is contracted to perform water, product, and environmental monitoring testing. 4. Digital records of product testing records are adequately maintained on site in the SafeFood 360 software - QC module. The following reports and support records were provided for review and found to be adequately maintained: item 4210 , concha, lot 050237 08/04/20, date 04/06/20 item 40401, cookies, lot 045707 10420, date 04/07/20 item 74470, mantecadas, lot 61745 10420, date 04/07/20

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.4.4 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.5.5 Internal Audits and Inspections (Mandatory)

1. & 5. The facility has implemented a formal internal audit program described in the Internal Auditing & Inspections procedure. The program is managed by the SQFP and the scope includes an annual review of SQF modules 2 & 11 elements. An internal audit schedule is maintained on the Verification Audit Schedule and results of the audits are reported on the schedule worksheet. Complete system review was lastly completed on 05/08/20. 2. The SQFP and those delegated to perform internal audits & inspections have documented internal audit training dated 05/05/20. 3. Interior and exterior facility GMP inspections are performed per the Internal Audits & Inspections procedure. The activity is performed daily inspections recorded on the Daily Inspection Checklist. The report includes program audited, date, findings, and corrective actions. The last inspections completed for the current month were provided for review during the audit. 4. The SQFP schedules the audits and GMP inspections such that staff are not auditing their own programs or areas, typical just performed by the QC.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.5.4	Where practical staff conducting internal audits shall be independent of the function being audited. **RESPONSE:** COMPLIANT
2.5.5.5	Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained. **RESPONSE:** COMPLIANT

2.6.1 Product Identification (Mandatory)

1. The methods for identifying materials, WIP & finished products are described in the Product Identification Program procedure. The Director of operations and warehouse manager is responsible for program oversight and implementation. Material identification and traceability is implemented through the application of labels that have lot numbers and package contents applied to all containers in the facilities. Packaging was observed to be adequately identified in the facilities. 2. Product identification records are adequately maintained as digital and written records on site in production batch records or SafeFood 360 inventory management software. Sample production, shipping and inventory records used for material identification were provided for review during the audit. 3. Product start up and changeover procedures during product packaging are described in the Product Change-over Procedure. The activity includes a review of removal of previous product, line cleaning, and label accuracy. The results of the review are recorded on the Preoperational inspection checklist and the Procedure and Changeover Checklist by the QC technician and the production line lead.

2.6.1.1	The methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in -progress, process inputs and finished products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure: i. Raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are clearly identified during all stages of receipt, production, storage and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements. **RESPONSE:** COMPLIANT
2.6.1.2	Product identification records shall be maintained. **RESPONSE:** COMPLIANT
2.6.1.3	Product start up and changeover procedures during packing shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label, and that the changeover is inspected and approved by an authorized person. **RESPONSE:** COMPLIANT

2.6.2 Product Trace (Mandatory)

1. Material and product traceability methods are described in the Product Trace Withdrawal & Recall procedure. The warehouse and plant managers are responsible for program implementation. Raw materials and finished product each have unique lot numbers that help identify where materials are used in production and to where finished product is shipped. The Prism inventory control software system is used to help implement material traceability. In order to verify the effectiveness of the traceability program, an annual one up and back trace exercise is conducted on raw material, packaging, and finished product. The last trace exercises were successfully completed as follows: 02/03/20, finished product & material, 100% recovery within 3 hrs. 05/06/20, packaging, 100% recovery within 1.5 hrs. 2. Records of raw material use and product dispatch are maintained on site. The following sample records providing material traceability were provided for review during the audit: PRIMs production software database Production workorder Production Report Pre-Operation Daily Checklist mixer, line, packaging Ingredient / Batch Temperature Information Sheet Sample Retention Form Raw Product Weight Check Sheet Code Date Verification Shipping & receiving documents

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

2.6.3 Product Withdrawal and Recall (Mandatory)

1. The product recall program is described in the Product Trace Withdrawal & Recall procedure. The document includes provision for the following: Recall classification Recall team & team member responsibilities Detailed procedures for performing withdraw of product Designated Recall Coordinator Communication with regulatory agencies 2. The recall procedure requires the investigation and establishment of the root cause for the recall. It was indicated that the facility has not been involved in any product recalls. 3. The Product Recall procedure includes the requirement to review and test the effectiveness of the program annually. The facility had completed a mock recall which included a material trace exercise on 05/06/20. 4. The requirement for notification of SQFI and SQF certification body within 24 hours of the event is also included in the procedure. 5. The recall activity is recorded on the Mock Recall Summary form. The last mock recall was provided for review during the audit. It was indicated that there have not been any actual product recalls for the 2019/20 time period.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

1. Facility security and defense is described in the Food Defense Plan. The document includes establishment of team, team lead - Director of Operations measures for management of interior and exterior security, and communications and response actions. 2. Per the food defense plan, facility security provisions include implementation of the following: Locked doors Management of visitors and contractors Employee awareness training Employee background checks Trailers locked and seal check verification Computer password protection The security measures observed in place help provide adequate facility control. There were no obvious facility security issues observed during the audit. 3. - 4. The food defense plan includes the provisions for the performance of an annual site threat assessment lastly completed on 11/11/19. The program also requires a test and review of the plan, lastly completed on 05/11/20. The challenge scenario was an incoming trailer without required lock & seal.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.7.1.3	The food defense plan shall be reviewed and challenged at least annually. **RESPONSE:** COMPLIANT
2.7.1.4	Records of reviews of the food defense plan shall be maintained. **RESPONSE:** COMPLIANT

2.7.2 Food Fraud

1. - 2. The methods for prevent food fraud in the site and for incoming materials are described in the Food Fraud Program procedure. The SQFP is responsible for program oversight and implementation. Program review is to be performed annually, lastly reviewed 10/17/19. 3. A documented food fraud vulnerability assessment was completed for the site. With exception noted in item 2.4.4, the assessment includes a review of general adulteration vulnerabilities within the site and general mitigation controls. 4. The vulnerability assessment with associated mitigation plan was provided for review during the audit.

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

2.8.1 Allergen Management for Food Manufacturing (Mandatory)

1. The producer is involved in the direct handling of four of the eight major allergens (soy, egg, wheat & milk) however only one (soy) is unique to products. The control of the allergens in the facility is described in the following documents: Allergen Management Cleaning Validation & Verification The documents includes the following provisions: Allergen listing Material risk assessment Staff awareness training Supplier assessment & allergen guarantees GMP practices, handwashing and the restriction of food from the facility Storage and labeling practices Spill response Allergen workplace-related assessment 2. Product and material labels have ingredient statements that include listing of allergens included in the product. 3. Material and product traceability is defined in the product identification and traceability procedures. Traceability of allergenic materials and products was observed to be adequately implemented during the audit. 4. Between allergen and non allergen containing products full cleaning and sanitation is performed of all product contact equipment per associated equipment SSOPs. 5. Verification of cleaning effectiveness is performed using ATP & protein specific allergen swabs on product contact equipment after cleaning and sanitization is performed. Recent testing records were provided for review for raw material dispensing area and blender. 6. Line clearance and changeover verifying line sanitation and label accuracy is performed between all products. Staff effectively demonstrated the procedure and record keeping requirements during the audit. 7. - 8. Finished products have labels that include an ingredient statement with all allergens used in the product. Regulatory review of labels is performed by the QA department during the product development process. 9. Ingredient traceability for ingredients and packaging is captured in the production batch record and shipping and receiving documentation. 10. The management of rework and like into like processing with record keeping and release procedures are described in the product rework program 11. The facility handles allergens.

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

2.8.1.2	Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in progress, rework or finished product on how to identify, handle, store and segregate raw materials containing allergens. **RESPONSE:** COMPLIANT
2.8.1.3	Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored. **RESPONSE:** COMPLIANT
2.8.1.4	Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided where satisfactory line hygiene and clean-up or segregation is not possible. **RESPONSE:** COMPLIANT
2.8.1.5	Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented. **RESPONSE:** COMPLIANT
2.8.1.6	Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact. **RESPONSE:** COMPLIANT
2.8.1.7	The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured. **RESPONSE:** COMPLIANT
2.8.1.8	The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in-progress and finished product is true to label with regard to allergens. Such measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures. **RESPONSE:** COMPLIANT
2.8.1.9	The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used. **RESPONSE:** COMPLIANT
2.8.1.10	Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable. **RESPONSE:** COMPLIANT
2.8.1.11	Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introducing unintended allergens through supplier, contract manufacturer, employee and visitor activities. **RESPONSE:** COMPLIANT

2.8.2 Allergen Management for Pet Food Manufacturing

1. - 2. The producer is not involved in pet food manufacturing.

2.8.2.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those inputs and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A list of allergens which is accessible by relevant staff; and iv. The hazards associated with allergens and their control incorporated into the food safety plan. **RESPONSE:** NOT APPLICABLE

2.8.2.2 Product labeling, in accordance with regulatory requirements, shall include allergens where risks from cross-contact have been identified.

RESPONSE: NOT APPLICABLE

2.8.3 Allergen Management for Manufacturers of Animal Feed

1. - 2. The producer is not involved in animal feed manufacturing.

2.8.3.1 Sites that exclusively manufacture animal feed and do not manufacture, handle or store food or pet food products are not required to implement an allergen management plan unless required by regulation or customer requirement.

RESPONSE: NOT APPLICABLE

2.8.3.2 Where an allergen management plan is required by regulation or customer specification, the requirements of 2.8.2 shall apply.

RESPONSE: NOT APPLICABLE

2.9.1 Training Requirements

1. - 2. The facility administers documented GMP, HACCP, hygiene, and task specific on the job training (OJT) to manufacturing and warehouse staff. The provisions for training staff are described in the following Employee Training procedure. Training events are recorded and were provided for review. Based on interviews, observations and records review staff demonstrated understanding in food safety principles and proper operation in a GMP environment.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

1. The provisions for training staff are described in the Employee Training procedure. The program is administered by the SQFP and the Director of Operations and includes provisions for training full and part time staff. The training program is documented and covers topics such as GMPs, food safety, and HACCP programs.

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

RESPONSE: COMPLIANT

2.9.3 Instructions

1. There are documented SOPs that cover operational, cleaning, and support activities performed in the facilities. Procedures are written in English (primary language) and Spanish available to staff in both digital and hard copy form..

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

RESPONSE: COMPLIANT

2.9.4 HACCP Training Requirements

1. The members of the HACCP team involved in the implementation of the program and associated CCPs or CPs have documented HACCP training. Based on interviews, observations and records review staff demonstrated adequate understanding of the implementation of the food safety and HACCP program.

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

RESPONSE: COMPLIANT

2.9.5 Language

1. Training is documented and administered in English & Spanish. All staff interviewed during the audit could adequately understand and communicate in English & Spanish during the audit.

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

RESPONSE: COMPLIANT

2.9.6 Refresher Training

1. Refresher training that includes the following topics is administered to staff annually: GMPs Food safety Allergen control Food defense Sanitation Personal hygiene Blood borne pathogens Review of selected staff training records found training current.

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

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

1. Training is recorded and managed using ISolved software which has the ability to generate a register that includes staff name, training module, and date training completed. Training events are also recorded in the ISolved software and trainee comprehension and competency is assessed through the administration of quizzes. Review of the following selected staff training information found the training records to be complete and adequately maintained: h.t. QC tech, HACCP & food safety, 05/19/20 a.p., production lead, HACCP & food safety, 05/19/20 m.m., mixer operator, HACCP & food safety, 05/19/20 c.c., sanitation tech, HACCP & food safety, 05/19/20 k.w., maintenance tech, HACCP & food safety, 05/19/20

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

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

1. The facility is located in a mixed rural / commercial area bordered by an asphalt roadway, other light commercial buildings and open space. During the tour of the exterior facilities there were not adjacent facilities, operations or roadways in the immediate vicinity considered as having a negative impact on this operation or products handled therein. Exterior facility condition is reviewed during regular GMP inspections. 2. The facilities are built to local regulations and registered as follows: FDA food facility registration, due 12/31/20 Arizona Dept. of Revenue, 12/31/20

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.1 Materials and Surfaces

1. Product contact surfaces in the processing, packaging, cleaning, and loading & unloading areas were composed of cleanable stainless steel and unpainted synthetic surfaces. No obvious food safety risks were observed with other support area non product contact surfaces.

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

RESPONSE: COMPLIANT

11.2.2 Floors, Drains, and Waste Traps

1. - 2. Processing area floors are permanent, smooth, and epoxy coated concrete or sealed brick. They were generally cleanable and in adequate condition during the audit. 3. Floor drains are installed in the processing area. They were observed to be adequately maintained and clean during the audit. 4. Waste trap systems were not observed to have been installed in the facilities.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Waste trap systems were not observed to have been installed in the facilities.

11.2.3 Walls, Partitions, Doors and Ceilings

1. Processing and warehouse area interior walls are composed of permanent light colored insulated sheet metal, drywall, cinder block or concrete. Walls were observed to be clean and in good condition during the audit. 2. Wall to floor junctures in the processing, warehouse, and support areas are clean, smooth, and designed to allow for effective cleaning. 3. - 4. Overhead utility ducting and support piping throughout the processing and warehouse areas are accessible and composed of cleanable smooth surfaces. The equipment was observed to be clean and adequately sealed to help prevent potential overhead waste contamination of product during the audit. 5. The facilities are constructed with solid doors, which were found to be in good condition with smooth, painted cleanable surfaces. The facility windows of the same solid construction and shatterproof glass, were also observed to be in good condition. 6. The facilities are constructed with structurally sound walls, roof and permanent ceilings The structure is adequate in providing an integral protected area for the handling and storage of materials and product. 7. Processing support areas have drop ceilings that have been adequately designed with removable ceiling tiles to help provide access for service.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.3.3 Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed to prevent the contamination of food, ingredients and food contact surfaces and allow ease of cleaning.

RESPONSE: COMPLIANT

11.2.3.4 Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients and food contact surfaces, and shall allow ease of cleaning.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.3.6 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.4 Stairs, Catwalks and Platforms

1. There are stairs and platforms used in manufacturing and support areas for equipment and process monitoring access. The equipment was observed to have been maintained in good condition, cleanable and not an obvious potential source of contamination.

11.2.4.1 Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1).

RESPONSE: COMPLIANT

11.2.5 Lightings and Light Fittings

1. The processing, inspection and support areas are sufficiently lit with overhead fluorescent and LED lighting of adequate intensity. 2. The lighting in the production and support areas is shatterproof and contained. There were no signs of breakage during the facility tour. 3. The lighting in the processing, loading & unloading, and support areas is shatterproof and contained. There were no signs of breakage during the facility tour.

11.2.5.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.6 Inspection / Quality Control Area

1. The manufacturing areas, where material and product inspections occur have adequate work space, stainless steel tables and lighting to allow staff to perform thorough material inspections. 2. The inspection area on the production floor has a stainless steel table with adequate space and lighting. A hand wash station has been installed nearby for easy access.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.7 Dust, Insect, and Pest Proofing

1. Windows and doors in the warehouse area were functional and observed to be adequately sealed to help prevent entry of pests and dirt into the facility. 2. The personnel access doors into the processing area are located on the first floor of the facility. The doors were observed to be self closing, functional and adequately sealed when closed. 3. The commercial roll up warehouse doors in the loading and unloading areas were observed to be in good operational condition, adequately sealed and with door openers. The doors were observed to be closed when not in use during the audit. 4. Electric insect control devices are located on perimeter walls near to doors and entrances with little contamination risk to the product, packaging or processing equipment. Poison or rodenticide bait is not used inside product or ingredient storage or processing areas.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.8 Ventilation

1. - 2. The facility is adequately ventilated with exterior air through an HVAC system which is included in a regular maintenance program. 3. Ovens are used for baking activities in the manufacturing process. The baking area is sufficiently ventilated with no obvious accumulation of steam or dust noted during the audit.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.9 Equipment, Utensils, and Protective Clothing

1. Equipment, utensils and PPE specifications purchasing procedures are described in the following documents: Fixed Asset & Capitalization Memo Approved Supplier Program 2 - 3. The producer utilizes stainless steel tables and conveyors composed of cleanable stainless steel and synthetic surfaces for handling and manipulating product. The equipment was found to be in good condition and clean during the audit. 4. Reusable product handling sampling utensils were observed in use in the facility. The utensils are composed of plastic or stainless steel and found to be in good condition and clean. 5. Waste & overflow water is not generated in the facility. 6. Protective clothing other than hair & beard nets, gloves, and disposable aprons are not required in the operation. The items are designated for use in food manufacturing facilities. 7. Coat racks are provided to staff for temporary storage of personnel clothing in the employee locker room and at the employee entrance into the processing area. 8. Equipment and utensils are subject to regular cleaning after and prior to use per the cleaning and sanitation procedures.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Waste & overflow water is not generated in the facility.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.10 Premises and Equipment Maintenance

1. The methods and responsibility for the maintenance of plant, equipment and buildings are described in the Maintenance Program procedure. Unscheduled or emergency work is documented per the non-conforming materials and equipment program. The Facility Manager is responsible for program oversight. 2. A maintenance schedule to cover building, equipment and other areas of the premises is documented in SafeFood 360 - Maintenance. The schedule includes processing equipment, facilities and utilities and associated frequencies. The following PM activities for the following facility equipment were reviewed and found to be current and complete per schedule: Mixer, monthly, 05/22/20 Compressed air, quarterly, 08/07/20 Sifter, quarterly, 04/10/20 Packaging line, monthly, 05/12/20 Oven, 6 weeks, 05/25/20 Spiral freezer, weekly, 05/22/20 Water backflow device function testing, 07/02/19 3. The facility maintenance program includes provisions for the management and documentation of equipment failures. 4 - 5. In order to help ensure processing equipment is maintained per GMPs, in-house maintenance staff are subject to GMP training as part of qualification as technicians. Contractors are also required to read and sign the Contractors Visitors Sign in log, Safety and GMP policy statement upon entrance into the facility. Based on observation, the handling of equipment is performed according to schedule and per GMPs. 6 - 7. Equipment pre work and return to production and cleaning requirements are recorded on the PM workorders. 8. The management of temporary repairs is included in the maintenance program Such repairs were not observed on production equipment in the facility. 9. Tool accounting is included in the maintenance work order record and pre-operational inspections are performed prior to returning equipment to service. 10. Product handling equipment is maintained with only food grade lubricants. Based on review of product labels the materials were confirmed to be NSF H1 allergen free and acceptable for use in food processing applications. The materials were stored in a cabinet in the maintenance area dedicated for food grade lubricants. The application of lubricants on production equipment was applied judiciously without excess or obvious potential for product contamination. 11. Paint was not observed to have been applied in processing handling areas or contact zones. Paint applied on storage racks was observed to be in good condition without obvious flaking or potential for product contamination.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.11 Calibration

1. Calibratable instrumentation is used for product and process monitoring. The methods and responsibility for the calibration of the instrumentation is described in the Calibration Program procedure. The program is administered by the Maintenance Manager and the QC department 2. The provisions for addressing the disposition of potentially affected products related to out of calibration (OOT) are described in the Calibration Procedure. The facility manager and QA department are responsible for investigating and determining product impact. It was indicated that there have not been any such events since the last audit. 3. Instrumentation was found to be organized and clean, adequately protected and securely maintained in the processing and packaging areas on stainless steel work benches. 4. Based on review of selected calibration records, instrument calibrations are performed according to manufacturer's recommendations or industry standards utilizing N.I.S.T. standards and recognized methods and frequencies. 5. Instrumentation is tested and calibrated utilizing N.I.S.T. standards and documented industry recognized methods. The methods used to calibrate were found to have been recorded either in the Calibration procedure or on the instrument calibration certificate. 6. Written calibration records are maintained on site. The following records were provided for review and found to have been adequately documented and maintained: Thermometers, storage & distribution freezers and handheld devices, weekly, 05/21/20 Scales, annual, semi annual, 02/24/20 Metal detector, annual, 02/24/20 Magnet, annual pull test, 05/08/20

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.11.6 Calibration records shall be maintained.

RESPONSE: COMPLIANT

11.2.12 Pest Prevention

1. Facility pest management is defined in the Pest Control Standard Operating procedure. Pest control is performed utilizing integrated pest management methods to monitor, prevent, and eliminate pest activity in the facility. The responsibilities for pest management have been delegated to licensed contractor (PCO) Assured Audit who performs bi-weekly site service. 2. During the audit, obvious pest activity was not observed in the facility interior or exterior support, storage or processing areas. 3. The non conforming material and incident reporting process includes the requirement to segregate and dispose of materials and product affected or contaminated by pest activity. It was indicated that no such events have occurred since the last audit. 4. The pest management procedure and the PCO service contract include contractor responsibilities, monitoring frequency, methods and devices used, pesticide management, and staff training requirements. During the audit it was noted that exterior bait stations, tin traps, and ILTs are used for facility pest control. 5. Bi-weekly site inspections are performed by the PCO. The activity is recorded on service reports which are filed in the site pest control program site binder. The reports include findings and corrective actions. The following reports were reviewed and found to be current and adequately documented with proactive monitoring and control of pests. 05/04/20, interior 04/22/20, interior / exterior 04/06/20, interior / exterior 6. The PCO records material applications on the site service reports and pesticide usage log. Review of the service reports found the following selected applications to be adequately record, interior, insects 01/14/20, final all weather blox, exterior, rodents 7 & 9. Pesticides are managed off-site by the PCO. During the audit there were no pest control related chemicals observed stored or used on-site. 8. The PCO performing site service is a local licensed commercial pest control management company. Evidence of qualifications are included in the PCO pest control site binder. Company qualification information includes the following: Commercial service contract, 05/02/20 Liability insurance, exp. 07/22/20 Technician license exp.05/31/20 Device map, 05/02/20 Material labels and SDS Approved Registered Material List Business license exp. 05/31/20

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

RESPONSE: COMPLIANT

11.2.12.2 Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.12.6 Records of all pest control applications shall be maintained.

RESPONSE: COMPLIANT

11.2.12.7 Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.4 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces.

RESPONSE: NOT APPLICABLE

EVIDENCE: Pesticides are managed off-site by the PCO. During the audit there were no pest control related chemicals observed stored or used on-site.

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Pesticides are managed off-site by the PCO. During the audit there were no pest control related chemicals observed stored or used on-site.

11.2.13 Cleaning and Sanitation

1. The producer has a formal facility and equipment cleaning program described in the following procedures: Sanitation Master Cleaning Schedule SSOPs for unique areas & equipment in the facility Production Equipment Cleaning Validation & Verification The documents include specific cleaning responsibilities, tools, materials, and verification activities for cleaning. 2. The cleaning program is generally adequate, cleaning records maintained and equipment, facilities were observed to be clean. 3. There is one facility wash area located adjacent to the pre-mix suite in the manufacturing building. It has a stainless steel wash sink, floor drain, hot & cold potable water and a rack for equipment storage. The area was clean and organized during the audit. 4. CIP systems are not used in the facility. 5. The producer has implemented an inspection program described in the Pre-operation Inspection procedure where operations staff perform recorded pre operational inspections. The inspections include a review of equipment and area cleaning, hygiene, and equipment readiness. 6. Support areas are inspected and reviewed by the QA department during monthly GMP audits. 7. The cleaning verification is described and recorded per the Sanitation procedure. The program includes supervisory verification upon completion of the cleaning activity & weekly ATP testing. Review of cleaning records noted verification to be performed as required. 8. - 9. The facility cleans production equipment with dedicated brushes and sanitizes with a premixed no rinse Quat based sanitizer. Review of product labels and SDS, noted the material to be acceptable for use in food processing applications. The quantities are inventoried and securely stored in a locked area in the warehouse and used per label requirements. Sanitizer concentration is verified daily and calibrated by chemical supplier monthly. 10. Obsolete or empty bulk containers were not observed on site. The producer discards containers per label requirements. 11. Pre-operational inspection, material inventory records, and cleaning records are maintained on site. Review of recent selected records for 1st - 2nd quarter 2020 found documentation to be current and adequately maintained.

11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Methods used to confirm the correct concentrations of detergents and sanitizers, and vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.13.3 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils shall be provided as required.

RESPONSE: COMPLIANT

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

11.3.1 Personnel

1. - 2. Personnel are instructed during GMP and Personal Hygiene training, when ill, that they are not allowed to work in processing areas. The training also includes contact control of materials with bodily fluids. Production supervisors and QA staff are responsible for the oversight and implementation of program. Based on observation staff understand and were found adhering to this policy during the audit. 3. During GMP and Personal Hygiene training staff are instructed that if they have open wounds they are restricted from handling product. Based on observation and interview staff understand and were observed adhering to this policy during the audit. 4. Staff are instructed during GMP training that smoking, eating, spitting or drinking are not permitted in the facility production, warehouse and support areas. Staff understand and were observed adhering to this policy during the audit.

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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.2 Hand Washing

1. Hands free wash facilities are located at the entrance into manufacturing and warehousing areas and in rest rooms. 2. The hand wash stations are cleanable, stainless steel or ceramic and supplied with hot & cold potable water, soap & sanitizer and disposable paper towels 3. The facility is not involved in high risk processing activities. 4. Hand wash signs, written in English & Spanish, are affixed to the walls in the rest rooms, break areas and processing area entrances. 5. Staff were observed washing hands upon entrance into the facility processing area prior to beginning production activities. 6. Gloves are worn by operators involved in product handling in the manufacturing operation. Staff were observed washing hands between glove replacement.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The facility is not involved in high risk processing activities.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3 Clothing

1. The site has completed a hair & clothing risk assessment identified as the Risk Assessment - Employee Clothing, dated 02/10/20. The document includes area, hazard threat, severity, likelihood, and clothing mitigation measures. 2. - 4. Staff were observed wearing clothing that is clean, not excessively soiled and adequately maintained. The clothing is stored on lockers within the staff locker rooms. 5. Gloves are worn by operators involved in product handling in the manufacturing operation. The gloves are changed when staff leave the production area or if they become damaged during use. Staff were observed adhering to the policy during the audit.

11.3.3.1	The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food and food contact surfaces from unintentional microbiological or physical contamination. **RESPONSE:** COMPLIANT
11.3.3.2	Clothing worn by staff engaged in handling food shall be maintained, stored, laundered and worn so as not to present a contamination risk to products. **RESPONSE:** COMPLIANT
11.3.3.3	Clothing, including shoes, shall be clean at the commencement of each shift and maintained in a serviceable condition. **RESPONSE:** COMPLIANT
11.3.3.4	Excessively soiled uniforms shall be changed or replaced where they present a product contamination risk. **RESPONSE:** COMPLIANT
11.3.3.5	Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or designated sealed containers in personnel lockers and not on packaging, ingredients, product or equipment. **RESPONSE:** COMPLIANT
11.3.4	**Jewelry and Personal Effects** 1. The GMP training program includes the policy that jewelry (except plain wedding bands) and loose objects are prohibited from being worn or taken into the processing operation. Staff were observed adhering to the policy during the audit.
11.3.4.1	Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and prescribed medical alert bracelets can be permitted, however the site will need to consider their customer requirements and the applicable food legislation. **RESPONSE:** COMPLIANT
11.3.5	**Visitors** 1. When entering the warehouse & manufacturing areas visitors are subject to the same clothing and jewelry restrictions as operations staff. 2. When entering the storage, manufacturing or loading areas visitors are subject to the same gowning requirements and clothing and jewelry restrictions as operations staff. 3. Visitors are required to follow the same practices as production staff in relation to illness prevention. 4. Visitors enter through the main entrances to the facility designated for visitors. 5. Visitors are instructed on and required to read and acknowledge a Visitor's Policy that includes, GMP, gowning and restrictions prior to entering the facility.
11.3.5.1	All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area. **RESPONSE:** COMPLIANT
11.3.5.2	All visitors shall be required to remove jewelry and other loose objects. **RESPONSE:** COMPLIANT
11.3.5.3	Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed. **RESPONSE:** COMPLIANT
11.3.5.4	Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all hand washing and personnel practice requirements. **RESPONSE:** COMPLIANT
11.3.5.5	All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing or handling areas or shall be escorted at all times in food processing, handling and storage areas. **RESPONSE:** COMPLIANT

11.3.6 Staff Amenities

1. The lunch area is accessible and conveniently located outside of the manufacturing area adjacent to the entrance into the facility. The area is supplied with adequate lighting and ventilation.

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

RESPONSE: COMPLIANT

11.3.7 Change Rooms

1. Staff are not required to change clothes in the facility. 2. The facility is not involved in high risk processing activities. 3. Storage areas have been provided in staff locker rooms. 4. The producer has determined that showers are not required for this processing operation.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Staff are not required to change clothes in the facility.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The facility is not involved in high risk processing activities.

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: The producer has determined that showers are not required for this processing operation.

11.3.8 Laundry

1. The producer is not involved in either high soiling or high risk product processing activities.

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

RESPONSE: NOT APPLICABLE

11.3.9 Sanitary Facilities

1. Clean and well maintained rest rooms have been installed outside of manufacturing and warehouse areas. The rooms have a self closing door and are included in the daily cleaning and sanitation schedule. 2. The facility drainage has been fabricated per local construction codes and routed directly to the municipal sewer system. 3. Cleanable well stocked hand wash facilities are located in the rest rooms.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.10 Lunch Rooms

1. The lunch break areas are accessible and conveniently located outside of the manufacturing and warehousing area in a dedicated lunch room. 2. The lunch rooms have adequate lighting and are outfitted with a refrigerator, microwave, clean tables & chairs, a sink with hot and cold potable water, and cleaning supplies. The areas are included in the facility pest control program and were found to be clean and routinely inspected by the PCO. 3. There is an outside eating area available to staff. The area has table & chairs, waste receptacles and was organized and clean during the audit. 4. The lunch areas have posted signage that reminds staff of hand wash requirements after consumption of food and prior to re-entry into processing and support areas. Based on interview, staff understand hand wash policies and the restriction of food from the inside of the facility.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

1. Staff are trained on GMPs during initial and annual refresher training. The training includes operational & personnel practices, hygiene and contamination control. Operations staff were observed to be generally implementing these contamination control practices, following GMPs, and performing duties per operational practices. 2. Sensory evaluations are not performed in the manufacturing area. 3. Utility hoses are adequately coiled and hung on wall mounted hangars off of the floor.

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Sensory evaluations are not performed in the manufacturing area.

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

RESPONSE: COMPLIANT

11.5.1 Water Supply

1. The producer utilizes potable water for facility cleaning and employee hygiene activities. The water is considered to be potable and supplied to the facility by local domestic water supply purveyor, City of Phoenix. The management of the water is described in the Water Quality program procedure. 2. Hot and cold water drops have been installed throughout the facility for facility and process cleaning and sanitation. 3. Water delivery on site is via integral piping with no non-potable or waste line interconnections and the use of annually tested back flow devices on supply lines. 4. Non-potable water is not used on site. 5. There are no water holding tanks on site.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Non-potable water is not used on site.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: There are no water holding tanks on site.

11.5.2 Water Treatment

1. - 4. Water treatment is not performed on site.

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.5.3 Ice Supply

1. - 2. The facility utilizes an ice maker to produce ice used in the dough mixing step. The machine is has stainless steel and cleanable synthetic surfaces which are in good condition. The unit is cleaned every 6 months & preventative maintenance is performed on the same schedule.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.4 Water Quality

1. - 2. The facility water is subject to semi annual testing for E. coli & total Coliform to federal potability standards. Recent, 05/15/20 testing results for both the manufacturing supply and the ice maker were provided for review and found to be compliant within specifications. 3. Review of water testing records noted that analysis is performed by commercial ISO 17025:2005 certified lab IES Labs laboratories using EPA and FDA SM recognized analytical test methods.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.5 The Quality of Air and Other Gasses

1. - 2. Compressed air is utilized in the facility for equipment cleaning and operation. The system has point of use filtration to 0.01 micron, is included in the facility PM program and is tested for yeast & mold and APC. Recent testing results were provided for review and found to be conforming to specifications.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.1 Storage and Handling of Goods

1. The site storage plan is described in the following documents: Inventory Procedure Facility map The documents define the facility process flow, dedicated process areas and specific storage areas for both raw materials and finished product. 2. Stock rotation practices are described in the Product Identification procedure. Product and material rotation is per FIFO principles. The SQFP and shipping and receiving staff are responsible for program oversight and implementation. The facility utilizes Prism Inventory management software for stock rotation. The system has been coded to rotate materials based on receipt and shelf life date. 3. The facility handles raw material and finished products that have shelf life or expiration dates. Control of these materials is performed, as noted previously, through the inventory management software. Monthly inventory cycle counts are also performed in facility warehouses. Materials are reviewed for condition and remaining shelf life. However, comparison of documentation of four materials with shelf life dates noted the following discrepancies with two of the materials: a. Molasses Manufacturer shelf life = 6 months Manufacturing date = 03/16/20 Expiration date in Prism = 09/14/20, does not match manufacturer recommendation b. Eggs Manufacturer shelf life = 30 days Manufacturing date = 03/26/20 Expiration date in Prism = 04/29/20, does not match manufacturer recommendation 4. The warehouse area for material, packaging and product storage is adequate in space and organization to help facilitate effective material movement and area cleaning and inspection. 5 - 6. Alternate or temporary storage not designed for safe storage are not needed at this time as the facility has sufficient space for holding all materials and product.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: The facility handles raw material and finished products that have shelf life or expiration dates. Control of these materials is performed, as noted previously, through the inventory management software. Monthly inventory cycle counts are also performed in facility warehouses. Materials are reviewed for condition and remaining shelf life. However, comparison of documentation of four materials with shelf life dates noted the following discrepancies with two of the materials: a. Molasses Manufacturer shelf life = 6 months Manufacturing date = 03/16/20 Expiration date in Prism = 09/14/20, does not match manufacturer recommendation b. Eggs Manufacturer shelf life = 30 days Manufacturing date = 03/26/20 Expiration date in Prism = 04/29/20, does not match manufacturer recommendation

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: As corrective action for this minor, all warehouse technicians involved with entering information into the PRIMS software have been re-trained by Warehouse Manager. Additionally, lot-code explanation information tool has been introduced which will allow the warehouse technicians to better-understand the lot codes for different ingredients and decipher accurate expiration dates.

VERIFICATION OF CLOSEOUT: Lot code book and staff training record provided for review.

COMPLETION DATE: 06/04/2020 **CLOSEOUT DATE:** 06/15/2020

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Alternate or temporary storage not designed for safe storage are not needed at this time as the facility has sufficient space for holding all materials and product.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Alternate or temporary storage not designed for safe storage are not needed at this time as the facility has sufficient space for holding all materials and product.

11.6.2 Cold Storage, Freezing and Chilling of Foods

1., 2., 4. The producer is involved in the handling and storage of finished products in ambient storage and at 25F. The freezer is estimated to provide at least 100% capacity, it is organized and outfitted with calibrated thermometers within the room. The system temperatures are monitored daily and have automated alarming capability. The alarms are forwarded to the senior management. Review of recent temperature records for the coolers was provided review and found to meet required product storage specifications. 3. Discharge from the cooling and condensing units is generally adequately consolidated with drip pans and directed to piping and floor drains. However, Review of the walk-in freezer observed the following deficiencies: a. There was a significant buildup of ice & frost buildup was observed on the central condensing/cooling unit. The amount noted exceeded the footprint of the under unit drip pan, so that during defrost cycle the melting ice would drop on floor bypassing the drip pan. b. Observation, directly under the unit buildup of ice was noted on the floor. c. Additionally, observed significant buildup of ice and frost on the condenser return piping which did not have a drip pan directly underneath. 5. Loading and unloading docks are adequately organized and clean to help facilitate effective, controlled and organized material handling.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: Discharge from the cooling and condensing units is generally adequately consolidated with drip pans and directed to piping and floor drains. However, Review of the walk-in freezer observed the following deficiencies: a. There was a significant buildup of ice & frost buildup was observed on the central condensing/cooling unit. The amount noted exceeded the footprint of the under unit drip pan, so that during defrost cycle the melting ice would drop on floor bypassing the drip pan. b. Observation, directly under the unit buildup of ice was noted on the floor. c. Additionally, observed significant buildup of ice and frost on the condenser return piping which did not have a drip pan directly underneath.

ROOT CAUSE: Not Applicable

CORRECTIVE ACTION: As corrective action for this minor, Maintenance Dept. has increased the frequency of Preventive Maintenance (PM) on the area in question to once every three weeks. The frequency of defrost cycle has been increased from 4 times a day to 6 times a day. Additionally, the duration for defrost cycle has been increased from 30mins to 40mins. The condensate-return piping has been re-insulated to prevent the frost build-up on the piping.

VERIFICATION OF CLOSEOUT: Work order and pictures of completed work provided for review.

COMPLETION DATE: 06/15/2020 **CLOSEOUT DATE:** 06/15/2020

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

1. The warehouse areas for material, packaging, and product storage are adequate in space and organization to help facilitate effective material movement and area cleaning and inspection. During the facility tour the storage areas for ingredients and packaging were observed to be clean and organized. 2. The storage area racks are in good cleanable condition and have been installed with adequate perimeter spacing to allow for cleaning access. 3. Hand truck pallet jacks and fork lifts are used to move products and materials in the storage warehouse. The vehicles were clean, in good condition, not a potential source of contamination and appropriate for operation in a GMP environment.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

1. Hazardous chemicals are not utilized or stored on site. However, cleaning chemicals are stored and maintained in a segregated room in the warehouse and manufacturing areas away from processing areas with little potential for product contamination. 2. Processing or cleaning utensils were not observed to have been stored in the chemical storage areas. 3. Daily supplies of sanitizers are stored in 1 liter spray bottles used for miscellaneous equipment sanitization. The bottles were adequately labeled, maintained and stored away from product handing zones in processing areas. 4. Pesticides are managed and controlled off site by the PCO. No pest control related chemicals were observed on site during the audit. 5. As described previously, the producer does not handle hazardous materials.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Pesticides are managed and controlled off site by the PCO. No pest control related chemicals were observed on site during the audit.

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

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

1. Shipping and receiving responsibilities and methods are described in the Loading and Unloading procedure. The document describes how to perform truck and trailer inspections for material loading and unloading activities. The procedure includes documentation and record keeping requirements.

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

RESPONSE: COMPLIANT

11.6.6 Loading

1. Trailer inspections are performed on outgoing truck trailers by warehouse staff. Trailers are reviewed for condition, pest infestation, cleaning, and damage. Based on observation and interview inspections are performed as required. 2. Material and product loading and unloading is performed in an organized manner by trained operators. Pallets, materials and loading equipment are protected and handled with care during material movement and transfer. 3. Incoming and outgoing trailers have either a lock or seal on trailer door. Their presence is verified and recorded on the inbound & outbound trailer inspection log checklist.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.7 Transport

1. The facility sends product in refrigerated trailers. Prior to loading warehouse staff verify trailer thermostat & temperature. Product temperature is not checked, however risk assessment was provided, Storage & Handling of Goods justifying why temperature of product not measured during loading. 2. Trailer temperatures are recorded during transit via trailers that outfitted with remote temperature monitoring capabilities. Contracted service providers are required to have recording capability.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.8 Unloading

1. Miscellaneous products (milk & eggs) requiring refrigerated transport are received into the storage and distribution facility. Upon receipt warehouse staff record trailer thermostat, temperature and product temperature prior to and during unloading. Temp records are recorded in the Prims inventory database 2. Material and product loading and unloading is performed in an organized manner by trained operators. Pallets and materials are protected and handled with care during material movement and transfer into the warehouse storage areas.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.1 Process Flow

1. The facilities are designed and organized to help facilitate logical unidirectional flow from material receipt, processing, and storage to shipping. Obvious potential sources of contamination related to process or personnel flow were not observed during the audit.

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

RESPONSE: COMPLIANT

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

1. Dry products and packaging were adequately received, separated and stored in a separate receiving and dry storage warehouse area in the facility. Unprocessed raw materials are not received into the facility.

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

RESPONSE: COMPLIANT

11.7.3 Thawing of Food

1. - 4. The producer is not involved in the thawing of materials or product.

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.7.4 High Risk Processes

1. - 5. The facility is not involved in high risk processes.

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.7.5 Control of Foreign Matter Contamination

1. The provisions for foreign material control are described in the Foreign Matter Control Program. The procedures include the control of glass, plastic, and metal in the warehousing and manufacturing processes. Staff are trained and based on observation and interview demonstrate understanding of the program requirements. 2. There is a formal pre-operational inspection program where the manufacturing lead performs a review of equipment readiness at the beginning of day or product changeover. In addition, equipment inspections are also included in the facility preventative maintenance program. 3. The control of glass in the facility is described in the Glass & Brittle Plastics Program procedure. The document includes provision for the restriction of glass, protection of instrumentation, regular inspections, control measures for glass breakage, and SQFP release responsibilities. Glass & Brittle Plastics Register is maintained by location, item & description. 4. It was indicated that glass is not permitted in the manufacturing areas. 5. Monthly glass inspections of the processing and support areas are performed. The most recent inspection performed 05/09/20 was provided for review during the audit. 6. No glass dial covers or glass thermometers were observed to have been installed in open product handling areas. 7. Wood pallets are used for the transport of finished product to the warehouse. The pallets were clean and adequately managed during the audit. The pallets are regularly inspected for condition during GMP inspections. Wooden utensils were not observed in use in product contact applications. Wood Pallet Control Program 8. During the facility tour, loose metal objects or screws were not observed in use on processing equipment. 9. Retractable knives are used in the processing and handling operation for opening bulk material containers. The control of the knives is described in the Quality Control Program procedure and recorded on the Tool Box Sign Out Sheet. During the audit found instruments to be clean and adequately maintained.

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

RESPONSE: COMPLIANT

11.7.5.2	Inspections shall be performed to ensure plant and equipment remain in good condition, equipment has not become detached or deteriorated and is free from potential contaminants. **RESPONSE:** COMPLIANT
11.7.5.3	All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location. **RESPONSE:** COMPLIANT
11.7.5.4	Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing /contact zones. **RESPONSE:** COMPLIANT
11.7.5.5	Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register. **RESPONSE:** COMPLIANT
11.7.5.6	Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** No glass dial covers or glass thermometers were observed to have been installed in open product handling areas.
11.7.5.7	Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.11.7.5.8 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard. **RESPONSE:** COMPLIANT
11.7.5.8	Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard. **RESPONSE:** COMPLIANT
11.7.5.9	Knives and cutting instruments used in processing and packaging operations shall be controlled and kept clean and well maintained. Snap-off blades shall not be used in manufacturing or storage areas. **RESPONSE:** COMPLIANT

11.7.6 Detection of Foreign Objects

1. - 2. The facility has employed the use of metal detection on the packaging line, sifter on the flour & sugar supply line. The operation, use, and verification of the metal detector is described in the following procedures: Metal Detector Program Quality Control Program Sifter Tailings Examination Program The meta detector is challenged by the QC lead with three standards during the pre operation inspection per the CCP monitoring plan. The operation and use of the flour sifter is described in the sifter is inspected every shift by the manufacturing lead for damage, tears or foreign material. 3. The metal detector challenge is recorded on the preoperation inspection checklist and the sifter inspection is recorded SafeFood 360. Written records of the device inspections are maintained on site. Samples of the inspection records for 2019/20 were provided for review and found to be complete, properly verified, and maintained.

11.7.6.1	The responsibility, methods and frequency for monitoring, maintaining, calibrating and using screens, sieves, filters or other technologies to remove or detect foreign matter shall be documented and implemented. **RESPONSE:** COMPLIANT
11.7.6.2	Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected. **RESPONSE:** COMPLIANT
11.7.6.3	Records shall be maintained of the inspection of foreign object detection devices and of any products rejected or removed by them. Records shall include any corrective actions resulting from the inspections. **RESPONSE:** COMPLIANT

11.7.7 Managing Foreign Matter Contamination Incidents

1. Foreign material incidents are managed per the following procedures: Non Conforming Product procedure Incident Report form If an event occurs, samples of the product are retained, the product is isolated and event recorded on the Incident form then reported to the SQFP. No incidents have been reported since program implementation. 2. The control of glass in the facility is described in the glass control program. The program includes provision for the restriction of glass, area inspections, operations control in breakage, and SQFP release recording on the Incident Report form. The following breakage incident records were reviewed and found to be adequately maintained: 11/19/19, broken glass from unknown source, most likely from transport company, no product impact 12/10/19, broken glass from unknown source, most likely from transport company, no product impact

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.8.1 Location

1. - 3. The facility does not have an on site testing lab.

11.8.1.1 On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.

RESPONSE: NOT APPLICABLE

11.8.1.2 Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory wastewater outlet shall as a minimum be down stream of drains that service food processing and handling areas.

RESPONSE: NOT APPLICABLE

11.8.1.3 Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel.

RESPONSE: NOT APPLICABLE

11.9.1 Dry and Liquid Waste Disposal

1. Facility waste control methods are described in the Dry & Liquid Waste Disposal procedure. The plant manager and SQFP are responsible for program oversight. The program includes provisions for handling of packaging, chemical, product and recyclable waste. Based on observation of facilities and record keeping, facility waste was found to be adequately managed. 2. Waste removal is performed on a daily basis, during facility and process area cleaning. The facility was observed to be clean and organized during the audit with no signs of uncontrolled waste in processing, warehouse, or employee welfare areas. 3. The containers used to transport process waste out of the facility are dedicated, labeled and found to be clean and appropriate for use in a GMP facility. 4. Waste packaging was adequately managed and cleaned up in processing areas during the audit. 5. The facility packages products that have facility and trademark information and logos on secondary packaging. The instructions for disposal of these materials are described in the Dry & Liquid Waste Disposal procedure. The materials are to be defaced prior to placement in waste containers. Certification of Destruction is received from waste disposal site. 6. Inedible waste for feed is not generated on site. 7. All waste is transported outside of the facility into a dumpster compactor which is sealed with a lid. There were an adequate number of floor drains and waste containers located through out the facility for the management of process waste. 8. The manufacturing process does not generate liquid waste. 9. Daily facility cleaning is evaluated by the manufacturing lead and recorded on the preoperation checklist. Monthly GMP inspections that include a review waste management are also performed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.9.1.4 Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging.

RESPONSE: COMPLIANT

11.9.1.5 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

RESPONSE: COMPLIANT

11.9.1.6 Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing.

RESPONSE: NOT APPLICABLE

EVIDENCE: Inedible waste for feed is not generated on site.

11.9.1.7 Waste held on site prior to disposal shall be stored in a separate storage facility and suitably insect proofed and contained so as not to present a hazard.

RESPONSE: COMPLIANT

11.9.1.8 Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.10.1 Grounds and Roadways

1. The facilities' perimeter and grounds are well maintained without accumulation of debris. There is adequate perimeter access to the building for cleaning and maintenance activities. Facility condition is regularly reviewed by the SQFP during monthly GMP inspections. 2 - 4. The shipping and receiving docks, loading and unloading bays and the walkways on the front of the facilities are composed of concrete, gravel and asphalt and found to be in good condition and clean, without pooling water or obvious source of potential contamination. 5. The facility perimeter landscaping and grounds are well maintained with no obvious potential negative impact on facility operations. 6. The walkways leading into the facility entrances are composed of concrete and sealed asphalt and found to be in adequate condition.

11.10.1.1 Measures shall be established to maintain a suitable external environment, and the effectiveness of the established measures shall be monitored and periodically reviewed.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.10.1.4 Paths, roadways, loading and unloading areas shall be adequately drained to prevent ponding of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

RESPONSE: COMPLIANT

11.10.1.5 Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises.

RESPONSE: COMPLIANT

11.10.1.6 Paths from amenities leading to site entrances are required to be effectively sealed.

RESPONSE: COMPLIANT