# SQF Food Safety Audit Edition 9
## LiDestri Foods & Beverages - Pennsauken Packing Co., LLC

## Summary

**AUDIT DECISION**
CERTIFIED

**CERTIFICATION NUMBER**
10388 | 157245

**AUDIT RATING**
97
Excellent

**DECISION DATE**
07/11/2022

**AUDIT TYPE**
UNANNOUNCED

**RECERTIFICATION DATE**
05/07/2023

**AUDIT DATES**
06/01/2022 - 06/03/2022

**EXPIRATION DATE**
07/21/2023

**ISSUE DATE**
07/12/2022

## Facility & Scope

**LiDestri Foods & Beverages (39781)**
Pennsauken Packing Co., LLC
1550 John Tipton Blvd.
Pennsauken, NJ 08110
United States

**Food Sector Categories:**
16. Ice, Drink, and Beverage Processing
21. Oils, Fats, and the Manufacturing of Oil or Fat-based Spreads

**Products:**
Beverages, Edible Oils; Exclusions: None

**Scope of Certification:**
The aseptic packaging of beverages and the repackaging of oils

## 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:** Mazariegos, Alfonso (134129)
**Technical Reviewer:** Sodhi, Gurpreet (205005)

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

## Non-Conforming

### 2.4.3 Food Safety Plan (Mandatory)

There are prerequisites applied by the site included in the FS Plan: Raw material / packaging controls and receiving Foreign body controls Allergen controls Staff controls Calibration Sanitation Pest control Maintenance Water Material and traceability controls Control of non-conforming product Finished product controls Chemical controls Waste controls Food defense, crisis management, among others. The plant has one HACCP Plan based on the Codex Alimentarius Commission HACCP Guidelines and HARPC. The HACCP plan assures the manufacture of safe packaging products. There are prerequisites linked more robust that the exigence of the HACCP analysis that made the system more reliable. There is a multidisciplinary team formed by the SQFP (QA Manager), HACCP Training: Jan 9-10 2020, 10 years of experience in the food industry. PCQI: 11-23-2019, FDA 6-24-2021. Food Défense 6-26-2020, FDA Food emergency response 2019. SQFP Backup (Production Manager), HACCP Training: June 14, 2016, SQF Training: June 15, 2016, 12 years of experience in the food industry. Plant Manager, 4 years of experience, Last HACCP Training 2021-03-09 Maintenance Manager, 6 years of experience, Last HACCP Training 6-14-2021 Warehouse Manager, 12 years of experience, Last HACCP Training 6-12-2021 Sanitation Manager, 4 years of experience, Last HACCP Training 2021-03-08 Facilities engineering Manager, 4 years of experience, Last HACCP Training 2021-04-15 Microbiologist, more than 10 years of experience, Last HACCP Training 2021-03-04 The scope of the FS Plan includes all the Site processes cover by the SQF certificate: Main processes are: Beverages production Edible Oil production There are product descriptions for Beverages: Product families: Soft drinks, juice drinks, water based drinks, and Edible Oil. Product: Beverages, Product description: Turbulent flow-pasteurized, high acid beverage product commercially sterile with pH below 4.6 Intended use and consumers: Drinks for human consumption. Packaging: PET Bottle Method of storage: room temperature Shelf-life: one year Low risk (Low acid products), high risk (High acid products). RTE Country of distribution: USA and Canada No alternative uses identified. Labelling instructions: May contain allergens. Edible Oils: Product: Edible Oil (Olive oil, sunflower Oil, grapeseed oil), Aw: 0 Product intendent use: Food service as an ingredient in another recipe of process (Ingredient). Method of storage: room temperature Shelf-life: one year Low risk RTE Country of distribution: USA No alternative uses identified. There are two flow diagrams for beverages and Edible Oils dated 5-31-2022, 5-26-2022. The steps are reception of materials storage of materials (refrigeration if apply), reception and treatment of water, weighting, blending, sterilizing or pasteurizing, sterilizing of bottles and caps, filling, cooling, capping, and palletizing. The investigation of hazards is made by the HACCP team using severity and probability analysis to evaluate the hazards and verifying or implementing prerequisite programs to ensure their elimination or reduction to acceptable levels. There is a HACCP analysis for raw materials as water, coconut water, coconut flavour, several juices, primary packaging as plastic bottle, among others. Microbiological hazards include: Pathogens, E Coli, Salmonella, listeria, among others Chemical hazards includes: allergens, residual chemicals of cleaning, among others. Physical hazards includes: foreign matter from machines, shipping, among others. Documented measures are inspection of filters, Preoperational inspections, visual inspections, SSOP, Suppliers control, Product sampling and inspection, specifications control, Visitors policy, among others. For Line 1 and 2, HACCP CCP are pH of product in Blend System (Less than 4.5). Allergens information in the Label For Line 3, HACCP CCP are Pasteurization (time 8.07 seconds or more, 279°F or more, 110 GPM Maximum Allergens information in the label. Cap Sterilization, sterilant concentration ($H_2O_2$ Level 33-35 ppm) Preform sterilization, sterilant concentration ($H_2O_2$ level 33-35 ppm) For Edible Oil CCP are Screen: intact. The HACCP Master plans includes critical limits. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. The HACCP Master plans includes what, who, how monitor the behaviour of the device, corrective actions in case of failures, and verification. Monitoring of the CCP are by the operator or by QA, and verification by QA." Suspicious product is separated, analysed, and disposed to no offer FS risks. The HACCP process includes a validation plan execution. Line 1,2: last validation in 5-25-2022. Line 3: last validation in 5-26-2022 Edible Oil: last validation in 5-31-2022 Monitoring of CCP is verified by inspections, supervision, and verification of the activity. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. There is a corrective actions process ready to work in case of a failure of CCP. No failures in the last 12 months. The system follows the Codex Alimentarius Commission HACCP, and HARPC. The HACCP process includes a verification plan execution. Line 1,2: last verification in 5-25-2022. Line 3: last verification in 5-26-2022 Edible Oil: last verification in 5-31-2022 Minor: Coconut water is an allergen, it is controlled as such in the plant, however in the HACCP analysis this chemical danger for the raw material is not defined.

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

**RESPONSE:** MINOR

**EVIDENCE:** Coconut water is an allergen, it is controlled as such in the plant, however in the HACCP analysis this chemical danger for the raw material is not defined.

**ROOT CAUSE:** The HACCP analysis for the ingredient Coconut water was not clearly identified as an allergen under chemical hazarder for the raw material the wording Environmental Chemicals was utilized, which refers to a chemical compound or chemical element present in air, water, food, soil. dust, or other environmental medias such as consumer products (National Biomonitoring Program, CDC, ND).

**CORRECTIVE ACTION:** The ingredient hazard analysis for Coconut water was evaluated and the chemical hazard only listed Pesticides and Environmental Chemicals. The specification sheet of the raw material was reviewed to verify the raw material was identified as an allergen; and was confirmed. Allergen was added to the ingredient chemical hazard. In addition to, the following added to the justification column: The US FDA recognize eight major food allergens: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybean. A consumer with food allergies can experience the following allergic reaction symptoms; anaphylaxis, hives, flushed skin, or rash, tingling or itchy sensation in mouth, face/tongue/lip swelling, vomiting, diarrhea, abdominal cramps, coughing or wheezing, dizziness/lightheadedness, difficulty breathing, loss of consciousness. In addition to, the following added to the measures applied column: Allergen Monitoring Program, and allergen labeling on finished product at a later step. The HACCP team will review annually or when ingredients or process changes.

**VERIFICATION OF CLOSEOUT:** HACCP Analysis

**COMPLETION DATE:** 06/17/2022 **CLOSEOUT DATE:** 06/24/2022

## 11.2.2 Maintenance Staff and Contractors

Maintenance contractors' agreements to comply hygiene requirements are defined in the Contractor Orientation document SFP 007 (5) that includes Topics of Food defense, Confidentiality, General rules, GMP, PPE, Housekeeping, among others. Reviewed agreement letter signed by Osage Company in 12-07-2021 and evidence of review of information list dated 5-3-2022. Roof maintenance contractors' agreement document dated 5-1-2022 (renovation in each WO). Air handling units' contract since 2-25-2020. Cleaning instructions are included into the app. Reviewed example of housekeeping completion dated 5-5-2022 included into the filler rotary GEA physical inspection. There is a sheet with the rules of GMP in the list of attendance of visitors to the plant. All the visitors have to read it before their entrance to the plant. Jobs are inspected by the maintenance area. Area has been cleaned at the final of the job. Start-up inspections of the line are defined. Minor NC: A contractor was observed wearing a watch inside the plant.

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

**RESPONSE:** MINOR

**EVIDENCE:** A contractor was observed wearing a watch inside the plant.

**ROOT CAUSE:** The contractor failed to follow the agreed GMP policies that was acknowledged at initial access point. The contractor stated the apple watch was placed on during his break and forgot to remove.

**CORRECTIVE ACTION:** An outside contractor was sighted by auditor wearing a watch, QC instructed to immediately leave the production area and to comply with company GMP policies. The supervisor of contractors onsite was notified of non-compliance after acknowledging the GMP policy agreement; The contractor stated, "the apple watch was placed on during break and forgot to remove it," the gentlemen was also removed from the site for not complying with company GMP policies. Owner from the hired contractor company was scheduled for a meeting with senior management (phone conference) to discuss the contract and company policies requirements and expectations. Facilities manager verified that contractor who was non-compliance be removed from working onsite. Visitors siging and GMP electronic form was reviewed and deemed to be acceptable with capturing all requirements in gaining access to production areas.

**VERIFICATION OF CLOSEOUT:** Evidence of communication with contractor

**COMPLETION DATE:** 06/02/2022 **CLOSEOUT DATE:** 06/24/2022

## 11.2.4 Pest Prevention

There is a pest prevention program Pest Prevention Procedure IPM Service and strategies i. Methods and responsibilities are defined including inspections, application of chemicals, and maintenance of the system. ii. Records of pest sightings and trends were reviewed iii. Methods to prevent pest problems were reviewed (inspection, housekeeping, cleaning). iv. Elimination methods were described in the Manual. v. Frequency of inspection is defined (every 2 weeks). vi. There is a map of pest control devices 1-1-2022 vii. There is a list of chemicals into the book of the contractor viii. Awareness to the staff about the contact with the bait station is by refresh training. ix: The handling of chemicals and baits is by the contractor. x. The effectiveness of the program is verified by trends and inspections. There is a Pest Prevention Procedure IPM Service and strategies Information of the pest control Service: Last annual assessment 2-1-2022 License of the company expiration date 10-31-2022 by the Department of Environmental Protection of New Jersey, and of the contractor license expiration date 10-20-2022 by the same department. Training evidence of the technician was reviewed. List or relationship of approved chemicals by the FSS contractor. All the chemicals have EPA number. Reviewed Evergreen product. Their use is recorded in the Pesticide usage log summary. Service reports of 1-18-2022, 3-30-2022, and 4-29-2022. Issues are communicated to the QA Manager. Trends of pest behaviour. Reviewed last 90 days trends with favourable behaviour. Reviewed 1st Quarterly trend data report dated 6-1-2022. Contract and annual assessment dated 2-1-2022. No observed pest activity into the site. Product affected by a possible contamination of pest is segregated as NCP There are not pesticides stored in the plant. No animals observed into the site. Areas with parts of equipment and other machines were observed in the warehouse arranged in such a way that the area cannot be inspected or cleaned. Minor NC Cobwebs were observed on the walls of different areas of both warehouses.

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

**RESPONSE:** MINOR

**EVIDENCE:** Areas with parts of equipment and other machines were observed in the warehouse arranged in such a way that the area cannot be inspected or cleaned. Cobwebs were observed on the walls of different areas of both warehouses.

**ROOT CAUSE:** Due to Covid-19 pandemic the company experienced massive turn overs and was unable to retain employees throughout the fiscal year to complete smaller task; understaff.

**CORRECTIVE ACTION:** Cobb webs was notice in the warehouse area in between the beams. Non-compliance was inspected by sanitation manager and Quality Assurance Manager. Cobwebs were removed from affected areas; area was cleaned and sanitized. Temp employees were scheduled on 6/17/2022 to fully complete additional oversighted areas throughout the dock areas and storage areas. Along the equipment storage area, a permanent yellow guided trail walkway is being placed to ensure access between stored equipment, and access to outer parameters areas of storage area. Sanitation Manager will evaluate all dusting procedures are completed quarterly, if areas are displaying struggles due to staffing concerns the sanitation manager will consult an outside contractor. Due to Covid-19 pandemic the company experienced massive turn overs and was unable to retain employees throughout the fiscal year to complete smaller task; understaff. Quality Assurance manager visually verified removal of cobwebs, and sanitation manager captured pictures in RedZone of cleaned and sanitized areas. Discuss in weekly meeting of utilizing temp personnel to help with sanitation procedures that has no chemical usage. Discuss about having an outside cleaning contractor for dock and warehouse storage areas for dusting procedures in future if personnel concerns continue.

**VERIFICATION OF CLOSEOUT:** Pictures of the correction Notes of the agreements of the meetings.

**COMPLETION DATE:** 06/03/2022 **CLOSEOUT DATE:** 06/28/2022

## Audit Statements

| | |
|---|---|
| **SQF Practitioner Name** | Name the designated SQF Practitioner<br>**RESPONSE:** Darsea Smith |
| **SQF Practitioner Email** | Email of the designated SQF Practitioner<br>**RESPONSE:** dsmith@lidestrifoods.com |
| **Opening Meeting** | People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas)<br>**RESPONSE:** Darsea Smith: Quality Manager, Joseph Eastlack: Production Manager, Alfonso Mazariegos: auditor |
| **Facility Description** | Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details<br>**RESPONSE:** This is an unannounced audit. The plant is located in an industrial zone of warehouses, manufacture of mechanical parts and some food a little further. The plant has two lots separated by the parking area. In one there are three beverage production lines (built in 1979) and in the other the edible oil line and warehouse of finished product and final packaging lines of the finished product bottles (built in 1968). The bottle arrives at the packing facility via a conveyor that crosses the parking area over a bridge. In January of this year, line 3 of beverages was built. All beverages made at the plant are customer designs and carry their formulas and labeling. The edible oil process consists of dividing the container received by the customer into smaller volume containers. The generated products also carry the customer's label and as a specification, the CoA of the divided lot. There are 4 HACCP plans. Size of the plant: Beverages Site: 130,000 sqf + 120,000 sqf for Edible Oil. Configuration of shifts 6 am to 6 pm and 6 pm to 6 am 4 teams. 24/7 Total personnel 132 facilities, 32 offices Total of personnel in the main shift 80 Allergens: Coconut and Almond (only in Line 3). Market: USA mainly and Canada. Other certifications: Kosher, GF, Organic, Halal, and GMO. |
| **Closing Meeting** | People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas)<br>**RESPONSE:** Darsea Smith: Quality Manager, Joseph Eastlack: Production Manager, Alfonso Mazariegos: auditor |
| **Auditor Recommendation** | Auditor Recommendation<br>**RESPONSE:** The plant can be certified once corrective actions are responded to and verified. |

## Section Responses

## 2.1.1 Management Responsibility (Mandatory)

The site has a food safety policy. Signed by SQFP and Plant Manager. Last update, 3-10-2022. The Policy statement covers customer safety requirements and high-quality standards, and regulatory requirements, food safety culture, the use of continuous improvement through the application of auditing techniques, tracking and trending protocols, and corrective actions, among others. The Policy is communicated to the facility's staff by publish it in several points of the site like the access to the personnel. The statement is in English and Spanish. The Site has established and maintain a food safety culture deployed from the Direction. Communication of food safety objectives and performance measures is through KPI review and information posted in the plant. As example, the next KPI were reviewee Safety training completion, target more than 05% behaviour Q3 complying. CIP Walk schedule compliance, target more than 90% behaviour Q3 complying. Safety GMP Score, target more than 85% behaviour Q3 complying. Velocity action item closure, target more than 90% behaviour Q3 complying. Hazard ID Submissions, target more than population, behaviour Q3 complying. Hazard ID Closure, target More than 85% behaviour Q3 complying. Focused safety observation, target major than 90% behaviour Q3 complying. The people is involved to the situation by Q3 complying. Adequate resources to meet food safety objectives were observed. The food safety practices adaptation were carried out by several ways, as training in FS Culture among others. Last training on to the FS Team. Regulatory and food safety responsibilities of employees are informed through their Job Descriptions, and procedures. Reviewed the Job Descriptions of Production Manager, Technician QA, Machine operator. Some activities carried out regarding to the FS Culture Program were: Annual training in GMP, Awareness information in the electronic screens on the plant, awareness to the people to notify any problem in the site regarding food safety, quality or other topic. There is an Organization chart updated 05-25-2022; back up for key positions are defined in the Job description. Examples reviewed Plant Manager, QA Technician, Sanitation Manager. SQF primary is the SQF Lead Practitioner (QA Manager), is member of the company, and the substitute is the Production Manager, member of the company too. They have authority over the development of implementation, review, and maintenance of the SQF System, take action to ensure the integrity of the SQF System, and communication to key personnel to ensure the SQF System implementation and maintenance through visual aids information, training, daily meetings, interviews, among others. Training evidence of both can be seen in the HACCP System Multidisciplinary team chapter of this report. Training needs are covered according 2.9. (Topics planned, Statement of purpose, hold and release program, food defense, HACCP, SQF, equipment facility, FIFO, FS Objectives, chemical control, among others). The training is uploaded in the Alchemy platform. There are job instructions training. Evidence of attendance list for the course of labelling and palletizing dated 20-21-21, and CCP Training in 4-20-2022. In the event of organizational or personnel changes, the operation is ensured by their backups or the key positions. They are defined in the Job descriptions of the site. The plant has the blackout dates for this audit.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.1.2 Management Review (Mandatory)

There is a procedure for Management review included in the SQF Manual. In the annual meeting are reviewed all the points required by the standard. Last annual meetings were carried out in 1-13-2022. It was presided by the QA Corporate, and Plant Manager, and had the attendance of the rest of the Managers, among others. Topics reviewed were Changes of the policy statement, internal audit findings, corrective actions and investigation of them, complaints following, HACCP last updates, previous management meeting pending points review, Food Safety Culture Performance, Corrective, and preventive actions, among others. SQF practitioner updates to the Plant Manager about any issue of the FS System is at least Monthly. Commonly during the senior management food safety and quality review. Annual review of the HACCP system was on May 31, 2022. Records of changes and reviews are maintained.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.1.3 Complaint Management (Mandatory)

There is a corporate complaint attending system. There is a procedure for complaint attention CQCP 008 (4). All the reports are updated in a Corrective actions Database with information about customer incident, date, client, tests, shipment process, sample retained, condition of the customer sample, test of the customer sample, results. The complaints are reported by the client and are received by the SQF Practitioner. There are 397 complaints in 2021 and 165 in 2022. No trends. The complaints are linked with a corrective action. Corporate carries out the solving with the participation of the plant. Reviewed example: Complaint solving by CAPA, 9-23-2021 Label mistake. Applied root cause analysis

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.2.1 Food Safety Management System (Mandatory)

The FSS is documented in paper and electronic media (FS Manual). It contents the information regarding to the 7 HACCP Principles. During the audit were reviewed the accessibility of documents in several areas (As Production, QA, of finished products, production, and raw materials reception). FS Policy and organization charts are located in walls of the site. The scope of the certification is disseminated by the exhibition of the last certificate. All the finished products of the site are included in the certificate. FS regulations that apply to the System can be found in the HACCP Manual, among other documents. Specifications of raw materials, ingredients, packaging, and finished products were available Process controls can be found in each line. The main documents of the system are the HACCP Plans and prerequisite documents (All of the SQF Prerequisites). The Manual includes any change needed to update the system. The interested parts are communicated by a HACCP Team member or by their manager. Changes of the system are validated by the HACCP Team. No changes in regulatory requirements in this moment. Backup of the System is in real time.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.2.2 Document Control (Mandatory)

The methods for document control Document & Records Control Procedure "Document Management" CQC-010 are documented and implemented. The controls include approval, reapproval, updating, distribution, and archiving. There is a current document register in place Corporate and Plant procedures Master List. Documents reviewed and referenced in this report were observed to be current and available to the staff as needed.

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

**RESPONSE:** COMPLIANT

## 2.2.3 Records (Mandatory)

The requirements for records are described in the Document & Records Control Procedure CQC-010. Records of inspections, analyses, and other essential activities were reviewed during the audit and traceability exercises. They were found complete and adequate. Records of inspections, analyses, and other essential activities were reviewed during the audit and traceability exercises. They were found complete and adequate. All records are maintained for 6 years (Shelf life is 18 months).

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.3.1 Specification, Formulation and Realization

The plant does not design products. All the designs are by the Customer. Ongoing formulations are agreed with the client and comply with FDA and other regulatory requirements. The client carries out the regulatory investigation. Any new product to implement in the site is analysed against the HACCP requirements. No new designs during the last 12 months. Changes are notified by the customer. No changes during the last 12 months. The process flows for all new and existing manufacturing processes are designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination. No new designs or changes

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The plant does not design products.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

Specifications for raw materials, packaging and ingredients are authorized by the Client, Corporate and HACCP Team of the plant. The client authorized an spec due their quality system and can verify the result with the CoA of each shipment. Specifications are stored in a data base of the management system. Reviewed specifications: Finish product BAI Coconut LT00083 dated 7-29-2019 Califia Farms Unsweetened almond milk LT00113 dated 3-15-2022. For the oils, the CoA of the lot is used as spec and maintains their trademark. The site has own specifications for all the products and materials. There are current registers in place for the specifications of raw materials, packaging, hazardous chemicals, processing aids, and packaging with impact in the Finished Products safety. Reviewed the next specifications: Please review 2.3.4.2. The specifications update is maintained by QA If a raw material did not have changes during the year, their review is evidenced into the management system verification records. The plant does not receive materials from sister plants. Raw materials are validated to ensure that product safety, regulatory requirements and quality are met by means of the verification of CoA against the spec. Suppliers of raw materials shall notify to the plant changes in their product composition that could have impact on product formulation. The customer is notified by them and if is agree authorize the change and notify to the Company. Packaging material is verified through CoA Regulatory compliment is established in the product specification. The customer define the packaging design. Guarantee of compliment evidence is GFSI certificate (Please review 2.3.4.2). Approving of packaging information as legislation compliment is by GFSI Certification of the supplier and/or letter of guarantee (Please see 2.3.4.2). The plant has service providers of external lab, calibration, pest control, waste management among others. There are contracts or certification supporting their services. Services contracts reviewed: Pest control contract (Please review pest control chapter) The Review process of the specifications including raw materials, packaging, chemicals, processing aids, contract services, and finished products are carried out every year with schedule. If some supplier has changes in their specs he send to the site the new document. Changes of specifications can be required from the clients. There is a list of all the specifications updated in the ORACLE.

| | |
|---|---|
| **2.3.2.1** | The methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications shall be documented.<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.2** | Specifications for all raw materials and packaging, including, but not limited to, ingredients, additives, hazardous chemicals, processing aids, and packaging that impact finished product safety shall be documented and kept current.<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.3** | All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation in the country of manufacture and country(ies) of destination if known.<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.4** | Raw materials, packaging, and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose.<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.5** | Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may vary by crop or by season).<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.6** | Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.7** | Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel.<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.8** | Description of services for contract service providers that have an impact on product safety shall be documented, current, include a full description of the services to be provided, and detail relevant training requirements of all contract personnel.<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.9** | Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable: i. Microbiological, chemical, and physical limits; ii. Composition to meet label claims; iii. Labeling and packaging requirements; and iv. Storage conditions.<br><br>**RESPONSE:** COMPLIANT |
| **2.3.2.10** | Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained. A list of all the above specifications shall be maintained and kept current.<br><br>**RESPONSE:** COMPLIANT |

## 2.3.3 Contract Manufacturers

The plant does not use services of contract manufacturers.

| | |
|---|---|
| **2.3.3.1** | The methods and responsibility for ensuring all agreements with contract manufacturers relating to food safety, customer product requirements, their realization, and delivery shall be documented and implemented.<br><br>**RESPONSE:** NOT APPLICABLE<br><br>**EVIDENCE:** The plant does not use services of contract manufacturers. |

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The plant does not use services of contract manufacturers.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The plant does not use services of contract manufacturers.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The plant does not use services of contract manufacturers.

## 2.3.4 Approved Supplier Program (Mandatory)

There is a register of approved suppliers including the supplier code, item number, description of the material, inventory item status, vendor name, vendor code, approved supplier status, double flag, and creation date. Some ingredients suppliers are defined by the Customer. The information of suppliers includes the contact information for each one. There is a risk assessment for the suppliers of the Site. Due the risk of the materials, the documents required to the suppliers are: Specification sheet Ingredient statement Kosher status Organic status Allergen statement Letter of guaranty Country of origin GMO Status Third party audits Reviewed some documents for the next suppliers Coconut water concentrate, Supplier Celebs coconut corporation Address Purok 4, Barangay Banza, Republic or Philippines. Specification sheet: No date, includes Origin, application, colour appearance, chemical, microbiological, packaging, storage. Ingredient statement: into the spec. Kosher status no declared Organic status ok Allergen statement ok Letter of guaranty covered by the GFSI Certificate Country of origin: Philippines. GMO Status no declared Third party audits: Exp date 07-24-2022 Extra virgin Oil: Supplier Borges Address Route de Manhdia km 10, Tunisia Specification sheet dated 2019-08 including declaration, Ingredient statement: declared in the spec Kosher status no declared Organic status ok Allergen statement: None Letter of guaranty: covered by the GFSI Certificate Country of origin: Tunisia GMO Status no declared Third party audits: June 13, 2022. Oatmilk powder, Supplier: Innovative Proteins USA Address: West sixth street, Galesburg IL, USA Specification sheet: including moisture, ash, protein, fat, microbiologic, Gluten Free, and Non GMO 02-01-2022 Ingredient statement: Kosher status: done in April 2, 2021 Organic status: no declared Allergen statement: Declared Letter of guaranty declared Country of origin: USA GMO Status declared in the spec. Declared. GF Statement: declared GFSI: expiration date 6-11-2022 Almond meal, Supplier: Treehouse California Almonds LLC, Earlimart, California Address: 6914 Road 160, Earlimart, CA 93219, USA Specification sheet: including origin, physical parameters, microbiological, sensory, allergens information, among others. Ingredient statement: declared in the spec, letter 01-2020 Kosher status: declared in the spec. Country of origin USA GMO Status: declared (01-2020). Third party audits: Exp date 08-01-2022 HALAL: 10-31-2022. PET Bottle: Supplier: Graham Packaging Company Specification sheet including dimensions, materials, primary PET resin, no barriers or additives, Ingredient statement Kosher status: no declared Organic status: n.a. Allergen statement: n.a. Letter of guaranty Country of origin USA. GMO Status no declared. The verification of raw materials includes the CoA, product and truck inspection. Reviewed: Material: Olive oil extra virgin RM90208 Date of reception: 5-3-2022 Truck inspection record and date: 4-18-2022 CoA: 2-18-2022 Comments: seals verified. Material: Almond Meal RM90682 Date of reception: 5-15-2022 Truck inspection record and date: 5-16-2022. CoA: 5-12-2022 Comments: Additional information of BOL, Reception report, Material: Coconut water RM90760 Date of reception: 4-28-2022 Truck inspection record and date:4-28-2022 CoA: 3-3-2022 Comments: Refrigerated units limit 10°f. Material: Oatmeal powder RM90882 Date of reception: 3-10-2022 Truck inspection record and date:4-28-2022 CoA: 2-17-2022 Comments: BOL including seals numbers Trucks inspection cover: clean exterior, seals, rodents or pest activity, conditions of the material expected receipts report, among others. There are not non-approved suppliers. The plant does not receive materials from other sites. Due the risk analysis results by suppliers there are not needed to audit them.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.1 Food Legislation (Mandatory)

There is a food legislation procedure ""Methods and Responsibilities for staying current - 2022). All the products are validated by the customer The site complies with the normativity of the FDA - included FSMA -, and clients' requirements. All the products are delivered to USA Clients, according to their specifications. Specifications include weight, nutritional requirements, content, lot, among others. The plant has to comply with FSMA. The SQFP and SQFP Backup are the QI. Preventive controls: Allergens, Sanitation, Supply-Chain, CCP. The procedure includes the documentation of changes of legislation. The clients deliver to the site any change of legislation. The Procedure includes the notification to the certification body and SQFI in case of regulatory warning event. In their Crisis Manual, the site has defined the notification of SQFI and CB in case of a crisis that implies some regulatory warning. The Manual includes notification to foodsafetycrisis@sqfi.com.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.2 Good Manufacturing Practices (Mandatory)

There are documented programs in place at the site that support Module 11 GMPs. The GMPs are validated and verified as required. Last validation in January 2022. The GMP procedures ensure their compliment under the scope of certification.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.3 Food Safety Plan (Mandatory)

There are prerequisites applied by the site included in the FS Plan: Raw material / packaging controls and receiving Foreign body controls Allergen controls Staff controls Calibration Sanitation Pest control Maintenance Water Material and traceability controls Control of non-conforming product Finished product controls Chemical controls Waste controls Food defense, crisis management, among others. The plant has one HACCP Plan based on the Codex Alimentarius Commission HACCP Guidelines and HARPC. The HACCP plan assures the manufacture of safe packaging products. There are prerequisites linked more robust that the exigence of the HACCP analysis that made the system more reliable. There is a multidisciplinary team formed by the SQFP (QA Manager), HACCP Training: Jan 9-10 2020, 10 years of experience in the food industry. PCQI: 11-23-2019, FDA 6-24-2021. Food Défense 6-26-2020, FDA Food emergency response 2019. SQFP Backup (Production Manager), HACCP Training: June 14, 2016, SQF Training: June 15, 2016, 12 years of experience in the food industry. Plant Manager, 4 years of experience, Last HACCP Training 2021-03-09 Maintenance Manager, 6 years of experience, Last HACCP Training 6-14-2021 Warehouse Manager, 12 years of experience, Last HACCP Training 6-12-2021 Sanitation Manager, 4 years of experience, Last HACCP Training 2021-03-08 Facilities engineering Manager, 4 years of experience, Last HACCP Training 2021-04-15 Microbiologist, more than 10 years of experience, Last HACCP Training 2021-03-04 The scope of the FS Plan includes all the Site processes cover by the SQF certificate: Main processes are: Beverages production Edible Oil production There are product descriptions for Beverages: Product families: Soft drinks, juice drinks, water based drinks, and Edible Oil. Product: Beverages, Product description: Turbulent flow-pasteurized, high acid beverage product commercially sterile with pH below 4.6 Intended use and consumers: Drinks for human consumption. Packaging: PET Bottle Method of storage: room temperature Shelf-life: one year Low risk (Low acid products), high risk (High acid products). RTE Country of distribution: USA and Canada No alternative uses identified. Labelling instructions: May contain allergens. Edible Oils: Product: Edible Oil (Olive oil, sunflower Oil, grapeseed oil), Aw: 0 Product intendent use: Food service as an ingredient in another recipe of process (Ingredient). Method of storage: room temperature Shelf-life: one year Low risk RTE Country of distribution: USA No alternative uses identified. There are two flow diagrams for beverages and Edible Oils dated 5-31-2022, 5-26-2022. The steps are reception of materials storage of materials (refrigeration if apply), reception and treatment of water, weighting, blending, sterilizing or pasteurizing, sterilizing of bottles and caps, filling, cooling, capping, and palletizing. The investigation of hazards is made by the HACCP team using severity and probability analysis to evaluate the hazards and verifying or implementing prerequisite programs to ensure their elimination or reduction to acceptable levels. There is a HACCP analysis for raw materials as water, coconut water, coconut flavour, several juices, primary packaging as plastic bottle, among others. Microbiological hazards include: Pathogens, E Coli, Salmonella, listeria, among others Chemical hazards includes: allergens, residual chemicals of cleaning, among others. Physical hazards includes: foreign matter from machines, shipping, among others. Documented measures are inspection of filters, Preoperational inspections, visual inspections, SSOP, Suppliers control, Product sampling and inspection, specifications control, Visitors policy, among others. For Line 1 and 2, HACCP CCP are pH of product in Blend System (Less than 4.5). Allergens information in the Label For Line 3, HACCP CCP are Pasteurization (time 8.07 seconds or more, 279°F or more, 110 GPM Maximum Allergens information in the label. Cap Sterilization, sterilant concentration ($H_2O_2$ Level 33-35 ppm) Preform sterilization, sterilant concentration ($H_2O_2$ level 33-35 ppm) For Edible Oil CCP are Screen: intact. The HACCP Master plans includes critical limits. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. The HACCP Master plans includes what, who, how monitor the behaviour of the device, corrective actions in case of failures, and verification. Monitoring of the CCP are by the operator or by QA, and verification by QA." Suspicious product is separated, analysed, and disposed to no offer FS risks. The HACCP process includes a validation plan execution. Line 1,2: last validation in 5-25-2022. Line 3: last validation in 5-26-2022 Edible Oil: last validation in 5-31-2022 Monitoring of CCP is verified by inspections, supervision, and verification of the activity. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. There is a corrective actions process ready to work in case of a failure of CCP. No failures in the last 12 months. The system follows the Codex Alimentarius Commission HACCP, and HARPC. The HACCP process includes a verification plan execution. Line 1,2: last verification in 5-25-2022. Line 3: last verification in 5-26-2022 Edible Oil: last verification in 5-31-2022 Minor: Coconut water is an allergen, it is controlled as such in the plant, however in the HACCP analysis this chemical danger for the raw material is not defined.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** MINOR

**EVIDENCE:** Coconut water is an allergen, it is controlled as such in the plant, however in the HACCP analysis this chemical danger for the raw material is not defined.

**ROOT CAUSE:** The HACCP analysis for the ingredient Coconut water was not clearly identified as an allergen under chemical hazarder for the raw material the wording Environmental Chemicals was utilized, which refers to a chemical compound or chemical element present in air, water, food, soil. dust, or other environmental medias such as consumer products (National Biomonitoring Program, CDC, ND).

**CORRECTIVE ACTION:** The ingredient hazard analysis for Coconut water was evaluated and the chemical hazard only listed Pesticides and Environmental Chemicals. The specification sheet of the raw material was reviewed to verify the raw material was identified as an allergen; and was confirmed. Allergen was added to the ingredient chemical hazard. In addition to, the following added to the justification column: The US FDA recognize eight major food allergens: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybean. A consumer with food allergies can experience the following allergic reaction symptoms; anaphylaxis, hives, flushed skin, or rash, tingling or itchy sensation in mouth, face/tongue/lip swelling, vomiting, diarrhea, abdominal cramps, coughing or wheezing, dizziness/lightheadedness, difficulty breathing, loss of consciousness. In addition to, the following added to the measures applied column: Allergen Monitoring Program, and allergen labeling on finished product at a later step. The HACCP team will review annually or when ingredients or process changes.

**VERIFICATION OF CLOSEOUT:** HACCP Analysis

**COMPLETION DATE:** 06/17/2022 **CLOSEOUT DATE:** 06/24/2022

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.4 Product Sampling, Inspection and Analysis

The plant has defined responsibilities and methods of sampling, inspecting, and/or analysing raw materials, work in progress on the HACCP and Quality Plan. The test are for all the lots: the measures are pH, ° Brix, acidity, density, among others. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. There are recognized methods for the analysis of physic chemical characteristics, Aw and Moisture by the use of devices with the predefined methods (AOAC Standards). External analyses are carried out for the next tests: Microbiological environmental tests and water microbiological tests. External laboratories are accredited under ISO/IEC 17025, expiration date 2-16-2024. Annual proficiency testing is carried out based in the QC Proficiency testing /training QCP 094 The laboratory is located out of the production site process. There is no allowed access by locked door. Restricted area signage was observed. Lab waste is mainly trash It is managed by normal disposition of trash. There are retention samples of all the products. They are retained for one year or more if the client require. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Lab waste is mainly trash

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

**RESPONSE:** COMPLIANT

**2.4.4.6** Records of all inspections and analyses shall be maintained.

**RESPONSE:** COMPLIANT

## 2.4.5 Non-conforming Materials and Product

The plant has a program for Non-conforming product. Non-conforming products are identified with label colour red Non-conforming products are verified by QC for each lot. The product is evaluated mainly for pH and other parameters as Brix, density, among others. Reviewed example of colour vegetable juice, date 4-2-2022. The NCP is recorded in the ORACLE system and can be released by QA. Quarantine information is recorded in the ORACLE System.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.6 Product Rework

The rework product can be due some correction in labels. Corporate generate a Rework WO and the material can be reworked. The product is released and recorded in the rework report into the production WO. The rework is released in ORACLE by Quality. The rework does not affect the FS or integrity of the product.

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

**RESPONSE:** COMPLIANT

## 2.4.7 Product Release (Mandatory)

There is a Product Release Procedure All the lots are released by previous pH and other critical parameters. Once all inspections and analyses are successfully, the product can be released. The release is by chemical testing. Examples reviewed: Product: Califa Farms Lot 8022131pn3, dated 5-11-2022, with information about solids, pH, Density, Bacteria. Product: Extra virgin Oil. Due that the process consists in the re-packaging of the bulk to other size of containers, the original CoA of the oil is attached to the finished product information as evidence of the compliment with specs. Off-Site or contract warehouses are not needed.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.4.8 Environmental Monitoring

There is an environmental monitoring procedure that uses sonification of the site. The test per zone is: Z1: Food contact surfaces (Post production) Z2: Production area near of food contact surfaces (Weekly) Z3: production area far contact surfaces environment (Weekly) Z4: non-production area impact zone (monthly) The lab analysis is carried out by the plant and by external lab. Reviewed the records of the If there is some positive results, there is another swabbing, CAP is carried out (clean again and looking for the root cause analysis and solution), segregation of product if needed, among others. No positive cases have been present. Internal results reviewed of 2022 for salmonella, listeria. External results reviewed: (monthly frequency) dated 3-2-2022 ISO 17025 Certificate of the external lab was reviewed.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.5.1 Validation and Effectiveness (Mandatory)

There is a schedule of the verification of the system planned in the HACCP. The verification of the System is in the HACCP too, The validation schedule covers all the clauses of the SQF 9 Code. Reviewed the validation of the HACCP (5-2022).

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

**RESPONSE:** COMPLIANT

## 2.5.2 Verification Activities (Mandatory)

There is a documented verification program (included in the HACCP) in place at the site. The verifications are by GMP inspections, facility inspections, Internal audit, PCQI review of documents, and records. Verification / validation schedule are defined (Reviewed the HACCP verification 5-2022).

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.5.3 Corrective and Preventative Action (Mandatory)

There is a documented corrective and preventive action program (ICA Form for CAPA) in place. Corrective actions are required for customer complaints, plant inspection findings, HACCP deviations, holds, audit findings, among others. Reviewed the application of the CAPA: Complaint solving by CAPA, 9-23-2021 Label mistake. Applied root cause analysis Please see information of evidence reviewed in the chapter of handling of complaints, and handling of NCP to see evidence.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.5.4 Internal Audits and Inspections (Mandatory)

Internal audits are carried out by the Corporate. Last 2021 the audits were on 12-6-2021. All applicable requirements of SQF 9 are audited. Objective evidence of each one is recorded. The Directive team, HACCP team and owners of the process audited are notified." There is one internal auditor (By the corporate). Training evidence reviewed (Principles of internal auditing dated 09-2019) and 08-2017, about SQF, and HACCP dated 09-12-2018. Internal inspections are carried out by the QC Technicians with frequency of weekly inspections. Topics inspected: cleaning and housekeeping of each area, doors, exteriors, building, equipment conditions, materials in warehouse, brittle materials, (dates reviewed 5-5-2022, 3-31-2022) Reviewed issues of brittle material in a filler dated 3-2022. WO is generated and maintenance sends a email when the pending is covered. Internal audits reports and NC are documented in the Corporate report. Corrective actions are followed by them. No NC of the last audit.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.6.1 Product Identification (Mandatory)

The identification of the raw materials, packaging materials, WIP, and finished product are carried out in the Electronic Control system monitored since the Control Room. The materials are identified by bar code, into the labels (Information about name of the product, UPC barcode, allergen contain, nutritional factors, ingredients, date of production among others). Start-up of products is by CIP Verification, and pre-operational inspections for each equipment. Reviewed record of Blend tank 2 section 6. Changeover of products is carried out before each change of product. Reviewed the changeover procedure of flavour change on the fuji sleever PP 080. Reviewed coconut beverage record dated 5-31-2023. Reviewed records of May 23 for line 2. Conciliation of labels was reviewed for Coconut beverage Line 1 dated 5-31-2022.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.6.2 Product Trace (Mandatory)

There is a documented traceability program in place at the site for Trace and Withdrawal/Recall Procedure. Finished product is traceable at least one step forward to the customer and at least one step ack from the process to the manufacturing supplier. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded. Reworked product is identified in a WO of the ORACLE System Results of the last traceability exercise are: Product challenge for the company: Product name: PK 91081. Date of exercise: 3-7-2022 Production date: 1-28-2022 Production quantity 17234 cases Times: Start 12:43 pm, finish 13:00 pm Mass balance: 100%

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

**RESPONSE:** COMPLIANT

## 2.6.3 Product Withdrawal and Recall (Mandatory)

There is a documented Recall program (part of the FS Plan dated 5-23-2022) in place at the site. The Site has a requirement for an investigation to be performed for the cause of a recall and the failure of any mock recall. The site has an emergency committee ready to act in case of one or in case of a recall event. There have been no recalls or withdrawals during since the foundation of the Company. Mocks include one back and one up exercises. Testing was carried out on products from different shifts and for materials. Reviewed recall test of Product (clause 2.6.2). There procedure includes the notification to SQFI and CB information at least in 24 hours.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.6.4 Crisis Management Planning

There is a Procedure Crisis management last update 06-2021. The crisis team is formed by Plant Manager, Production Manager, QA Manager, and sanitation Manager among others. Controls are implemented based on the control of personnel security, equipment and product. Affected product is controlled by NCP procedure. Corporate is the responsible to the communication of relevant about the crisis. Last crisis mock was carried out on 4-14-2022 with a simulation of contamination of fresh water supply of facility. The crisis team acted immediately with the protection of the people, and executed three steps: react, respond, and recover, among others.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.7.1 Food Defense Plan (Mandatory)

There is a documented food defense plan 04-01-2022 designed to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident. The procedure includes the assessment analysis with information about process step, process description, score and rationale, 1,2,3, sum, explanation, and actionable process step. The food defense plan was assessed in 04-01-2022 to identify potential threats that can be caused by a deliberate act of sabotage or terrorism. The assessment includes methods for prevention sabotage or terrorist-like incidents. There is an analysis of all the steps of the process. All the controls are implemented. The vulnerable points have card access control. Controls include security cameras, employee training, data backup, chemical control program, shipping procedures, personal card electronic locks, restricted areas (as ingredients adding points) among others. Reviewed challenge of 4-14-2022 with a simulation of contamination of fresh water supply of facility. The result was successful.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.7.2 Food Fraud (Mandatory)

There is a Food Fraud Procedure ""Food fraud program overview"", last update 01-05-2022. There is a documented food fraud assessment, (including susceptibility to raw material or ingredient substitution, finished product mislabelling, dilution, or counterfeiting). The risk of food fraud is part of the Food Safety assessment. The procedure includes a mitigation plan (including approval program, shipping inspection, label review, CoA, seals number in the BOL of the trucks, letter of commitment, among others) in place including identified food safety vulnerabilities of ingredients (no ingredient classified as vulnerable). Gaps and corrective actions documented are carried out into the internal audits. Instructions as review of CoA, seals in trucks, among others are provided to the staff} (records of Olive Oil were reviewed in the supplier approving chapter). Last review of the plan was carried out in 01-2022.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.8.1 Allergen Management (Mandatory)

There is an allergen policy Policy 05. There is a procedure for allergen control it prevents sources of allergens from contaminating products by: i. A risk analysis of raw materials, ingredients and processing aids is included in the HACCP. Lubricants are food grade. Reviewed 730 Spragrip ii. An assessment of workplace from locker rooms, vending machines, lunchrooms, and visitors is included in the GMP Rules. iii. A list of allergens of country (USA). iv. A list of allergens accessible to relevant staff v. A control of hazards incorporated into the FS Plan (Labelling, order of production, CIP, inspection before the starting of a product, swabbing protein presence, clothing protection as aprons and sleeves, among others) (reviewed record of 3-2-2922 for line 3, filler area, allergen tested: coconut (included in the procedure for allergen testing QCP 217). vi. Management plans for control of identified allergens are included in the HACCP." There is a procedure (referred in the HACCP) for handling the product since raw material to finished product including reworking. The procedure includes the controls named in 2.8.1.1. Identification of allergens is by labelling. The monitoring is by swabbing and visual inspection. "There is a procedure of cleaning allergens SP 011 and sanitization between changeovers (Example by CIP). The measurement is by rinsing residues and swabbing. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. Line 1 and 2 uses coconut, line 3 uses coconut and almond, oil plant does not use allergens. The separation of lines in the moment of cleaning is by Sanitation area. The validation and verification of allergens cleaning is by swabbing. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. There is a changeover procedure for each equipment and line to avoid cross-contact by allergenic materials presents. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. Identification of product in line and equipment is by Policy 05 in accordance with regulatory requirements. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. Allergenic products are included into the trace system by identification of their ingredients The allergens are identified in the labels of the finished products. They match with the recipes. Labels are verified during the reception as raw material and blending. Labels reconciliation during the production is by the packaging staff. Obsolete labels are disposed by the warehouse staff. Labels are controlled during the changeover by the packaging staff. Re-worked product with allergens is not carried out. The control of allergens by suppliers, contract manufacturers, site personnel and visitor activities are by GMP Training.

| | |
|---|---|
| **2.8.1.1** | The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors; iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known; iv. A list of allergens that is accessible to relevant staff; v. The control of hazards associated with allergens and incorporated into the food safety plan, and vi. Management plans for control of the identified allergens.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.2** | Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.3** | Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.4** | Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.5** | Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.<br>**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.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.7** | The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.8** | The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.9** | The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.10** | Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable.<br>**RESPONSE:** COMPLIANT |
| **2.8.1.11** | Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.<br>**RESPONSE:** COMPLIANT |

## 2.9.1 Training Requirements

There is a documented training policy in place that includes new hire and refresher training (Topics as HACCP, FS Plans, monitoring of CCP, Personnel hygiene, Quality, food fraud, among others). Interviews with several employees (supervisors mainly) during the audit indicated that the training program was implemented and task essential to the maintenance of the SQF program were understood. New people are trained during 14 days in the main GMP topics. The next level has a topics pack including the Process operation, Loadout operators are preparate in loadout procedures among others. They can be uploaded in the training platform defining expiration date or programmed as presential event. For all the fulltime employees there is a schedule of training including all the prerequisites, CCP, and HACCP. Training requirements of essential positions as Filler Sterilization of caps operator CIP operator Sterilization operator Supervisor were reviewed.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 2.9.2 Training Program (Mandatory)

There is a training policy. The topics of training include GMP, HARPC, prerequisites, quality, among others. The schedule of training is uploaded for two options: eLearning, or presential. In the case of e-learning, each course is uploaded for the persons assigned and is defined a due date to take the event. In the case of a presential event, the people is programmed and sign an attendance list. Both options include exam. Key personnel like HACCP Team take a HACCP Training among other events. Reviewed info for CIP, CCP, GMP training events among others. The PCQI or Corporate delivers the materials. Training records include attendance list, skill descriptions linked with the job descriptions, training topics, date, competent trainer (generally the SQFP).

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.1.1 Premises Location and Approval

The site's buildings, property and surroundings were observed during the audit to not pose a food safety risk to products. Measures have been established to maintain a suitable external environment and the facility performs external inspections as part of their internal audit program. No external inspections have been carried out. The site maintains the required approvals by relevant authorities: By New Jersey Department of health, expiration date January 31, 2023., FDA registration confidential xxxxxxx6550 expiration date Dec 31, 2022.

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

**RESPONSE:** COMPLIANT

## 11.1.2 Building Materials

There were no issues noted with the construction of floor. There were no issues noted with standing water or drains. Waste traps are not used. There were no issues noted with the construction of walls, partitions, ceilings or doors. The junctions were observed to be clean. Ducting, conduit, and pipes of steam, or air have sanitary design and are easy to clean. There is a risk analysis conducted. No risks observed No pipes were observed over product lines or storage areas. There is a risk analysis conducted. No risks observed. There were no issues noted with doors and windows. Their materials of construction are solid and windows are of shatterproof glass. The ceiling did not appear to present a contamination hazard. There were no drop ceilings in the production areas. There were no issues noted with stairs, catwalks or platforms.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Waste trap is not needed

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.1.3 Lightings and Light Fittings

There is a interior lighting inspection carried out quarterly by the maintenance area. Includes the parameters and results. Reviewed report of 5-12-2022. Regulations of light-intensity verification report was carried out by the site. Light fittings were observed with design that not put in risk the product or process (warehouses, production area, staff installations, etc.). Light fixtures over product exposed was protected.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.1.4 Inspection/ Quality Control Area

The site does not have inspection control area

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

**RESPONSE:** NOT APPLICABLE

## 11.1.5 Dust, Insect, and Pest Proofing

External personnel access doors are provided in the three sites. They enter the plant through the change room of the personnel in the first level of the Site. All the process is a closed system. The finished product is contained in thanks and into the car rail or truck tank to their shipment to the client. The Warehouse of packaged powders and liquids is closed with locked door and with no holes or open spaces. The plant has methods for insect-proofed: Self-closing devices and adequate sealing of each level were observed. There is a closed system of transportation of the product. The plant uses insect control devices and multi-catch traps in the interior of the sites. Poisson rodenticide baits are used outside the site.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.1.6 Ventilation

Adequate ventilation was observed. Positive air is applied. Ventilation filters are MERV 13. The ventilation cleaning was adequate. It is part of the cleaning program. Not condensations were founded. Ventilators were observed protected against insect. No ventilators were observed over product area.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.1.7 Equipment and Utensils

There are specifications for the site's equipment, utensils, and purchase procedures for equipment. Equipment, Utensils were seen to be appropriately implemented. The main production equipment has the standard of design of the engineering designs for their process. Prior to purchase new piece of equipment, the potential items are researched to ensure they meet the industry standards using the Hazard Analysis Checklist Form. No new equipment installed during the last 12 months. No observed rooms for storage of equipment. Equipment surfaces were observed to be smooth, impervious and free from cracks and crevices. Equipment and utensils, including tanks, mixers, blowers, filters, and hopers are in adequate interior conditions for contact with the product. These items were found to be in good conditions and stored properly after use to prevent cross contamination. Containers and bins are made of non-toxic materials and were identified by the name of the material contained. Cleaning utensils are identified by colour, and good conditions. Wastewater from tanks, tubs and other equipment is discharged to the floor drainage system and meets requirements. Utensils of cleaning were observed clean. All equipment and utensils are cleaned at appropriate frequencies and are properly stored to prevent contamination. Lifters were observed with adequate Performance. Last Preventive Maintenance on May 29, 2022 NCE is segregated out of the operation area identified by their location in the plant.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** No observed equipment storage rooms.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.1.8 Grounds and Roadways

The external environment is a neighbourhood of non-polluting factories, neat and clean with paved streets, small stones area. Exteriors are free of trash, there is an open field around the site by security measure for the process. The roadways are of cement and small stones area with no hazard to the food safety of the premise. The product is conduced into a closed system. Not observed problems of street drainage. Surroundings are neat and free of trash.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.2.1 Repairs and Maintenance

Maintenance procedures are defined and included in the Sprocket app for the area. There can be weekly, monthly, quarterly, semi-annual, and annual frequencies of maintenance configurated in the app. The system gives a list of maintenance jobs to carry out. (Information of priority, work order identification, short description, equipment identifier, equipment description, location identifier, request type, request code employee, date opened change, target start date, end cate, estimated hours, status). There are 26 persons in the maintenance team for production processes. The system updates the jobs in the tablet of the technician. The tasks are completed by the technician and notify to the shift owner the jobs completed. Refrigeration system is an external support in quarterly frequency for the inspection of the freezer room. Reviewed last inspection dated 5-31-2022). Reviewed last roofs inspection and maintenance dated 4-1, 5-27, and 2-27, 2022 "Maintenance schedule is updated in the app Last three maintenance jobs of equipment: Line 1 Pasteurizer Line one (May 6 to May 30). Vision system (Feb 25-2022 to 6-1-2022) Line 2 Filler 5-19-2022 to 5-26-2022 Liquefier Feb 19 to April 19, 2022 Labeller (May 29 to June 1). Corrective maintenance is controlled by non-planned wo and uploaded in the app. The plant supervisors receive notification about preventive and corrective repairs. Procedure of temporary repairs MP 007. Control of temporary repairs are by WO. No observed temporary repairs. No observed equipment lubrication points over open product. Lubricants are controlled in a closed and locked cabinets. There are MSDS sheets for each one including SDS, and technical sheets. There is a list of food grade lubricants and other chemicals. Reviewed technical sheets of FG Lubricant Chesterton and 720. Paint is not used for equipment

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Paint is not use for product contact surfaces.

## 11.2.2 Maintenance Staff and Contractors

Maintenance contractors' agreements to comply hygiene requirements are defined in the Contractor Orientation document SFP 007 (5) that includes Topics of Food defense, Confidentiality, General rules, GMP, PPE, Housekeeping, among others. Reviewed agreement letter signed by Osage Company in 12-07-2021 and evidence of review of information list dated 5-3-2022. Roof maintenance contractors' agreement document dated 5-1-2022 (renovation in each WO). Air handling units' contract since 2-25-2020. Cleaning instructions are included into the app. Reviewed example of housekeeping completion dated 5-5-2022 included into the filler rotary GEA physical inspection. There is a sheet with the rules of GMP in the list of attendance of visitors to the plant. All the visitors have to read it before their entrance to the plant. Jobs are inspected by the maintenance area. Area has been cleaned at the final of the job. Start-up inspections of the line are defined. Minor NC: A contractor was observed wearing a watch inside the plant.

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

**RESPONSE:** MINOR

**EVIDENCE:** A contractor was observed wearing a watch inside the plant.

**ROOT CAUSE:** The contractor failed to follow the agreed GMP policies that was acknowledged at initial access point. The contractor stated the apple watch was placed on during his break and forgot to remove.

**CORRECTIVE ACTION:** An outside contractor was sighted by auditor wearing a watch, QC instructed to immediately leave the production area and to comply with company GMP policies. The supervisor of contractors onsite was notified of non-compliance after acknowledging the GMP policy agreement; The contractor stated, "the apple watch was placed on during break and forgot to remove it," the gentlemen was also removed from the site for not complying with company GMP policies. Owner from the hired contractor company was scheduled for a meeting with senior management (phone conference) to discuss the contract and company policies requirements and expectations. Facilities manager verified that contractor who was non-compliance be removed from working onsite. Visitors siging and GMP electronic form was reviewed and deemed to be acceptable with capturing all requirements in gaining access to production areas.

**VERIFICATION OF CLOSEOUT:** Evidence of communication with contractor

**COMPLETION DATE:** 06/02/2022 **CLOSEOUT DATE:** 06/24/2022

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.2.3 Calibration

Calibration procedure During the audit were reviewed some devices: Moisture: daily based in the QCP 213, every shift. Densitometer (daily). Lab multimeter (daily). Scales of lab, last date 5-11-2022 based in the procedure QCP 179. The contractors use NIST traceable elements. Calibration program is carried out by a schedule. No legal requirements apply. The Calibration procedure includes the segregation and ID as NC Equipment. All the team members are trained that they are not touch or alter any calibrated item. Equipment is used only by QA Personnel. There is a list of equipment to be calibrated QSF 07 011 02 (6). with information about equipment, model, serial number, description, location, calibration interval, calibration date, due date, calibration state, calibration certification.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.2.4 Pest Prevention

There is a pest prevention program Pest Prevention Procedure IPM Service and strategies i. Methods and responsibilities are defined including inspections, application of chemicals, and maintenance of the system. ii. Records of pest sightings and trends were reviewed iii. Methods to prevent pest problems were reviewed (inspection, housekeeping, cleaning). iv. Elimination methods were described in the Manual. v. Frequency of inspection is defined (every 2 weeks). vi. There is a map of pest control devices 1-1-2022 vii. There is a list of chemicals into the book of the contractor viii. Awareness to the staff about the contact with the bait station is by refresh training. ix: The handling of chemicals and baits is by the contractor. x. The effectiveness of the program is verified by trends and inspections. There is a Pest Prevention Procedure IPM Service and strategies Information of the pest control Service: Last annual assessment 2-1-2022 License of the company expiration date 10-31-2022 by the Department of Environmental Protection of New Jersey, and of the contractor license expiration date 10-20-2022 by the same department. Training evidence of the technician was reviewed. List or relationship of approved chemicals by the FSS contractor. All the chemicals have EPA number. Reviewed Evergreen product. Their use is recorded in the Pesticide usage log summary. Service reports of 1-18-2022, 3-30-2022, and 4-29-2022. Issues are communicated to the QA Manager. Trends of pest behaviour. Reviewed last 90 days trends with favourable behaviour. Reviewed 1st Quarterly trend data report dated 6-1-2022. Contract and annual assessment dated 2-1-2022. No observed pest activity into the site. Product affected by a possible contamination of pest is segregated as NCP There are not pesticides stored in the plant. No animals observed into the site. Areas with parts of equipment and other machines were observed in the warehouse arranged in such a way that the area cannot be inspected or cleaned. Minor NC Cobwebs were observed on the walls of different areas of both warehouses.

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

**RESPONSE:** MINOR

**EVIDENCE:** Areas with parts of equipment and other machines were observed in the warehouse arranged in such a way that the area cannot be inspected or cleaned. Cobwebs were observed on the walls of different areas of both warehouses.

**ROOT CAUSE:** Due to Covid-19 pandemic the company experienced massive turn overs and was unable to retain employees throughout the fiscal year to complete smaller task; understaff.

**CORRECTIVE ACTION:** Cobb webs was notice in the warehouse area in between the beams. Non-compliance was inspected by sanitation manager and Quality Assurance Manager. Cobwebs were removed from affected areas; area was cleaned and sanitized. Temp employees were scheduled on 6/17/2022 to fully complete additional oversighted areas throughout the dock areas and storage areas. Along the equipment storage area, a permanent yellow guided trail walkway is being placed to ensure access between stored equipment, and access to outer parameters areas of storage area. Sanitation Manager will evaluate all dusting procedures are completed quarterly, if areas are displaying struggles due to staffing concerns the sanitation manager will consult an outside contractor. Due to Covid-19 pandemic the company experienced massive turn overs and was unable to retain employees throughout the fiscal year to complete smaller task; understaff. Quality Assurance manager visually verified removal of cobwebs, and sanitation manager captured pictures in RedZone of cleaned and sanitized areas. Discuss in weekly meeting of utilizing temp personnel to help with sanitation procedures that has no chemical usage. Discuss about having an outside cleaning contractor for dock and warehouse storage areas for dusting procedures in future if personnel concerns continue.

**VERIFICATION OF CLOSEOUT:** Pictures of the correction Notes of the agreements of the meetings.

**COMPLETION DATE:** 06/03/2022 **CLOSEOUT DATE:** 06/28/2022

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** There are not pesticides stored in the plant.

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

**RESPONSE:** COMPLIANT

**EVIDENCE:** No animals observed into the site.

## 11.2.5 Cleaning and Sanitation

There is a cleaning program for each equipment or area including their scheduling of cleaning. Reviewed SSOP of Almond base tank dated 4-28-2022 Includes Purpose, equipment, frequency, procedure, (inspection, operation of the CIP, and verification of effectiveness). Reviewed CIP cleaning procedure of ALMIX 1, 2 dated 5-8-2022 All the processes of cleaning are carried out by the production people if apply. Daily task records are uploaded in the REDZONE app or paper record and are supported by the team of sanitation. Verifications are by the Sanitation Manager. There is a List of chemicals QCP 445, including department of use, name of the chemical, supplier, container type, quantity, primary storage location, food grade (Y/N), among others. The people can consult the SDS in each moment by paper consult or a QR Link posted in several points of the plant. Inventory is maintained by external contractor and sanitation team. Detergents and sanitizers were observed properly stored. The chemicals are handled by sanitation people of trained operators. They have automatic dosing. Training evidence of the workers that use these chemicals was reviewed (5-24-2022, 4-11-2022) All the chemicals are used directly from the original dispenser. The site uses CIP: CIP system validation is by external contractor, reviewed report of 10-28-21 verification of rinse and operation are carried out by Sanitation team by swabbing and visual inspections. Training of the workers that apply this method. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. Records of monitoring of the parameters are updated in the platform REDZONE. There is a procedure QCP 131 ATP Swabbing applied at the end of the CIP or if is needed in another process. Reviewed results from 3-17-2022 to5-18-2022 The cleaning equipment is identified by colour code. Equipment areas are adequate. The area is separated and conditioned to avoid cross contamination. Racks are sufficient and adequate. Pre-operational inspections are recorded in REDZONE app in each lot. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. Staff locations observed clean and cleaning record in order.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** There are automatic mixing systems.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.3.1 Personnel Welfare

There are visual aids indicating to the personnel that they should notify if they feel bad and should not enter the plant. There is a Personnel Hygiene and Welfare procedure GMP Procedure. It includes training in allergens Newly hired operations personnel take the training based in the GMP Procedure. It has basic information about the compliance of GMP and SQF. Persons with suspicious to be il, or with visible cuts are not allowed into the processing area including contractors or visitors. The procedure includes care for injured people through first aid. Minor cuts, sores, wounds are healed and covered with visible element.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.3.2 Handwashing

There are defined points of handwashing. The staff washes their hands every time they get dirty. Handwash stations are in several points of the site and before the entrance of the production site. During the audit were observed correct application of the handwashing activities. Hand wash basins are of non-corrosive materials and supply potable water with liquid soap and sanitizer for hands, paper towels and disposition bins for them. There are not Hing-Risk areas. There are instructions of handwashing in each handwashing station. The gloves are disposable, used for some points of product contact equipment like mixers.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

### 11.3.3 Clothing and Personal Effects

There is a Risk assessment of clothing use is defined in the analysis “Hair, Clothing and footwear policy risk assessment” dated 3-16-2022. Based in the study, the clothing was considered adequate. Clothing and shoes of the people were observed clean and in good conditions. No observed excessively soiled uniforms. When used, the gloves are changed if they get dirty. No issues observed with the material of the clothing. The people changes their clothing daily. Allergens are handled with aprons, sleeves, and gloves. Racks for clothing are not needed. Jewellery or other accessories are not used.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Racks for clothing are not needed.

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

**RESPONSE:** COMPLIANT

## 11.3.4 Visitors

Visitors complies with the same GMP rules of the site staff. Visitors have to be recorded in a paper format and they have to read GMP rules if they want to enter. Visitors can not to use jewellery or other loose objects. The visitors have to notify to the contact in plant if they show visible signs of illness. The visitors have to enter to the manufacturing area by the entrance for visitors. The visitors who will stay in plant several days receive a complete training in GMP be the reading of the rules of behaviour in each visit. The visitors have to comply with the GMP rules of the site.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

Documented cleaning procedure is included in the cleaning documents of the Site. Change rooms are provided. Protective clothing is used (aprons, security shoes, daily changed of pants and shirts, cover for the administrative staff). There are not high-risk areas. The workers have their own lockers to store their clothing and personal items. Showers are no needed. For the Line 3 (high-risk products), the employees are supplied with uniform, and immediately replaced when torn or soiled. Toilet rooms are separate from processing areas, are sufficient, adequate construction to be cleaned, they are kept clean and tidy. Cleaning tools are separated. There are handwashing basins are near of the rooms. Sanitary drainages are not connected with the other drainage Handwashing basins are provided immediately out of the production or storage sites. Break room are separated of the production zone. Ventilated, with hot and cold potable water, with refrigerator and ovens. It was observed clean and free from waste materials and pests. No outside eating areas

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Showers are no needed.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** No outside eating areas

## 11.4.1 Staff Engaged in Food Handling and Processing Operations

All the staff engaged in food handling and processing operations have GMP training. The supervisor inspects the people hygiene practices daily and update the report to Redzone. The staff follows at least the following processing practices: i. Use of personnel access doors only, ii. The doors kept closed all the time. Iii. Not use of false fingernails or fingernail polish. iv. The written instruments with have lost items or lose items in wear are not permitted; v. Materials for the product elaboration or products are not in direct contact with the floor: vi. Waste is deposited in the recycling or waste bins only. vii. The staff cannot taste or eat any of the products or raw materials. Sensory evaluations are out of the manufacturing facility Sensory tests are only made by visual observation of odour, colour, and appearance. Hoses are hanged and not touch the floor. GMP Rules are implemented: no eat into the production site, no wear false fingernails and other potential contaminants, cover hair, cover beard, no smoke, chew, spit, etc, only can drink water in separated stations of the process, among others. There are cleared zones where the personnel can walk with minimum risk to the product. Sensory evaluations are in the lab with the needed equipment for the purpose.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.5.1 Water Supply

The water is supplied by well and if is needed, by the city. The water input system is maintained. The water is supplied by the city. There is a Potable water lockout procedure dated 5-9-2021. There is a supply of hot and cold water. Reviewed the last Test of potability of water by the state of New Jersey 2021. Reviewed Backflow system last inspection or maintenance (6 devices) The backflow system is inspected every year, last visit in 5-2-2022 The site does not use non-potable water Water is not stored in the site

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Non-potable water is not used.

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** Water is not stored.

## 11.5.2 Water Treatment

Reviewed Treated water plant testing record of 5-9-2022 was reviewed. Lab (Eurofins) has ISO 17025 Certification. The treatment includes filtering, UV, among other processes. The water is monitored regularly by the lab.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.5.3 Water Quality

There is a Water microbiological and chemical testing by the New Jersey State, annual report 2021. The plant does not use ice. The test is executed under reference standards and methods by a certified external laboratory. For microbiological testing information please see 11.5.1 Water is analysed using reference standards method (AOAC Methods)

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.5.4 Ice Supply

The plant does not use ice

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The plant does not use ice

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The plant does not use ice

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** The plant does not use ice

## 11.5.5 Air and Other Gasses

Air and nitrogen are used in the process. Air and nitrogen are used for the process. Compressed air filtering is monitored during the PM routines. Reviewed CoA of N2 with results of purity over 99.999

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.6.1 Receipt, Storage and Handling of Goods

There is a procedure of receiving and storage. The procedure covers the practices of storage aligned to SQF. All the products and transports are inspected before the loading looking for BOL, Carrier, ship to, number of pallets, po, cleaning of the box, damages, soil, pests' inspections among others. Receiving inspection report Product: coconut conc. Date: 4-28-2022 Inspected truck conditions, product conditions, Seal number, cleaning Attached the relationship of pallets, CoA, BOL Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. The procedure includes good storage practices. The Organization of the product were observed adequate. Rotation observed adequate. No materials used with exceeded shelf life were observed. No observed temporary or overflow conditions. Storage of raw materials, ingredients, finished products, chemicals, equipment are planned and are sufficient. There was not observed temporary storages.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.6.2 Cold Storage, Freezing and Chilling of Foods

Refrigeration and freezing processes are controlled in every lot by thermograph system. The information reviewed showed sufficient capacity of the refrigeration and freezing systems. Freezers last PM 4-20-2022 There is one freezer in the facility, one temperature-controlled room and one incubation room is for samples conservation, and one cooler rooms. The freezer and cooler are controlled by temperature disc recorder automatic system. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. No issues observed with defrost and condensate discharges.

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

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

Storage room is located in a dry environment. Racks are of impervious materials. Their observed clean and separated of the floor. The floor and walls were clean.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Hazardous chemicals are stored in separated way and are identified. There are SDS for them. The area of chemicals is identified and ventilated. Pesticides are not store into the site. Each chemical observed is labelled. No observed chemicals out of their area. Chemicals reviewed have EPA number. The area of chemicals is locked and only authorized personnel has access to it. The operation people is trained in the cleaning procedures and use the protective equipment as googles, among others. Training evidence of the workers that use these chemicals was reviewed (5-24-2022, 4-11-2022) Reviewed training of 4.11.2022. They follow the instructions of use of the chemicals. Empty containers are disposed as trash. There is a contractor for their disposition. The procedure includes actions and measures in case of spillage.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.6.5 Loading, Transport, and Unloading Practices

Loading transports procedure and a couple of examples of records Reviewed record dated 09-21-2021, product transported flavour strawberry conc 86111204 BAI, the report is uploaded in the Redzone Platform. Reviewed 1-13-2022 record. The PM of the lifters is included in the PM app program. The lifters are inspected daily and more deeply reviewed at least monthly. Vehicles are inspected before loading or unloading. Reviewed records of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. The inspection is recorded in the system linked with the control room system. The vehicles inspected use seal or lock to avoid tampering. Seal number is recorded in BOL. Trucks of shipping and receiving are always sealed. Reviewed Transport inspection report for shipment W-P066(5) Product/Client Bai Date 11-15-2021. Inspect truck conditions and cleaning, and is reviewed the BOL The truck is sealed. Docks seal with the box of the trucks at the moment of loading and unloading. Received refrigerated units' temperature is verified turing the truck inspection. The product is stored in the controlled temperature rooms immediately." Refrigerated units' temperature is controlled all the time with thermographs system. Units' maintenances are included in the PM System. The trucks are unloaded in fast way.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.7.1 High-Risk Processes

Line 3 is High Risk All the employees of the site are supplied with uniform, and immediately replaced when torn or soiled. In addition to, receiving fresh new uniforms annually. The line 3 is handles in a closed system with no product is exposed to the environment. The only point exposed is the blending area with only dry ingredients handling. Handwashing is performed after entering the production area, after breaks, restroom usage, and unsanitary conditions, during product changeover/ingredient changeover (applies to all production lines) Line 3 has separated batching and blending areas then lines 1 & 2 Separation of lines and designated personnel

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.7.2 Thawing of Food

No thawing of food

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** No thawing of food

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** No thawing of food

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

**RESPONSE:** NOT APPLICABLE

**EVIDENCE:** No thawing of food

## 11.7.3 Control of Foreign Matter Contamination

Foreign matter is controlled by several ways. Screenings, filters, during the CCP monitoring, CIP Cleaning, and PM of the equipment. Monthly GMP inspections (reviewed the records uploaded in REDZONE) of 11-15-2021, 2-22-2022, 03-31-2022, 4-11-2022 and of the products during the audit. The procedure for the foreign matter control covering wood, metal, knives, and brittle materials among others. Inspections are performed to ensure plant and equipment remain in good conditions and equipment is in good conditions and frere from potential contaminants. Verification records of screens, magnets, and filters is carried out by the maintenance team. Reviewed the filter 85324 inspection dated 5-5-2022 Magnets are verified against Calibrated Gauss Meter (Calibration dated 4-14-2021). The verification is during the pre-operational inspections reviewing at the same time the presence of foreign matter. (Reviewed quality check 3786222 DATED 2-5-2022) There is a brittle materials monthly checklist carried out during the inspections and PM. Brittle materials inspections cover parts of equipment. Attention to breakages is defined. No issues of breakages during the last 12 months. Wood control is verified by the Quality Checks (recorded in the Redzone app). No issues observed. No observed loose metal objects on equipment. Knives are inspected during the pre-operational inspections, reviewed and updated in the Redzone. There is a knife and cutting tool use procedure SFP 013, (2). There is an employee list knife tracking with information about the name of the employee, department, job title, type of knife, among others. Gaskets and other equipment parts are inspected during the maintenance routines. Equipment is inspected during the pre-operational checklist, PM, and CIP. No issues founded.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.7.4 Detection of Foreign Objects

There are several points of foreign matter retention and detection identified in the HACCP. Filters, magnets, or sieves are monitored and verified by CCP Monitoring, CIP inspections or PM." Controls and limits of detection are defined in the HACCP. For information about monitoring, validating, and verification of CCP please see the HACCP Section. For information about recording of metal detectors, please see HACCP Section Foreign matter is identified, and actions are taken based in the HACCP plans or NC root cause analysis. No issues founded during the last 12 months.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

## 11.8.1 Waste Disposal

There is a procedure for waste handling. The waste is mainly row materials packaging and common trash. No observed accumulated waste in the production site or in the exterior areas assigned for them. Trash is accumulated in plastic containers and disposed in the containers out of the site. Disposition is carried out frequently and not accumulate excessive quantity of trash. No observed overflow water in drainages system. The waste areas and bins observed in good conditions and clean. No pest presence observed. The disposition areas were observed adequate. Trademark wasted is not generated Animal feed is not processed The storage of waste is out of the production site into a closed container. Liquid waste does not offer hazards during their disposition. Waste management effectiveness is verified during the monthly inspections.

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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

**RESPONSE:** COMPLIANT

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