**Audit Report** **Global Standard Food Safety Issue 9**

| 1. Audit Summary | | | |
|---|---|---|---|
| Company name | Milne Fruit Products Inc | Site code | 1013340 |
| Site name | Milne Fruit Products | | |
| Scope of audit | The chopping, screening, filtering and thermal processing of fresh or frozen fruits and vegetables, to form purees and juices which are packaged into aseptic bags, poly-lined drums, plastic pails and tanker trucks | | |
| Exclusions from scope | None | | |
| Justification for exclusion | N/A | | |
| Audit start date | 2024-10-15 | Audit finish date | 2024-10-16 |
| Re-audit due date | 2025-10-28 | Head office | No |

| Additional modules included | | | |
|---|---|---|---|
| Modules | Result | Scope | Exclusions from Scope |
| Choose a module | Choose an item | None | |
| Choose a module | Choose an item | | |

| 2. Audit Results | | | | | |
|---|---|---|---|---|---|
| Audit result | Certificated | Audit grade | A | Audit programme | Announced |
| Previous audit grade | A+ | | Previous audit date | 2023-10-25 | |
| Certificate issue date | 2024-11-25 | | Certificate expiry date | 2025-12-09 | |
| Number of non-conformities | | | Fundamental | 0 | |
| | | | Critical | 0 | |

| 2. Audit Results | | |
|---|---|---|
| | Major | 0 |
| | Minor | 8 |

| 3. Company Details | | | |
|---|---|---|---|
| Site address | 804 Bennett Ave.<br>Prosser, Washington 99350 | | |
| Country | United States of America | Site telephone number | +15097862611 |
| Commercial representative name | Shannon Elkins | Email | selkins@milnefruit.com |
| Technical representative name | Ed Thomas | Email | ethomas@milnefruit.com |

| 4. Company Profile | | | | | |
|---|---|---|---|---|---|
| Plant size (metres square) | <10K sq.m | No. of employees | 51-500 | No. of HACCP plans | 1-3 |
| Shift pattern | 5-7 days per week, 2 or 3 production shifts (seasonally dependent), 07:00 to 15:00, 15:00 to 23:00, 23:00 to 07:00; Sanitation varies depending on production schedule. | | | | |
| Seasonal site | No | | | | |
| Seasonal opening times (Start/end date) | N/A | N/A | | | |
| Other certificates held | Organic – WSDA 94468, Kosher from OU expiry 2024-11-30, Halal from IFANCA expiry 2024-10-31, non-GMO from non-GMO project expiry 2024-11-13 | | | | |
| Outsourced processes | No | | | | |
| Outsourced process description | N/A | | | | |
| Regions exported to | Asia<br>North America<br>South America | | | | |

## 4. Company Profile

| | |
|---|---|
| | Europe<br>Oceania |
| Company registration number | FDA Bioterrorism Registration XXXXXXX4296; FDA FCE Number 29321; WSDA 596. |
| Major changes since last BRCGS audit | The site has closed the Vegetable plant and moved both the QA Manager and Plant Manager to this site. They install a new HTST heat exchanger. The site is installing an aseptic apple and pear aseptic line, which is scheduled to become operational in November. |

### Company Description

The Milne Fruit Products, Prosser, WA facility manufactures fruit and vegetable juices, purees and concentrates. This is a privately held corporation producing items which are sold as ingredients brand owners of fruit and vegetable-based products for further manufacturing into products to be sold retail or to food service providers. In addition to this site Milne Fruit Company has a facility located in Sunnyside, Washington which is currently inactive. They had a Vegetable plant which also located in Prosser which has been deactivated. The plant consists of 49,998 square feet under roof for production and storage and sits on 8.5 acres of land. It is in an industrial section of the city where approximately 100 full time employees conduct manufacturing operations 12 months per year, 5-7 days per week depending on the season and operates 24 hours per day. There are approximately 55 employees on the first shift including the support staff. The site was built in 1956 to manufacture ingredients for grape jelly. Currently the site receives fresh and frozen fruits and vegetables to form purees and juices that it sells. Additionally, the facility formulates and compounds custom blends to meet customer requirements. The management considers specific annual volumes, production capacities and inventory turnover to be proprietary and declined to divulge this information for this report.
GPS 46 12’ 8.94” N X 119 46’30.85” W

## 5. Product Characteristics

| | | | | | |
|---|---|---|---|---|---|
| Product categories | 06 - Prepared fruit, vegetables and nuts<br>11 - Low/high acid in cans/glass | | | | |
| Finished product safety rationale | Aseptic/thermal processed – pH < 4.6: Minimum processing temperature 163° F for 6 seconds; non-aseptic puree & concentrate heat treatment validated to give 5 log reduction of E. coli 1057, pH < 4.6, Frozen (<-18 °C) or refrigerated, shelf life 6 months to 3 years | | | | |
| High care | No | High risk | No | Ambient high care | No |
| Justification for area | Based on the decision tree in Appendix 2 of the BRCGS Food Safety Standard; the areas are enclosed product | | | | |

| 5. Product Characteristics | |
|---|---|
| Allergens handled on site | Nuts |
| Product claims made e.g. IP, organic | Organic, Kosher, Halal, non-GMO. |
| Product recalls in last 12 months | No |
| Products in production at the time of the audit | Grape juice |

| 6. Audit Duration Details | | | |
|---|---|---|---|
| Total audit duration | 18 man hours | Duration of production facility inspection | 6 man hours |
| Reasons for deviation from typical or expected audit duration | Almost all of the site's production occurs within enclosed tanks, heat exchangers and piping. | | |
| Combined audits | None | | |
| Next audit type selected | Announced | | |

**Present at audit**

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)

| Name | Job title | Opening meeting | Site inspection | Procedure review | Closing meeting |
|---|---|---|---|---|---|
| David Luther | VP of Operations | On-site | | | On-site |
| Michel Sorenson | CEO & President | On-site | | | |
| Edward Thomas | Director, Technical Services | On-site | | On-site | On-site |
| Crystal Johnson | QA Manager | On-site | On-site | On-site | On-site |

| | | | | | |
|---|---|---|---|---|---|
| Christopher Dowdy | QA Manager | On-site | On-site | On-site | On-site |
| Allen Roberts | Operations Supervisor | | | | On-site |

| GFSI Post Farm Gate Audit History | | | |
|---|---|---|---|
| Date | Scheme/Standard | Announced/Unannounced | Pass/Fail |
| 2021-10-27 | BRCGS Food Standard Issue 8 | Announced | Pass |
| 2022-11-01 | BRCGS Food Standard Issue 8 | Announced | Pass |
| 2023-10-24 | BRCGS Food Standard Issue 9 | Unannounced | Pass |

| Document control | | | |
|---|---|---|---|
| CB Report number | CPRJ-2023-166550; ACTY-2024-214650 | | |
| *Template name* | F908 Food Safety Audit Report Template | | |
| *Standard issue* | 9 | *Template issue date* | 2022-12-16 |
| *Directory allocation* | Food | *Version* | 1.1 |

## Non-Conformity Summary Sheet

| Critical or Major Non-Conformities Against Fundamental Requirements | | | |
|---|---|---|---|
| Clause | Detail | Critical or Major | Re-audit date |
| | | | |

| Critical | | |
|---|---|---|
| Clause | Detail | Re-audit date |
| | | |

| Major | | | | | | |
|---|---|---|---|---|---|---|
| Clause | Detail | Correction | Proposed preventive action plan | Root cause analysis | Date reviewed | Reviewed by |
| | | | | | | |

| Minor | | | | | | |
|---|---|---|---|---|---|---|
| Clause | Detail | Correction | Proposed preventive action plan | Root cause analysis | Date reviewed | Reviewed by |
| 3.8.1 | The site's Hold Product log notes disposition of held product, but it did not include records of the decision on the use or disposal of the product | A QA Manager meeting was held 2024-10-28. Notes will be linked to each hold for the ultimate disposition for each hold. At the time of this response, there have not been any hold releases since the BRC audit. Notes will be added to all future releases. | Each hold will include notes for detailing the ultimate disposition. The notes will be added at the time of release to ensure this step is not missed. | Inattention to detail. A requirement for keeping notes for disposition are included in our SOP and it was not being followed. The manager meeting should resolve the issue. | 2024-11-17 | John Clemence |
| 4.1.3 | The was a 2 inch by 4 inch cutout in the side of the rapid roll-up door frame on the door leading from the processing area to the receiving yard.<br>There was a 4" vertical gap along the side of the rapid roll-up forklift door into the aseptic room | One door has been repaired. The other needs parts. Parts have been ordered the repair. The repair will take place when the parts arrive on November 18. PO issued 2024-10-30. | A PM for the full inspection of doors has been placed. | We have a PM in place for the inspection of door sweeps. We discovered that our roll up doors do not have sweeps and were therefore not being inspected. The new PM will correct the situation by adding additional details to the work description. | 2024-11-17 | John Clemence |
| 4.2 | On the on-site portion of the audit the exterior door into the boiler room and the one into the shop were both unlocked | The doors have been locked. | Maintenance employees trained again on 2024-11-04 on the importance of locked doors. | Employee was not following the rules. These rules have been reinforced. | 2024-11-17 | John Clemence |

| Minor | | | | | | |
|---|---|---|---|---|---|---|
| 4.8.3 | In the locker rooms the employees' personal coats are hung intermixed with cold weather clothing worn by the workers in the plant | A new rack will be installed and labelled to allow for clothing to be separated. This is expected to be completed by the end of November 2024. A memo was issued 2024-11-10 on separation of clothing. | Employees will be trained on using the two racks, one for work cloths and one for non-work clothes. The training will take place after installation. | Employees are required to use their own clothing that meets Milne GMP expectations. We did not account for the fact that employees may wear clothing to work that may not meet expectations and then change into other clothing that do prior to reporting to work. Our corrective action will ensure these two options remain separated. | 2024-11-18 | John Clemence |
| 4.9 | There were numerous items such as clamps, trash, bolts on top of the electrical boxes throughout the plant | A plant walk through was performed and items were picked up. | An "Area Champions" system is being implemented so supervisors and managers take responsibility for the areas they are assigned to. As a part of this there will be regular inspections. This will ensure these housekeeping items are not missed as a daily requirement. | Our previous auditing and inspection process was not producing the results we expect. This new process will affect positive change in practice and culture. | 2024-11-17 | John Clemence |
| 4.9.1.1 | There was an unlabelled garden sprayer with some liquid in it the production room | This sprayer was discarded. | Labelling of containers will be included in the "Area Champions" program. | Our previous auditing and inspection process was not producing the results we expect. This new process will affect positive | 2024-11-17 | John Clemence |

| Minor | | | | | | |
|---|---|---|---|---|---|---|
| | | | | change in practice and culture. | | |
| 4.9.3.2 | There were several fluorescent light covers on the finisher deck with cracks | New light covers have been ordered on 2024-11-01. Light covers will be replaced when they arrive on November 27. | These light covers were missed during our most recent lighting upgrade. An inspection of these light covers will be included in our regular audits to prevent them from being missed in the future. | Sometimes it is not instinctive to look up when performing plant inspections. Without this specifically noted on our auditing paperwork, these lights were easily missed. Specifically including this on the regular audit eliminate the chances of missing this in the future. | 2024-11-17 | John Clemence |
| 4.14 | There were cobwebs on several of the ILTs | The pest contractor was contacted on 2024-10-22 and the cobwebs were removed. | A meeting was held with our pest control contractor and it was agreed that he would remove cobwebs from the ITL's during each service. | The pest control contractor agreed that he should have cleaned out the cobwebs. He indicated that he would make sure the ITL's were clean in the future. | 2024-11-17 | John Clemence |

| Comments on non-conformities |
|---|
| None |

## Additional Modules / Head Office Non-Conformity Summary Sheet

| Critical | | |
|---|---|---|
| Clause | Detail | Re-audit date |
| | | |

| Major | | | | | | |
|---|---|---|---|---|---|---|
| Clause | Detail | Correction | Proposed preventive action plan | Root cause analysis | Date reviewed | Reviewed by |
| | | | | | | |

| Minor | | | | | | |
|---|---|---|---|---|---|---|
| Clause | Detail | Correction | Proposed preventive action plan | Root cause analysis | Date reviewed | Reviewed by |
| | | | | | | |

## Audit team

| Lead auditor | | |
|---|---|---|
| **Auditor number** | **First name** | **Second name** |
| 20621 | John | Clemence |

| Audit team | | | | Attendance (YYYY/MM/DD, 24hr: MM) | | | Presence | |
|---|---|---|---|---|---|---|---|---|
| First name | Second name | Auditor number | Role | Audit Date | Start time | End time | Remote or physical | Professional recognition number |
| John | Clemence | 20621 | Lead Auditor | 2024-10-15 | 08:30 | 18:00 | Physical | |
| John | Clemence | 20621 | Lead Auditor | 2024-10-16 | 08:30 | 18:30 | Physical | |

## 1. Senior management commitment

**Quality Policy:**
The facility has a documented food safety and quality policy, it was signed by the CEO of the company on 2024-10-08 and published in the Quality Manual. A copy of the policy is posted in areas that are accessible to all employees. This is introduced in new employee orientation and refresher training for all employees. The statement includes a commitment to product safe and legal food, authentic products, meeting/exceeding customer requirements and regulations, train employees.

**Food Safety Culture:**
There is a *Culture of Food Safety and Quality Plan* reviewed 2024-03-20 which outlines the steps the site is taking to define and maintain a culture of food safety. The company utilizes several means of assessment to gauge the level of the food safety culture in the company.

- Employee Education – topics emphisized
  - HACCP
  - GMPs
  - Food Defense
  - FSMA and other important regulation
- Positive Influence
  - Employee recognition program
    - gift certificates
    - monthly birthday parties
  - Established a Company newsletter
- Measuring the program progress
  - Survey on annual basis: last completed in Sep 2023, -
    - The results were analysed over several months and implementation was begun in March
    - They identified areas for improvement – They implemented a Champions Programs in which supervisors are specifically assigned areas within the facility to assist employee identified issues.
- In addition, there is program of training given every 2 weeks, with a different topic emphasized each session.

The program was reviewed on several occasions, with plan to be reviewed at least annually. For example, the Internal audit of the program was done 2024-03-20.

In addition, the site has implemented Weekly Tabletop training sessions on food safety administered to all operational employees. They are made available in the break rooms. There are also informal daily production meetings involving all supervisors along with the QA Manager, Plant Manager and the Maintenance Manager to provide a detailed discussion of plant requirements and objectives for the day. There is a requirement for all employees to identify and report food safety concerns is documented in the refresher training. During the Grape season the sessions are being done daily.

**Objectives and Monitoring Quarterly:**
Senior management has established clear and measurable goals which include HACCP Training for Lab Technicians, Patulin testing proficiency of Lab Technicians, proficiency of Lab Technicians in printing Access reports, integrate QA data into Navision, create HACCP Plan for NFC (not from concentrate) apple and pear puree production, install new HTST for control of ACB (*Alicyclobacillus*) for fiscal year 2024.

The objectives for 2024 (fiscal year August 2023 to September 2024)

- All laboratory technicians to attend and pass specialized on-line Juice HACCP class (due to staff changes and market slow down, the training was postponed)
- All laboratory technicians to become and remain proficient in patulin training – met
- All laboratory technicians to become proficient in printing Access reports – met
- Integrate QA data into Navision – Not met as Navision is being updated by Microsoft and as a result the KPI was postponed
- Create HACCP plans for new NFC processing line due to start in November 2024 – in process
- Install new High Temp Short Time heat exchanger to control *Alicyclebacillus* (ACB) – met

For 2025, the following KPIs were established

- All laboratory technicians to attend and pass specialized on-line Juice HACCP class Patulin training
- All laboratory technicians to complete microbiological proficiency training
- Finish the HACCP plan for the NFC
- Commission the NFC line
- Fully implement the Culture of Food Safety Training Program
- Implement Document Compliance Network supplier automated management system.

Performance against these goals is monitored and reported to management quarterly and recapped at the annual senior management review. The performance was noted on reports dated

- 2023-12-06
- 2024-03-27
- 2024-06-26
- 2024-09-25

**Management Review and Meeting Program:**
Senior management reviews are held annually during which progress against all objectives is reviewed as well as reviews of the HACCP Plan. The most recent Annual Meeting was on 2024-10-11 and was attended by the General Manager, VP of Operations, Director Technical Services, Plant Engineer, VP Sales and Director Sales. The facility also communicates quarterly reviews to update the management on the ongoing performance.

There are weekly staff meetings which allow staff to bring issues to the attention to Senior Management, there are no formal minutes, but individuals keep notes related to areas of their concern.

**Confidential Reporting System:**
To allow staff to confidentially report concerns relating to product safety, integrity, quality and legality the site has contracted with a “Lighthouse” a commercial third-party service to maintain a phone site which allows anonymous reporting of any such instances. They maintain a Confidential Reporting System ‘hotline’ where anonymous calls can be made. There are posters in the plant and in the lunchroom providing information on the service. The HR Departments monitors the messages. The facility had not received any reported food safety or quality concerns since the last audit.

The QA Manager and Technical Director are responsible for keeping the facility informed of scientific and technical developments, industry codes of practice and all relevant legislation. The company is a member of the Juice Processors of America (JPA) and other industry associations. In addition, the company has an ongoing relationship with its food process authority.

During the audit, there was no indication that the Company’s senior management was failing to provide adequate human and finical resources required to produce a safe, authentic, legal products to the specified quality.

**Close out of NCR from previous audit:**
There were 10 minor non-conformance noted in the 2023 audit against clauses: 1.1.1, 1.1.4, 1.1.12, 3.4.1, 4.1.3, 4.4.8, 4.9.1.1, 4.10.3.2, 4.11.2 and 4.14.9. Corrective actions were undertaken by the site and no repeat non-conformances from the same root cause were noted.

**A copy of BRC standard:**
An electronic and a hard copy of Issue 9 of the BRC standard was on site during the audit.

**Recertification audit window and audit timing:**
Thie audit was performed within the audit window of 2024-09-29 to 2024-10-28.

The VP of Operations attended the opening and closing meetings.

The Director of Technical Services and QA Manager were available to review the FS & Quality Culture Plan during the audit.

The site utilizes the BRCGS logo on its website; it appeared to comply with the limitations for such uses.

**Site Registration:**
The site had up-to-date FDA Bioterrorism Registration XXXXXXX4645 (expiry 2024-12-31); FDA Food Canning Establishment Number 29321; Washington State Department of Agriculture License# 596 (issued 6-30-2024) in place.

**Organisation structure:**
There is an organization chart for the plant dated 2024-08-12; the facility had SOPs for every activity, acting as work instructions and job descriptions. The organization chart is maintained on-line which ensures it is current. The Quality Manager reports to the Director of Technical Services; this is designated in the organizational chart. The Quality Manager position is responsible for Quality and had a designated backup; the backups are indicated on the organizational chart. The facility management team is very small and multiple tasks were handled by a single person. The Director of Technical Services reports to the CEO and President.

**Deputation in absence:**
Alternates were listed in the team listing. There is a document *Key Staff Back-ups* dated 2024-01-08. The back up for President/CEO was VP of Operations. The back up of VP of Operations was Operations Manager.

**Job Descriptions:**
Job descriptions are documented for all employees and appropriate training programs have been developed and implemented. E.g., reviewed job description for Operations Manager (Jul 2022).

- Operations Manager – 2017-09
- Aseptic Operator – 2013-12
- Plant Engineer – 2017-09

The procedures are kept in a controlled access electronic server. Employees are trained annually on procedures by the Quality department. The employees are tested on their understanding of the requirements after training. Employees were observed complying with the requirements, and interviews demonstrated that the employees understood their accountabilities in relation to product quality and product safety.

The staff reported the issues to supervisor and/or supervisor.

| Details of non-applicable clauses with justification | |
|---|---|
| Clause/Section Ref | Justification |
| 1.2.4 | The site has sufficient in-house knowledge and food safety and quality systems are developed by site staff. |

## 2. The Food Safety Plan – HACCP

The plant's food safety plan is based on the HACCP system and follows Codex Alimentarius principles.

**HACCP Team:**
The HACCP team is made up of a multi-disciplinary group of employees. The Director of Technical Services is the team leader and has received HACCP training from an external source. Team members are

- Director of Technical Services – Team Lead – Basic HACCP – 2002-03-05 to 07
- VP Operations
- QA Manager
- Maintenance Manager
- Plant QA Supervisor
- Sanitation Lead
- Plant Engineer
- QA Manager – Basic HACCP – 2023-06-27 to 30

The newest team member (Plant Engineer) was trained by the team leader on 2022-05-17. The team leader trained the other team members on 2022-04-17.

**Products:**
The products were properly described and complete with the safety rational. The products are all thermal processed; there are some that are aseptically filled. Less than half products are ambient stable. The major of the products are frozen High acid products. High Acid products with a pH < 4.6 have a shelf-life of 6 months to 3 years. Intended for beverage and food industry, not for direct retail distribution.

The intended use is for industrial use only, there are no items produced which are intended for retail sales. Suitable for vulnerable groups e.g., infants, elderly, allergy sufferers except coconut water. Potential misuse; improper storage, poor seal management. Packaging; Aseptic Bags, Drums, Poly Liners, Pails, Bag in pail, bag in pail, bag in drums, bag in totes.

The process, customer uses, and packaging are also defined. Customer specific requirements, when required, managed as part of the change management procedure (e.g., customer specific kosher requirements). The basic processes are fruit receipt, enzymatic treatment, finishing, pressing, evaporation cooling and packaging. Each step in the process has received a risk assessment.

**Flow Charts:**

The site has 25 flow charts, they are based on the different processes varying with the type of fruit and the process; They fall into two general families, aseptic ambient stable and non-aseptic frozen. The various charts were verified on 2024-10-03 by multiple HACCP Team members. No changes were necessary.

The flow chart steps are similar for each; the process proceeds through the following steps: receipt, process – only 3 items are processed from seasonally available fresh fruit – grape, watermelon and cherry; the apples are stored in controlled atmosphere facilities by the fruit suppliers and are available throughout the year. Optional steps for frozen products may include, temper, washing, chop, enzymatic treatment, pressing, evaporations, cooling, puree, blending, thermal processed, aseptic packing, cold/frozen storage. Aseptic Products may be shipped or stored (usually refrigerated for quality concerns), non-aseptic products are frozen and stored in an off-site cold storage.

**Hazard Analysis and Hazards:**
A documented risk assessment (last reviewed 2024-10-07) has been carried out for all process steps and is incorporated into the hazard analysis. There are hazard analyses completed for each flow diagram. Ingredients (including packaging material and water) are listed. The hazards were listed for every step and analyzed for occurrence, severity which are then combined to extrapolate the risk level. The risk template and decision tree were appropriate for the process and products. The team considered the chemical (pesticide residues and heavy metals) and physical (metal, wood) risks. Biological hazards listed were *E. coli O 1*57:H7, *Cryptosporidium Parvum*, *Salmonella, Listeria* and *C. botulinum*; the heat treatment process destroys these, with the exception of *C. botulinum* in High Acid items where it is controlled by the product pH. Allergen risks are considered as part of the chemical consideration at the various processing steps. Radiological hazards were also considered. The control measures necessary to prevent, eliminate or reduce hazards to acceptable levels are included in the hazard analysis for each process step. Fraud and Malicious contamination are considered in separate risk assessments on 2024-10-12 and 2024-02-28 respectively.

A major resource utilized in the Hazard Analysis was the “Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition March 2004” issued by the FDA.

Pre-requisite programs have been established, these include items such as allergen management, sanitation, supply chain, pest control, maintenance, GMPs, etc. There are clearly defined control and monitoring procedures for these programs, their effectiveness is verified by various means including record reviews and internal audits.

**CCPs and critical limits:**
Based on risk assessment, 3 CCP’s have been identified;

- CCP-1– Thermal Process (the CCP is the same for both aseptic and non-aseptic)
  - Hold time and temperatures per validated processes (Minium processing temperatrure 163° F for 6 seconds, operating devert trigger temperature for non-aseptic 170° F and for aseptic a dropout temerature of 197° F)
- CCP-2 – Validated Allergen clean – for coconut water
- CCP-3 – Tanker (site installed)
  - Tanker seal

Note for apples and pears there are 2 additional CCPs for the control of mycotoxin (Patulin) both at receiving:

- Receiving – Patulin – Supplier guarantee – verification; periodic testing – actually test each lot (limit 50 ppb per customer requirements and WHO recommendations)
- Culling – Patulin – Visual Inspection –– verification; periodic testing

**Validation methods of CCPs:**

The site had documentation of how it determined the limits for each CCP

- CCP-1 – In the FDA regulation 21 CFR 120, the thermal process must achieve a 5 log for *E. coli* 0157 except apple and pear where the limit is for *Cryptosporidium*. The site's thermal processes had a validation performed and signed off by the site's Process Authority on 2009-10-30
- CCP-2 – Validated cleaning procedure
- CCP-3 – Finished product transport tanker
  - CP – Must have wash ticket no more than 24 hours old
  - Receiving intact seals which must meet those on wash and paperwork
  - Dispatch intact seals, numbers recorded on shipping documents

For the additional apple and pear Patulin CCPs the limits are regulatory based on the FDA limits for that mycotoxin.

**Monitoring and corrective actions:**
The site has established monitoring procedures and frequencies for the CCPs:

- CCP-1
  - Continous recorder chart reviewed by trained individual within 7 days
  - Operating - Flow rate and product temperature monitored every 30 minutes
  - Corrective actions are to stop product; hold the product produced since the last good check, evaluate it
  - Note pasteurizers have automatic divert valves: for aseptic production, the entire system shuts down, the restart requires the resteralization of the system
- CCP-2
  - Cleaning procedure requrements followed and documented (as an extra precaution the site sends a sample of the rinse water and the first bag of the next run after each clean to a certified lab for an allergen test)
  - Corrective actions – hold the product produced since the last clean and evaluate it
- CCP-3
  - Check wash documents on incoming tanker
  - Check seals on incoming tanker
  - Record seals applied to outbound tanker
  - Corrective actions for inbound are to refuse that tanker
  - Review shipping documents prior to release
- For the Apple Patulin CCPs the monitoring is the visual culling, the verification testing is done each lot – the corrective action is the reject the non-conforming products

The records for the CCPs must be reviewed by a HACCP trained individual within 7 days.

**HACCP Review:**
The HACCP Plans are subject to annual review by the HACCP team members, or if there is a change in conditions such as equipment, emergence of a new risk or products. During the most recent review on 2024-10-03, no changes were made to the HACCP Plans. Meetings notes were available for that meeting. The team continues to maintain and update the plans as needed to adhere to regulatory standards and ensure ongoing food safety and quality management. The site reported that there were no changes to the plant situation since the review.

**CCP Records reviewed:**
During the audit the CCP monitoring records for the following days were reviewed:

- 2024-08-04

- 2024-08-26
- 2024-08-27
- 2023-11-30
- 2023-11-01
- 2024-02-24

| Details of non-applicable clauses with justification | |
|---|---|
| Clause/Section Ref | Justification |
| Nil | |

## 3. Food safety and quality management system

### 3.1 Food safety and quality manual, 3.2 Document control, 3.3 Record completion and maintenance

**Food safety and quality manual:**
There is a Quality Manual available in an electronic version; all of the plant's documents are located on the Milne Foods intranet website.

All programs and procedures were reviewed annually based on a schedule by Dir. of Technical Services or designate.

**Document control:**
The company has a system which controls documents and data critical to product safety, legality and quality. All of the documents are available to employees in a pdf format; only members of the Corporate Quality Department have access in editable procedures or forms.

The policies, procedures and SOPs reviewed during this audit were well written and clear. Some of the procedures have pictures inserted to aid with the description. In addition to the electronic documents, the site makes use of posted pictures of various attributes for the employee reference. Work instructions are suitably detailed and appropriate to the requirement.

QA Manager and/or production supervisor updated forms to be used after a revision.

The site had document master list for procedures and forms.

Internal audits and monthly audits included document control to ensure that only the correct versions of documents, including recording forms, are available and in use. The procedure outlines the process for identification, version control, authorization, amendments and system to replace documents and is delineated in the Document Control Procedure.

There is a list of controlled documents. Those documents are electronically controlled; with access levels defined. Documents include the date, name and version number for the documents. The reason for revision for documents is available for the documents reviewed, those are documented in a running log on the bottom of the document. Laboratory procedures are included in the controlled documents.

**Record completion and retention:**
The site has a Record Completion and Maintenance Policy (M-QA-POL-013 dated 2024-03-20). The records viewed on-line and off-line throughout the audit were clear, legible, and properly signed or initialled. The records are retained in Production Folders which include the completed documentation for all quality activities (weight checks, packaging checks, CCP checks, lot numbers of materials, etc.). All CCP documentation was properly signed and verified by a Juice HACCP qualified individual (Dir. of Technical Services and QA Manager). Changes to records are to be made by a single line through and an initial of the individual making the change.
Paper production records are kept minimally 5 years; these are kept on site in plant management offices. Electronic records are never destroyed by corporate. The computer system is backed up daily off-site and in the cloud.

## 3.4 Internal audits

**Internal audit Programme scope and schedule:**
There is an internal audit program (QA-POL-008 dated 2023-11-20) in place to meet the BRC requirements, it is administered by the QA Department. The site conducted an extensive risk assessment to establish the audit schedule. The plant has a schedule of internal audits spread throughout the year, scheduled for each quarter). The audits cover all of the clauses in the Standard. The plant uses the BRC Version 9 Standard as a guide for the audits. There are internal audits scheduled such that over the period of a year with all clauses are covered. The QA team maintains the schedule. The auditors documented the reasons for conformance and non-conformance.

The audits are scheduled by quarter. The following audit reports were reviewed:

- 4.2 – Security – done 2024-10-03 by HACCP team – 0 NCs
- 3.4 – Internal Audits – done 2024-03-20 by QA Managers – 0 NCs
- 1.2 – Senior Managerment commitment – done 2024-03-20 by QA Managers – 0 NCs
- 4.3 – Layout – done 2024-04-12 by QA Managers – 0 NCs

Checklists are used so that audit documentation reports conformance as well as non-conformance. The audit program is fully implemented and executed on schedule.

The audits represent a comprehensive review of the Quality Management System. A target timeline is established on when Corrective actions are to be addressed; this includes root cause analysis and verification of effective close out of any non-conformances.

**Auditor competence and training:**
The audits are completed by the Quality Manager and Dir of Technical Services, the QA Supervisor of the site, and the QA Manager of the now closed Vegetable sister plant. The auditors received Internal Auditor Training provided by the Food Northwest Association on 2020-02-19, There is an audit trainee who received Internal Auditing training on 2017-09-25, but as of the date of the audit had not yet conducted an audit.

Assignments are made so as not to have auditors conducting audits of areas for which they are directly responsible.

**Site Inspections:**
In addition to the Systems audits there is a program of monthly facilities and GMP inspections conducted by QA Managers with goal of including operations personnel. The below inspections were reviewed and found acceptable: The site missed to performing the monthly inspections in the first ½ of 2024 due to shortage of staff; this was noted on an internal audit finding and a corrective action report was on file. The corrective action was to add move the QA Manager from the mothballed Vegetable Plant to the Main Plant staff. There were site inspections reviewed for

- 2024-07-23
- 2024-09-25

The August date was missed as the responsible individual was hospitalized for a month. All non-conformances had been addressed. Should there be unresolved items at the end of the month they are to be carried over to the next month.

## 3.5 Supplier and raw material approval and performance monitoring

### 3.5.1 Management of suppliers of raw material and packaging

There is a procedure to approve and monitor supplier performance POL-007 dated 2024-03-21. The purchasing processes that are critical to safety, legality and quality are defined and followed. The company has a documented risk assessment of raw materials and primary packaging to identify potential risks to product safety, legality and quality and includes risks of allergen contamination, foreign body risk, microbiological contamination, chemical contamination, variety or species cross-contamination, substitution or fraud, and risks associated with raw materials which are subject to legislative control. It lists documents required for various types of suppliers, ingredients, services, food contact, non-food contact, etc.

As most of the site's products are single ingredient, the major suppliers provide fruit or vegetables. Suppliers of primary vegetables and fruits are under contract with the company and are evaluated based on current performance. Suppliers of other fruit may or may not be contracted, but each load of fruit is individually evaluated against requirements established by Quality. New suppliers of raw agricultural products are brought under contract only after submission of a list of pesticides used, a letter of continuing guarantee and, for organics, and a nitrate statement. Frozen fruit is purchased from packaging houses, frozen warehouses or growers with on-site freezer capability.

Packaging suppliers are accepted based on documented certifications; for food contact materials and a GFSI. Certification.

A vertical audit was conducted as part of the traceability challenge and the approval criteria for the following suppliers of selected ingredients involved in that production were noted:

- Passion Fruit Concentrate – FSSC 22000, expiry 2024-06-27
- Guava Concentrate – FSSC 22000, expiry 2024-06-27
- Ascorbic Acid – BRCGS, expiry 2025-01-25
- Citric Acid – BRCGS, expiry 2025-01-25
- Annatto – SQF, expiry 2025 2025-03-04
- Bags – by policy, the site mixes its bag suppliers
    - Supplier A – FSSC 22000, expiry 2025-09-06
    - Supplier G – FSSC 22000, expiry 2026-10-23

### 3.5.2 Raw material and packaging acceptance, monitoring and management procedures

The site has an incoming raw material acceptance and monitoring procedure. The risk assessment forms the basis for the raw material acceptance and testing procedure and for the processes adopted for supplier approval and monitoring. An inspection is made of the trailer and the pallets of product and is entered on the Receiving Inspection Record.

There are procedures documented for receiving raw material and packing material into the facility.

Inbound raw material (bulk fruit in open flatbed trucks) documentation includes a CoA with specified limits. All parameters are checked against the CoA. For packing material there is a visual check on dimensions and type of material.

Reviewed receiving inspections for the following items involved in the vertical audit:

- Passion Fruit Concentrate – CoA 2022-10-18; incoming inspection 2024-03-08
- Guava Concentrate – CoA 2023-04-28; incoming inspection 2024-03-06
- Ascorbic Acid – CoA 2023-08-09; incoming inspection 2024-03-08
- Citric Acid – BRCGS, CoA 2023-10-10; incoming inspection 2024-03-08
- Annatto – CoA 2024-03-28; arrived by Fed EX and there was no incoming inspection
- Bags
    - Supplier A – CoA 2023-12-13; incoming inspection 2024-01-16
    - Supplier G – Incoming inspection 2023-03-13

## 3.5.3 Management of suppliers of services

There is a procedure Service Supplier Management dated 2024-03-21 for approval and monitoring of service suppliers to assure they are qualified and aware of the requirements to work on site. A major consideration is previous history. There is a list of approved service providers – this includes approved companies.

Contractor GMP and Safety training required for any person coming on site. The approved suppliers were investigated (pest control operators, calibration services, instrumentation and electrical contractors, etc.); these companies were included in the program. The vendor management system includes service suppliers.

Annual review was performed based on Vendor/Contractor Performance Evaluation Form was used. The services included the following:

- Pest Control – contract dated 2024-01-26
- Laundry Service – contract dated 2021-03-30
- 3rd party cold storage storage: contract dated Dec 1, 2022, AIB GMP audit on 2023-09-13
- 3rd party testing lab – no contract, used on an as needed basis
- Vending machines (managed by VP of Operations)
- Waste (arranged by city)

## 3.5.4 Management of Outsourced processing

N/A

## 3.6 Specifications

The Corporate office is responsible for maintaining all the raw material and finished goods specifications. The specifications for raw materials, packaging materials and finished goods are developed and available. Specifications for packaging material are defined (description of the materials and food grade guarantee). For raw materials, chemical, physical, microbiological and sensory requirements are defined.

Raw material and in process specifications are consistent with finished product specifications. Customer specifications are formally agreed to if applies; this agreement is documented. Primarily, the company has their own product specifications.

A vertical audit was conducted as part of the traceability challenge and the specifications for the following selected ingredients involved in that production as well as the finished product:

- Passion Fruit Concentrate – 2022-04-22
- Guava Concentrate – 2018-11-21
- Ascorbic Acid – 2019-02-25
- Citric Acid – 2020-09-17
- Annatto – 2015-11-03
- Bags – by policy, the site mixes its bag suppliers
    - Supplier A – 2020-04-22
    - Supplier G – 2018-01-01

The site's internal audits noted that there were numerous specifications which had not been reviewed within the last 3 years. It has implemented a corrective action of purchasing and subscribing to a supplier monitoring software service. This will track issues like maintaining a current GFSI certificate and updating specifications. That software program is in transition between versions and has not yet been fully implemented.

## 3.7 Corrective and preventive actions

The plant has a Corrective and Preventative Action Policy M-QA-POL-014 reviewed 2024-03-21. Those activities are managed through SharePoint include recording, follow-up and close-out requirements. Corrective actions are initiated when recurring problems are identified with GMP audits, process anomalies that lead to rework, customer complaints, for non-conforming product and continuing supplier issues. They are recorded on the *Corrective Action Form.* The person assigned the CAPA (or a team) is responsible for identifying the root cause and developing a corrective action.

Quality Manager can close out CAPAs after the corrective action has been verified.

Minor items noted on the site inspections, are handled on the inspection reports and a formal CAPA may not be issued, except for continuing issues.

The site reported they issued 4 formal CAPA's in 32024. An example was issued on 2024-01-16 in response to issues raised in the pest control survey. There were 38 interior rodent captures in 2023; corrective actions were undertaken including addition control devices and emphasis on keeping door closed; for 2024 to date there have only been 4 captures. The site QA Manager reviews the weekly service reports and there is a trend analysis done every quarter.

## 3.8 Control of non-conforming product

The site has a documented procedure to address the control of non-conforming material; It is handled through the Quality Hold Policy M-QA-POL-004, reviewed 2024-03-20. It describes the handling of non-conforming product from incoming raw and packaging material to finished goods. Held material is secured both physically with placards (orange) and electronically in the inventory control system.

The implementation of the policy is detailed in the Quality Hold Procedure M-QA-PRO-015 reviewed 2024-03-20. This describes how to enter the details in the computer inventory system.

All actions are reviewed by Quality Control Department on at least a monthly basis.

The Director of Technical Services has responsibility for the effectiveness of the hold program and the corrective action plans relating to food safety, legality and/or quality. The procedure stated that the authority of releasing held products/materials lies with Director of Technical Services.

The site reported that there were 27 holds in 2024; it noted that there were no holds due to a CCP failure. An example of a hold was reviewed during the audit. It was instituted on 2024-08-24 due to possible high microbiological test results. It was determined that there had been an error in reading the results and the product was released. This problem is unique to watermelon, it was explained that due to the nature of watermelon, extra dilutions are required and sometimes the technicians forget to take those into account when calculating the test results.

**Minor Non-conformity raised against clause:**
3.8.1 – The site's Hold Product log notes disposition of held product, but it did not include records of the decision on the use or disposal of the product

## 3.9 Traceability

**Site trace procedure and system labelling and records:**
There are procedures in place to trace all raw material lots through the process to the first level of distribution and all finished goods lots backwards to the original raw and packaging materials for which it was made. The materials at this facility are tracked through computer software. This program is described in the *Traceability Procedure*. The traceability data maintained includes grower#/name, truck #, date of process, tank #, lot# of finished product, etc.

All materials at the plant were observed identified for traceability, either through the application of labels, or the recording of equipment used in processing or storage. The traceability system is tested annually at minimum.

Rework is treated as an ingredient in this site and traced by its lot #. As there are multiple considerations which must be reviewed for a given rework situation there are no blanket guidelines for rework, each situation must be evaluated by QA.

**Client traces conducted, timings and mass balance across product range:**
The plant conducts a traceability exercise at least once a year per year, although in practice they may do more due to customer audits. These include food contact packaging, ingredients and finished goods, forwards and backwards.

During the audit the following exercise was reviewed

Done on 2024-09-17 on Strawberry Puree with a 100% recovery in 3 hours. The exercise included a mass balance of raw fruit and packaging.

It was noted that the site also does traceability challenges for multiple customer audits it receives during the year.

**Trace exercise conducted during the audit:**
As part of the audit a traceability challenge was conducted of a randomly selected production; POG formula made on 2024-06-27.

A total of 106,425 lbs. were produced on 2024-06-27 packed into 473 lbs. drums

There were 5,023 lbs. in inventory.

There had been 5 shipments:

- 22,704 lbs. shipped 2024-07-09
- 24,596 lbs. shipped 2024-07-22
- 35,948 lbs. shipped 2024-08-02
- 8,514 lbs. shipped 2024-08-02
- 9,460 lbs. shipped 2024-08-27

101,222 lbs.

The site accounted for 101,222 lbs. and 5,023 lbs totalling 106,245 lbs. which was 99.83 % of the finished product in 2 hours and 50 minutes.

All associated records (receiving, production, QC, shipping, supplier documents, packaging, etc.) were reviewed as part of the vertical audit were consistent with the programs and procedures.

## 3.10 Complaint-handling

The site's written Complaint handling policy is included in several documents including *Customer Complaints Procedure, Customer Complaints SOP*, CAPA SOP, *Customer and Supplier Complaints* M-QA-PRO-001 dated 2024-03-21 and *Complaints Tracking Log*. It defines the methods and responsibilities for handling customer complaints. This program has been properly implemented. Complaints are handled by QA and facility team. As per the procedure, all customer complaints received are recorded, investigated, root cause analyzed (if necessary), and corrective actions completed and verified. Records of all customer complaints are maintained. As per the policy, the investigation of complaints is handled by Plant Management, with corrective actions and records kept of each complaint and resolution.

None of the items from this plant are packaged in retail sizes, all are sold to commercial customers, as there are no retail sales all complaints come through commercial customers and routed to the Quality Manager who logs them into the database.

As per the Witten policy, the site also analyses trends of complaint data. Actions appropriate to the seriousness and frequency of the problems identified are carried out promptly and effectively by appropriately trained staff. Complaints are reviewed during food safety meetings. The Customer Complaint log was reviewed. The site reported 4 complaints in 2024, 1 – flex cracking bag due to transportation, 1 – leaking bag, bag manufacturing issue, 1 – bag rupture and 1 – tote rupture due to an exposed nail on the pallet. Trends in complaints were discussed in meetings and were investigated and corrective actions were recorded.

## 3.11 Management of incidents, product withdrawal and product recall

Crisis management procedures are in place that detail actions to be taken in case of emergency situations. The *Disaster Contingency Plan* M-PRD-SOP-001 dated 2024-03-21 identifies the activities to take in the event of natural disasters, bomb threats and workplace violence. This includes Disaster Recovery Plan; the procedure includes crisis communication to customers and contingencies for continuation of supply. Responsibility for customer communications is included in the procedures. There is a list of after-hours contacts.

The *Product Withdrawal & Recall Planning* procedure M-PRD-SOP-001 revised 2024-03-21 identifies the Recall Team. The Quality Director is the Recall Coordinator. The contact list contains the names of current managers. Legal counsel is listed in the Recall Program. There are links to the FDA websites that would be used in the event of a recall. Any recall would be administered Corporately. The program includes the requirement to notify the CB in 3 working days for recalls, withdrawals of significant food safety events.

Product recall and withdrawal procedures are tested annually. The results of plant tests of the recall system are reviewed by senior management during the management review process. The exercise included key activities such as inventory checks, sales, internal consumption, etc. Reviewed mock recall/trace exercise from 2024-09-17. The Product Withdrawal and Recall Advisory Group meet at least once a year to review procedures, titles, and staff preparedness as part of a training session and a time to update and revise procedures. The recall program was last reviewed on 2024-03-21 to verify the contact information.

The site reported that there had been no recalls, withdrawals or significant food safety incidents since the last audit.

| **Details of non-applicable clauses with justification** | |
|---|---|
| Clause/Section Ref | Justification |
| 3.5.4 | There are no out-sourced processing operations. |

## 4. Site standards

### 4.1 External standards

**Site construction, location and surroundings:**
The Milne Fruit Products, Inc facility is located in the town of Prosser (Population 6,062 in 2020 census) which is located in an agricultural region of Washington State. An inspection of the plant buildings and grounds showed them to be suitable for the manufacture of the products.

The surrounding properties do not pose a risk of either foreign material contamination or pest infestation. Structures near the plant are an elementary school and some private homes.

**External areas:**
Plant grounds and physical structure are well maintained with no obvious pest harbourage sites. The complex is a long narrow building. To the North is the raw material receiving yard then a light industry maintenance shop, a grade school on the East of the long side, parking, railroad tracks then the river on the South side, and finally a rail yard to the West on the other long side of the buildings. Buildings are surrounded by paved areas.

Visitors and contractors must read the company Good Manufacturing guidelines before entering the plant.

**Minor Non-conformity raised against clause:**
4.1.3 – The was a 2 inch by 4 inch cutout in the side of the rapid roll-up door frame on the door leading from the processing area to the receiving yard.
There was a 4” vertical gap along the side of the rapid roll-up forklift door into the aseptic room

### 4.2 Site security and food defence

**Food Defense program:**
There is a security team and a policy and procedures *Food Defense Plan* M-PRD-PRO-017 reviewed 2024-10-12. All members of the team have completed the FDA food defense training, that same course must be completed by each employee as part of the on-boarding procedure. Current security measures include key fob entry with only selected employees provided with cards, locked doors, exterior lighting, CCTV cameras, and employee training regarding challenging unknown personnel. Employees are screened prior to employment (drug testing and background checked). Employees are trained in security provisions – training is provided at induction.

The staff were trained on site security/food defence procedures and visitors and contractors must agree to follow the company Food Defense guidelines before being allowed to enter the plant.

**Plan Assessment**
The site utilizes the FDA Food Defense Plan Builder developing and updating its Food Defense program. There is a Food Defense team (Dir. of Tech. Services, VP of Operations, Plant Manager, QA Manager, Plant Engineer) which conducts an annual security assessment; this review was completed on 2024-10-12. All team members attended online Food Defense Training.

The site had a standalone meeting to review the Food Defense program, the most recent occurred on 2024-10-12; it was attended by the VP of Operations, the Director Technical Services, the QA Manager and the Plant Engineer.

**Minor Non-conformity raised against clause:**

4.2 – On the on-site portion of the audit the exterior door into the boiler room and the one into the shop were both unlocked

## 4.3 Layout, product flow and segregation

The plant design, construction and maintenance are intended to reduce the risk of product contamination. The process flow from receiving to shipping is organized to avoid potential contamination. There is a separate dry warehouse, the raw fruit receiving areas, and the original plant, some storage areas, followed by the aseptic processing building. The last building in the complex is the cold storage which is attached to the aseptic building. The process flow from receiving to shipping is organized to avoid potential contamination. Unprocessed material does not come into contact with finished goods.

There is a map of the site reviewed 2022-10-10, indicating the flow of personnel, raw materials and process flow, and finished goods. The site has enclosed, a few low-risk areas and packaged product areas only. Access points for all raw materials are indicated on the map. Raw produce arrives through receipt/ sorting operations at the end of the original plant. Frozen produce and packaging arrive in totes through receipt dock doors, located in the rear of the plant. There are grape de-stemmers located outside the building in a covered, roofed area.

Effective traffic control procedures are in place to minimize the risk of contamination of raw material, packaging material and finished product. In addition, processing takes place in an essentially closed system from blending to final filling and packaging. The segregation schemes in place at the facility take all necessary variables into account.

Visitors and contractors must read the company Good Manufacturing guidelines before entering the plant. The Maintenance Manager is responsible for assuring that contractors are aware of the low-risk areas of the plant. Employees are trained to alert the Supervisor if contractors are observed in their areas.

There were no temporary structures observed during the audit.

## 4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The fabrication of site, buildings and facilities observed to be suitable for intended purpose:

| | |
|---|---|
| Walls | The exterior walls are constructed of various materials including prefabricated concrete, sheet metal with insulation and brick and mortar. Interior walls are bare concrete, or sheet metal; no exposed product handling occurs near them. They were observed to be in well maintained conditions, no accumulation of dirt, condensation or mold. Walls are included in the cleaning program. |
| Floors | The floors are made of finished concrete and have been designed to meet the demands of the processing operations. They are capable of withstanding cleaning materials and methods, are impervious, and generally well-maintained. In some areas, they are epoxy coated in exposed product areas. |
| Drainage | There are a combination of open top trough and pot drains depending on the area which were appropriately located to remove any process or cleaning water away in processing areas. Where appropriate the floors have adequate falls, and no standing water was observed. Machinery |

| | |
|---|---|
| | and piping are arranged so that process water flows directly to the drains. |
| Ceilings and overheads | The ceilings and overhead areas are designed, constructed, finished, and maintained to prevent dirt accumulation, minimize condensation and mold growth, and facilitate cleaning. Most areas have high ceilings for ventilation purposes. There are no suspended ceilings present in the processing, packaging or storage areas. |
| Windows, roof glazing and ventilation | There are no externally opening windows in the plant. Adequate circulation and exhaust is provided in storage and processing areas to prevent condensation and accumulation of filth. Adequate circulation and exhaust are provided in storage and processing areas to prevent condensation and accumulation of filth. There were no signs of off odors or condensate in the facility and there is no requirement for a dust collection system. |
| Elevated walkways access steps and mezzanine floors | There were several locations with elevated walkways, they were observed to be constructed and maintained such that they did not pose a contamination risk |
| Doors | Internal and external doors were made of appropriate materials and well maintained. External doors and dock levelers are adequately sealed and kept closed when not in use. |
| Lights | The light level was judged to be adequate for process needs. Some inspection areas observed to have supplemental lighting to ensure adequate light for proper performance of their operations. |
| Strip curtains | There were no plastic strip curtains used. |

## 4.5 Utilities – water, ice, air and other gases

The site has adequate utilities available to it. Water is sourced from the city of Prosser and used for processing water, cleaning, emergency and personal use. The company uses carbon filtration to control the chlorine content to avoid off flavors in its finished products.

Utilities observed during the audit were designed, constructed, maintained and monitored to effectively control the risk of product contamination. Steam is only used for indirect heating; it has no direct contact with any products.

Tests of the water potability are done in-house quarterly, testing for TPC, Y&M and coliforms. Reviewed records from 2024, they showed satisfactory results.

The site had a copy of City of Prosser water report for 20
n23 as well as on-going (every 2 weeks) micro and chemical monitoring test results from the city.

There is a water distribution plan/ diagram in the plant dated 2022-05-19.

Compressed air is used for instrumentation only. Ice is not used.

Whilst the site has the capability to use Nitrogen to fill the head space of some storage tanks, preventing oxygen from degrading material at the surface, it reported that it has not utilized that option in at least 3 years. In the unlikely event that it resumes the use of Nitrogen, that gas must be purchased at a guaranteed purity which is certified by CoA.

## 4.6 Equipment

The facility had appropriate equipment designed and constructed for the purposes; it is stainless steel and generally meets the 3-A dairy requirements. Equipment is evaluated for suitable food processing design characteristics prior to purchase. This evaluation is performed by plant management and engineers following *Change Management procedures* M-PRD-FRM-045 reviewed 2024-03-21 which is risk-based. Cleaning and sanitation of a new was performed before use followed by visual inspection ATP swabbing ass applicable.

Equipment is positioned to permit adequate space for cleaning and maintenance activities. Food contact surfaces at this facility are mostly stainless steel. The informational literature accompanying the connecting hoses through which product passes contains verification of suitability for use in food contact applications.

The site was in the process of installing a new heat exchanger. Change Management Request Form was on file that was reviewed by a multi-disciplinary team.

Should it be necessary the moving of static equipment would be documented on a Change Management Request Form.

The site reported that no other new equipment had been installed since the last audit.

Battery charging equipment was not located in open product areas.

## 4.7 Maintenance

The preventative maintenance program is the responsibility of the maintenance supervisor and 10 mechanics. There is a preventative maintenance program in place, covering all plant and equipment. Preventive maintenance is managed through a computer based preventive maintenance program, “E-maint” that undertakes regular checks and repairs. Each piece of equipment is on a PM program. Maintenance activities can also be generated from inspections by production personnel. The preventive maintenance system is updated if there is a major breakdown of a piece of equipment. There is a program for tool cleaning, tool accountability, clean up after maintenance repairs.

Maintenance is mainly carried out by the company’s own engineers with the use of outside specialist contractors when required. Contractors are under the supervision of the site contact for the operation being undertaken. All equipment observed appeared properly maintained with no obvious risks of product contamination.

The facility’s maintenance program prohibits temporary repairs. When maintenance work is being done during operating hours, all adjacent equipment is protected from contamination with plastic shielding or the adjacent equipment is turned off until repairs are complete. The shift supervisor or team leads confirm the sanitary condition of equipment after maintenance and prior to resumption of production. Any breakage in

the product line requires cleaning. There must be a documented sign-off by a member of the sanitation staff before the equipment can be released for production.

An example reviewed was WO 482940 – of an overhaul of the Press 2 on 2024-01-30, it was sign-off by a Quality Technician who also performed a sock test of the liquid when it restarted.

The food grade confirmation and the allergen status for the following lubrication chemicals were reviewed:

- Summit HyPar FG-68 Food Grade Hydraulic oil – NSF – H1; allergen letter dated 2022-01-01
- Verax HD Sanitary Lube - NSF – H1; allergen letter dated 2022-01
- Sanitary Petrol Gel Lubricant – NSF – H! – allergen letter dated 2022-09-19

Random service records were requested for sample pieces of equipment:

- Pan 2 – Pre-heater – done quarterly – requested service record from 1st quarter
  - Due 2024-01-20 done 2024-01-20
- 2" RTD Calobration = done every 2 months – requested service record for June
  - Due 2024-06-19 done 32024-06-29
- Heat Exchanger 858-RTD 1, calibration/vefirification every 2 months, 9-20-2023, 7-20-2023

The maintenance manager is responsible for supervision of contract maintenance personnel.

## 4.8 Staff facilities

Staff facilities are suitable in size and number to support the employees working at the site while posing no risk of product contamination.

Adequate changing facilities are provided for all personnel. There are two separate break rooms, one for the original plant and another for the aseptic facility. Each employee had a locker where they store their personal items during working hours, they are included within the restrooms complex. The toilets were located next to the locker rooms. They were observed to be equipped with sinks, liquid soap and driers. Signs were noted to be posted on the back of the entry doors reminding employees to wash their hands before leaving the restrooms.

The breakrooms are provided with suitable lighting, tables, chairs, beverage and snack vending machines, as well as microwaves and refrigerators. There is a contracted food vending company which has packaged items; there is a CCTV camera which monitors those supplies to ensure that they are properly purchased. All food items must be consumed in a designated area, which was observed to have appropriate trash receptacles present.

Personnel changing facilities are suitably sized and positioned. There were proper hand cleaning supplies, hot water and wash hand signs. Single use towels are provided near hand-wash stations. All staff facilities were functional at the time of the audit. Toilets are suitably constructed and do not open into production areas. Catering services available at this site are limited to vending machines serviced by 3rd party. Visitors and contractors use employee facilities.

Production personnel wear their own clothing including shoes on the plant floor.

The State of Washington forbids smoking within a building and the entire plant is smoke free. There is a smoking area outside the building and receptacles are provided to collect the trash.

All staff facilities were functional at the time of the audit and no issues were noted when inspecting these areas.

**Minor Non-conformity raised against clause:**

4.8.3 – In the locker rooms the employees' personal coats are hung intermixed with cold weather clothing worn by the workers in the plant

## 4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

**Minor Non-conformity raised against clause:**
4.9 – There were numerous items such as clamps, trash, bolts on top of the electrical boxes throughout the plant.

### 4.9.1 Chemical control

There are procedures in place to prevent contamination from metal or other physical and chemical contaminants. The program is the responsibility of operators, storage supervisors in the plant and is overseen by the Quality staff. This includes a list of approved chemicals, storage, labelling and handling requirements.

Appropriate facilities and procedures were generally observed to be in place to control the risk of chemical or physical contamination of the product. The HACCP Plan addresses the potential chemical and physical risks, with most being controlled through the site's SOPs. Procedures are in place to prevent contamination from chemical contaminants. The program is the responsibility of operators and stores manager in the plant. This includes a list of approved chemicals, storage, labelling and handling requirements as well as maintaining the SDS for each chemical.

Chemicals are to be purchased from a chemical supplier from an approved list dated 2022-09-19). New chemicals are to be approved prior to being purchased. There is a spill kit, containment pallets, personal protective gear, an SDS book, shower and eye wash. All operators are trained in the use of chemicals, as cleaning occurs on all shifts.

Empty chemical containers or obsolete chemicals were disposed off in accordance with regulations. Empty chemical containers were triple rinsed and sent back to the supplier or double rinsed and recycled.

Housekeeping and GMP audits are conducted monthly; these monitor the use and storage of chemicals on site.

With the exception noted below the chemicals observed during the audit were adequately labelled and stored securely. There is a chemical storage in a locked cage (and chemicals in use in the CIP room, where they are dispensed), lubricants are located in cabinets in the shop; there are separate cabinets for food grade and non-food grade chemicals.

SDS sheets are maintained for all chemicals handled at the site; SDS sheets for the chemicals noted in clause 4.7 and some randomly selected cleaning chemicals were confirmed during the audit

- Summit HyPar FG-68 Food Grade Hydraulic oil – SDS dated 2022-12-14
- Verax HD Sanitary Lube - NSF – SDS dated 2019-10-07
- Sanitary Petrol Gel Lubricant – SDS dated 2023-10-25
- Ecolab Ultrasil 84 – SDS dated 2019-11-01
- Ecolab Ultrasil 09 – SDS dated 2021-12-03
- Ecolab – XY-12 – SDS dated 2018-03-22

There were no strongly scented or taint-forming materials observed in use by the site.

**Minor Non-conformity raised against clause:**
4.9.1.1 – There was an unlabeled garden sprayer with some liquid in it the production room.

## 4.9.2 Metal control

There are sharp metal implements used in the plant (knives for opening cartons). These are issued and inspected upon return. The plant has a procedure (listed in the Plant GMP procedure to address sharp metal implements. There is a policy to control the use of knives (clean and in good condition) issued by the management and inspected.

Staples are not allowed in the plant (the packaging materials used do not require the use of staples).

## 4.9.3 Glass, brittle plastic, ceramics and similar materials

The site has a program *Glass Policy* M-PRD-POL-010 reviewed 2023-08-09 to handle risks from glass, brittle plastic and similar materials; glass, brittle plastic, ceramics and similar materials are not allowed in the plant. The lights are shielded as are those in the ILTs, in addition those in the ILTs are behind a metal grid to prevent breakage. There is a list of glass/ brittle plastic items in the plant. These are inspected annually; the procedure allows for a single audit annually or sections monthly. A example from 2024-06-05 was reviewed; no issues were noted. In addition, the monthly GMP audits include glass/brittle plastic inspections.

There are documented breakage procedures to include the requirements to clean, inspect, and release the area and personnel, as well as evaluate product. The site reported that there have been no breakages in the past year.

**Minor Non-conformity raised against clause:**
4.9.3.2 – There were several fluorescent light covers on the finisher deck with cracks.

## 4.9.4 Products packed into glass or other brittle containers

N/A

## 4.9.5 Wood

The site has a program to minimize any risk from wood. Wood is not allowed in areas where product is exposed Wood is used as pallets; these were noted in reasonable condition in process areas. There are defined pallet condition requirements. Receiving and operational personnel check on the condition of pallets entering the plant and being used in the plant.

## 4.9.6 Other physical contaminants

The site receives a minimum amount of ingredients in bags; it has instructions to address the risk of physical contamination resulting from the opening of dry ingredient bags; the site cuts open paper wrapped bags.

Pens in use in the plant are company issued and metal detectable and contain no small parts that might contaminate finished goods. The process through to filling operations is done in enclosed piping.

## 4.10 Foreign-body detection and removal equipment

### 4.10.1 Selection and operation of foreign-body detection and removal equipment

**Foreign body risk assessment conducted in association with the HACCP study and controls include:** the HACCP risk assessment, pre-requisite programs, visual inspections and the installation of a foreign material detector. The plant uses screens, magnets and metal detectors to remove foreign materials.

All the foreign material removal devices are documented in the flow diagrams for the HACCP Plans. Metal detectors are identified as CCP's and they are located on prior to the transfer of the product to the heating tubes. The metal detectors are set at the maximum sensitivity based on the validation and are checked at the start and end of each run. Magnet and screen checks are monitored every run. None of the product is direct loaded, the finished goods are available to hold in-house in the event of a failure.

The design of the equipment makes it impractical to place test pieces directly into the product flow. The timing of the product ejection is verified during the annual service.

Investigation was performed for foreign material findings.

### 4.10.2 Filters and sieves

Screens and finishers are installed; these are located appropriately. The juice screens differ with the product and its brix level, they have a maximum opening of 1 µ mesh, depending on the nature of the material being screened. Purees are screened through a finisher with a maximum opening of 0.03 inches. The screens are checked at the beginning and end of each production run. Metal found on screens will likewise be inspected and evaluated for origin. Corrective actions in the event of a screen integrity failure involve placing the current batch of finished product on hold until senior management can decide on disposition.

### 4.10.3 Metal detectors and X-ray equipment

The site has installed in-line metal detectors on the packing lines and the tanker fill lines. Metal detector monitoring is conducted, with piece sizes and composition documented. The metal detectors are checked at the beginning, middle of the run and end of each production run; also, at shift changes if the production runs for more than a single shift. The metal detector at the bulk loading of tanker trucks are checked before and after loading.

The metal detectors have automatic reject devices that divert product flow to a receptacle and alarm the operator; the contents of which are examined to determine the source of any rejected metallic contaminant.

During the floor audit the aseptic area supervisor demonstrated the metal detector checks by passing the three wands through the aperture of the detector. The test pieces used for the metal detectors were 1.0 mm Fe, 1.5 mm non-Fe, 2.5 mm SS for packing line and 1.5 mm Fe, 2.0 mm non-Fe and 2.5 mm SS 316 for tanker truck loading.

Corrective actions in the event of a metal detector check failure involve placing the current batch of finished product on hold until senior management can decide on disposition.

The site does not have an X-ray unit.

## 4.10.4 Magnets

The site utilizes magnets on in production lines, are located appropriately and are appropriately positioned and maintained to prevent foreign body contamination; these fall into two categories, there are some at the start of the process, these are installed for equipment protect and there are others located in-line on the packing line. Magnets are placed between the packaging screen and the metal detector. Per the plant's foreign material control program, the strength of all magnets is to be tested at least annually. Thresholds are established to determine when magnets need to be replaced. The facility uses a gauss meter for magnet strength assessment. The magnets are designed based on manufacturer's specifications. The minimum Gauss rating is specified. Atypical findings initiate an investigation and subsequent corrective actions.

They were last tested on 2024-05-31, they identified a low strength in the Aseptic line, due to heat, they were replaced with high temperature specific magnets.

## 4.10.5 Optical sorting equipment

N/A

## 4.10.6 Container cleanliness – glass jars, cans and other rigid containers

There was no container-cleaning equipment used. The rigid containers such as pails are manually inspected during filling.

## 4.10.7 Other foreign-body detection and removal equipment

N/A

## 4.11 Housekeeping and hygiene

Housekeeping and cleaning systems are in place to ensure appropriate standards of hygiene are maintained and the risk of product contamination is minimized. The plant and all of the equipment was visibly clean during this audit, including equipment not in use at the time of the visit. Clean-as-you-go was observed being practiced during the visits to the production areas. During periods of continuous production, there is a system clean weekly, when doing smaller batches there is a cleaning cycle done between different products. The cleaning program is the responsibility of operators in the plant. There is a master sanitation schedule and a general sanitation schedule and procedures for common and warehouse areas, employee facility areas, and procedures and policies for equipment cleaning. There is a dedicated sanitation crew who work after the production shift, in addition some operators are trained to conduct sanitation operations.

Training is provided for cleaning; all training records are kept; this includes training from the chemical supplier. There is a very limited allergen and no identity preserved products on site which require specialized product changeover cleaning requirements.

There is a Master Housekeeping Schedule, with weekly and monthly tasks. Weekly items include drains, with them also getting a more concentrated cleaning on a monthly basis.

The majority of the food contact surfaces in the packing and filling room are enclosed and are cleaned by a CIP system. Equipment that is not part of that system are disassembled, cleaned and sprayed with a sanitizer spray. There are equipment SOPs for the raw material room and equipment, they include the

sanitization solutions for CIP tanks, equipment sanitation procedures, approved list of cleaning chemicals, concentrations and personnel responsible for the cleaning activities.

Cleaning verifications are done through pre-operational inspections and monthly housekeeping/ site standards inspections. In addition, the site conducts ATP tests (<10 RLU) every two weeks. They target 6 to 8 swabs for each round of sampling. Reviewed pre-op inspection records, failures and recleaning noted to occur occasionally.

### 4.11.7 Cleaning in place (CIP)

As much of the transport and thermal process occurs within enclosed pipes; the site makes use of a CIP system. That system is made up completely of stainless-steel piping and sanitary fittings. CIP lines are removed when the process is complete to minimize risk during production. CIP techniques are in place and appropriately monitored. The CIP cycle consists of rinse, caustic, rinse, sanitization and inspection. The time of each leg of the cycle, chemical concentration and temperature are all controlled throughout the cycle; these parameters are recorded in documentation. The CIP program has been in place for many years; the program is validated and verified by an ongoing ATP swab sampling program.

The process is electronically controlled, with the operator's input required to progress to the net step. The program goes through a rinse, chlorinated caustic wash, rinse. The temperature and pH of the caustic solution are verified prior to starting the CIP process and the final rinse pH is also monitored. The site targets a pH of 8.1 for the final rinse.

System was designed by site engineers validated by site engineers.

### 4.11.8 Environmental monitoring

The plant has developed a risk-based *Environmental Monitoring program* M-QA-POL-001 reviewed 2024-04-12. The site conducts environmental swabs for *Salmonella* and *Listeria*. The program calls for the following samples: 10 to 15 samples per month split between *Salmonella* and *Listeria* with 25% of the samples for *Salmonella* samples; those samples are a mix from Zones 2 and 3.

Trending indicated no unsatisfactory results since the last audit.

There are corrective actions in place in the event of unacceptable results, they follow the FDA recommendations; a reclean and retest until there are 3 consecutive negative results.

### 4.12 Waste and waste disposal

Waste collection containers are in place in production and warehouse areas as required. Trash is emptied out routinely. Dumpsters are emptied routinely.

Waste generated at this facility is disposed of in accordance with all state, federal and local requirements. Trash dumpsters are clearly identified and designed to be cleanable and pose a no contamination risk to finished product.

All waste containers are clearly identified. Trash is collected in fully labelled and color coded 33-gallon rubber containers which are removed and emptied in outdoor dumpsters when full. Dumpsters are removed and replaced with empties on a weekly basis. All interior containers are covered with lids. Waste receptacles are well maintained and are not pest harborage sites.

The waste pick-up is arranged by the city.

## 4.13 Management of surplus food and products for animal feed

The site's finished products are ingredients in bulk qualities to be used by its customers to be combined with other ingredients to make consumer products; as such it is highly unlikely that its products would be suitable for employee sales or donation.

Downgraded product is sold to companies that further process it for the components (sugar, color, flavor) that are not compromised by the downgrade. This material is managed in accordance with relevant legislative requirements.

No customer branded products are packaged at this site.

The some of the site's by-products such as fruit pulp, stems and skins are collected by a third party, some of it may be used as cattle feed. It is handled according to the collector's requirements.

## 4.14 Pest management

**Pest Control program:**
The company employs the services of a registered pest control contractor to manage the preventative pest control program which is responsible for the control of rodents, flying and crawling insects (including ILTs). There is a contract dated 2024-01-26. There is a summary of services which calls for the service of the exterior rodent bait stations monthly, the interior curiosity rodent traps weekly and the ILTs once a month from November to March and weekly from April to October. It also calls for spot treatments as required. The contractor has a license from the State of Washington with an expiry of 2024-12-31; the service representative has a license which expires on 2024-12-31. The service has liability insurance with an expiry of 2025-01-01.

There are 2 up-to date plans of all the site pest control measures, both dated 2024-08-01. There are 36 exterior bait stations, 63 interior curiosity traps, and 15 ILTs. Toxic baits are used on the exterior only; the bait stations were observed to be robust, secure in place with a concrete block inside the unit and of tamper resistant construction. The ILTs have all their lights shielded and there is a metal grid over the lights. The units are located to where they do not present a risk to product from expelled insect parts.

Inspection reports provide details of the inspections conducted, if any activity is reported inside or outside the facility, recommendations are provided and actions are taken over such recommendations. The results of the pest control inspection are trended by the service on an on-going basis and are available at the site through an on-line website. While there are notations of occasional flying pest captures in the ILTs and mouse capture in an interior trap at the entry door to the raw production handling area, there was no indication on the monitoring records of any infestation within the production and storage areas.

**Pest Control Records:**
The service representative leaves a service report with the site at the end of each service visit. The organization has a list of approved pest control products used including SDS. Detailed records of applications and the inspection files are maintained. Inspection reports were viewed for the season to date. All monitoring was noted to be adequately recorded. There are records of all control chemicals used in the past year; they were limited to

- Flatline soft rodent bait; EPA registration number 7173-308

Service records were reviewed from:

- 2024-08-06
- 2024-08-13
- 2024-09-03
- 2024-09-10

- 2024-09-17
- 2024-09-24
- 2024-10-09

**Management of infestations:**
The program includes formalized pest Thresholds which list actions to be undertaken should evidence of an infestation be encountered. The service reports as well as the catch analysis trending provide evidence to support that in the last 12 months there has not been infestation. In 2023, the site experienced a higher-than-normal incidence of interior rodent captures (38 captures), it consulted with the Pest Management Company and working with them took steps to reduce incidence of that activity. They created a Corrective Action Plan dated 2024-01-16 which included adding additional control devices, employee training and greater emphasis on keeping doors closed. For the year-to-date 2024, there had only been 3 interior rodent captures

**Annual Pest control Survey:**
The site has a program of reviews of the program based on a risk assessment. They are done by a representative of the Pest Control company; there are reviews done at least annually by the Pest Management Company Operations Manager; the most recent review was done on 2024-01-10; the site reacted to that review as was noted above.

The site had access to the pest contractor's website which enabled it to download and print trend analyses for periods ranging from monthly to annually. There was notation of sporadic feeding at the exterior bait stations, but no significant infestation. There were no signs of a pest infestation observed during the audit.

The training of the site staff is conducted on the Alchemy; there is a module on Pest Control.

**Minor Non-conformity raised against clause:**
4.14 – There were cobwebs on several of the ILTs

## 4.15 Storage facilities

The facilities used for the storage of raw materials, packaging, in-process products and finished products were deemed to be suitable for purpose. Procedures to maintain the product safety and quality during storage include segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake, storing materials off the floor and away from walls and specific handling or stacking requirements to prevent product damage. Documented procedures are in place to assure that materials are stored appropriately.

Palletized finished goods are stored in the warehouse until the product is tested and confirmed to meet all the specifications, including microbiological limits were applicable.

Storage facilities and transport vehicles were clean and clutter free. Vehicles are inspected before loading and unloading to assure structural and sanitary suitability and to assure proper operation. All storage and transport facilities and equipment were well designed and maintained and suitable for their purpose.

There is limited storage at the site itself, finished product containers are transferred to off-site storage which is about 1 mile from the facility as soon as practical. The site has two controlled temperature storage areas:

- Freezer – target minus 10°F; alarm set for 10°F
- Chilled room – target 45°F; alarm set for 55°F

The storage areas can be used for either raw ingredients or finished products. Finished product is stored frozen (non-aseptic or specially packaged aseptic material) or refrigerated (aseptic only). Directly off the packaging line, the product is placed into freezers at the plant for a minimum of five days after which it is either shipped to a customer or to an off-site freezer for longer term storage. Product is manufactured and shipped on a customer order basis. FEFO is followed based on customer requirements.

Aseptic drums are stored chilled off-site for quality reasons. The off-site storage is summarized below:

- Low-acid aseptic chilled – stored chilled
- High-acid aseptic chilled - stored chilled
- Non-aseptic filled product – high acid – stored frozen.

Manufactured raw materials such as ascorbic and citric acids are used on a FEFO basis where appropriate. Raw fruit is not stored long term at this facility. Drums of raw fruit are stored in freezers until ready for use at which time they are removed from the freezer and kept outside for tempering. While outside all drums remained sealed. Controlled atmosphere storage of certain finished juice products involves nitrogen in the head space of storage silos. The pressures of the nitrogen are controlled to assure adequate exclusion of oxygen from the vessels.

There are no segregation requirements of materials due to allergen or IP status.

## 4.16 Dispatch and transport

There are documented procedures in place to ensure the product is protected during dispatch and transport. Truck-loading areas are designed and maintained adequately. Shipping and receiving records confirm the suitability of transport truck condition prior to loading or unloading. Truck-loading areas are designed and maintained adequately; the finished trucks are loaded in a covered bay. Shipping and receiving records confirm the suitability of transport vessel condition prior to loading or unloading.

Both the fruit and vegetables arrive either fresh or frozen. The site ships aseptic items to customers from the plant; for juice concentrate the site ships to an outsourced finished goods warehouse; shipments to customers take place at that facility. Numbers are recorded at shipment to maintain traceability to the finished goods warehouse.

The trailers are inspected for trailer damage, infestation, odors and potential contaminants. Wash tickets for tanker trucks were checked. The results are reported on the shipping paperwork and retained with copies of the CoA and BOL. The trailer/tanker truck inspections of the shipment of the product involved in the traceability challenge noted that the trailers were of acceptable condition and were chilled to proper temperatures.

The forklifts used in the shipping and receiving areas are on a preventive maintenance program.

Reviewed outbound shipping records from 2024-07-06, 2024-07-22, 2024-08-02 and 2024-08-27 associated with the finished product shipping records involved in the traceability challenge. All that product was shipped at ambient temperatures.

| **Details of non-applicable clauses with justification** | |
|---|---|
| Clause/Section Ref | Justification |
| 4.2.2 | There were no raw materials or products identified as at risk of deliberate attempts to inflict contamination or damage. |

| | |
|---|---|
| 4.2.3 | There were no raw materials or products identified as at particular risk. |
| 4.3.6 | There were no temporary structures observed |
| 4.4.5 | There are no suspended ceilings |
| 4.4.7 | There are not any windows or roof glazing in the plant which are designed for opening. |
| 4.7.2 | The site has not identified any equipment as a particular risk of product contamination for equipment damage |
| 4.9.1.2 | There are no strong scented or taint forming materials used |
| 4.9.2.2 | Packaging materials contain no staples or other potential contaminants. |
| 4.9.4 | No products are packed into glass or brittle containers. |
| 4.10.3.5 | There is no x-ray used. |
| 4.10.5 | There are not any optical sorters used in this plant. |
| 4.10.6.2 | There was no container-cleaning equipment used. |
| 4.10.7 | There was no other foreign body removal equipment |
| 4.12.4 | The plant does not generate customer trademarked product |
| 4.13.1 | The site does not package customer branded product. |
| 4.13.2 | Products were not sold to staff or passed on to charities. |
| 4.13.3 | The plant does not make any products available as animal feed |
| 4.14.3 | The plant does not do any of their own pest control. |
| 4.15.4 | There are not any controlled atmospheric storage requirements |

## 5. Product control

### 5.1 Product design/development

The site's New Product Development Program; *Change Management Process* reviewed 2024-03-20; it outlines methods and responsibilities associated with new products development. The facility team (Lead by the site R & D) is involved with new product development. In this operation, various departments (Marketing, R & D, QA, Operations/ Plant Management & Production) are involved with the new product development process. All product changes and new product trial runs are approved by the Plant Manager, and R & D Team**.**

All hazards associated with new ingredients, processes and products are assessed before any new product is introduced on production lines. Internal team has been engaged to verify that food safety, quality, legality, and authenticity has been assessed for new products before sale. Once a new product development project is approved by senior management specifications, labels and processing steps are developed. Plant engineering identifies commissioning and start-up costs.

Procedure for New Product Development requires that private label customers be informed of all changes and modifications to their products, and grant approval prior to implementation. HACCP plans are reviewed whenever any changes to existing formulations and processes are made. All new formulations and products are verified by the Research and Product Development and QA Manager.

The initial shelf life of new products is based on that of similar existing products comparing it with similar products in the market, scientific literature, and the evaluation of retention samples. No new products were developed within the last 12 months period.

### 5.2 Product labelling

All products are labelled to meet legal requirements for the designated country of use. The shipping containers have labels affixed to them. These provide basic information including the plant identity, the product name or description, storage information, production date, use by dates where appropriate and weight. They are site printed, and self-adhesive.

The product development procedure assures that labels are reviewed for any new product, process, raw material or in response to changes in legislation or regulations.

There is no customer branded or retail ready product made at this site.

There have been no new labels approved since the last audit.

### 5.3 Management of allergens

**Assessment of Raw materials:**
The site has a system for the management of allergenic materials that minimizes the risk of allergen contamination of products and meets legal requirements for labelling in the country of sale. Allergen risks are included in the HACCP Plan and the Supplier Approval process. All raw materials entering the facility are evaluated for allergen status.

The only allergen handled by the site was coconut water, however, the product was not produced since the last audit.

The allergen management program POL-019 reviewed 2024-09-30 includes allergen training for employees and a review of all raw materials to assure that no allergens are allowed into the plant.

The raw material assessment has been conducted which determined that only coconut water contained coconut allergen. The site does not run this product that frequently and there was no coconut water handled/stored during the audit.

All packaging material and food grade lubricants are suitable for non-allergenic food contact.

**Controls in place:**
The site has a formal *Allergen Management Policy* POL-019 reviewed 2024-09-30. The site only handles a single allergen, Coconut water. It arrives frozen in steel drums; to minimize any potential issues, the site only brings enough of the water onto its grounds to fill scheduled orders. There is no long-term inventory maintained on site.

To preserve formula composition all rework of finished goods is only like-into-like. The site produces numerous concentration strengths and has multiple customer specifications, all rework is managed by the Director of Technical Services

**Cross contamination preventive measures:**
To address allergens that employees may have brought in for personnel consumption the GMP procedures require that no food be consumed in the plant and that employees wash their hands when returning to work. Employees are trained in inadvertent allergen introduction; this includes hand-wash and clothing standards to assure allergens are not a contamination threat.

The site does a formal allergen clean after each changeover from the production of formulas containing Coconut Water.

The allergen cleaning procedure was validated on 2022-08-20. In addition, each allergen clean is verified by sending a sample of the final rinse water and the first bag of the next product produced to an external laboratory for testing. The last coconut water production was performed on 2023-08-09, the verification test samples were mislaid and have just recently been submitted. They had not been returned at the time of the audit. The site reported that they had never had a test which showed a cleaning failure. The most recent test results completed were done on 2023-03-10 which reported <2 ppm coconut protein.

## 5.4 Product authenticity, claims and chain of custody

**System in place to review threats to the supply chain:**
There is a system in place to review threats to the supply chain; the site has a formal risk assessment Q-QA reviewed 2024-02-28 in place to minimize the risk of purchasing fraudulent or adulterated food raw materials and to ensure that all product descriptions and claims are legal, accurate and verified. The parent company holds memberships in trade associations and corporate monitors government sources and suppliers for changes that could affect the adulteration risk profile of its products and raw materials. A vulnerability assessment determined that the risk of adulteration of the plant's products was very low. A major protection against fraudulent ingredients is that the majority of the site's raw materials are intact fruits and vegetables which make substitution difficult.

The vulnerability assessment considered historical evidence, economic factors, ease of access, sophistication of routine testing and nature of raw material.

**Documented Vulnerability assessment completed and reviewed annually:**
Vulnerability assessments have been performed on ingredients, with literature searches to check on the historical evidence of fraud of ingredients. The site monitors several websites to remain current of incidences of food fraud' it also receives information from the Juice Processors Association.

The Vulnerability Assessment is updated and reviewed annually, most recently on 2024-02-28; it confirmed that no ingredients were identified of concern. Raw fruit is purchased whole and is very difficult if not impossible to substitute and any juice concentrates must be purchased from approved sites.

The details and completeness of the vulnerability risk assessment interview during the audit indicated that QA Team understood the potential food fraud risks, had knowledge of raw materials and principles of vulnerability assessment. The assessments included all 5 items required in clause 5.4.3 for consideration.

The facility produces items which depend on the status of the raw material, those which are declared non-GMO. The producers must provide certificates to guarantee the status, also there generally are little or no GMO varieties. For example, there is only 1 variety of GMO apple, so they are easy to avoid. The site is certified by the non-GMO Project and must undergo their certification process.

This facility produces items which depend on the methods of production under 3 certification schemes: Organic, Halal and Kosher products. The status of each batch is verified, and records kept. Organic products are run only after thorough cleaning of all lines and transfer connections. All necessary records are maintained to substantiate the claim. Proper control is being exercised at this plant regarding maintenance of organic status. The site's Organic certificate is issued by the Washing State Department of Agriculture, and it undergoes an Organic audit by one of their representatives annually. The Organic certificate is valid unless it is revoked by the certifying body.

It also produces products which comply with the Kosher requirements of the Orthodox Union and there was an up to date a certificate was on file; the facility undergoes period visits by a rabbi representing that group. The final scheme which involves the method of production is Halal; it undergoes annual recertification and had a certificate which was up to date.

## 5.5 Product packaging

Product packaging is suitable for the intended use. The packaging used at this site is either poly-lined 55-gal steel drums, plastic pails, aseptic bags or totes of various sizes, it includes specialty aseptic bags which are designed to hold aseptically processed food products, and which fit within barrels and totes of various sizes. The bags are radiation sterilized at the time of manufacturer and certified as such. Packaging is stored in the dry product area, was observed to be kept in a good and hygienic manner in the storage. It is away from the processing area. Separate sections of the warehouse are used for packaging material and food products. Partially used packaging material is returned to its original storage site. The procedure to manage obsolete packaging (including labels) is covered as part of waste management and it includes mechanisms to prevent accidental use of obsolete packaging, and the control and disposal of obsolete packaging.

Certificates of Phthalates compliance was dated 2017-08-08-2017 and 2022-6-16 were on file for primary packaging (drum bags) involved in the traceability challenge.

## 5.6 Product inspection, on-site product testing and laboratory analysis

**Product testing program:**
The site has a system of conducting routine quality checks of both in-process and finished product. The frequency of product checks is documented on the Filler Production Report (hourly checks for package integrity metal detection and coding). Temperature checks are performed at the end of the cooling cycle.

Testing of finished product and work in progress (WIP) is conducted to assure forward transfer of the batch – specifications are available for all products and in process testing. Tests including pH, viscosity and Brix, acidity, color, flavor and aroma among others, are conducted at frequencies that vary according to the type of fruit and whether the product is a puree or juice.

Finished product testing prior to shipment is done to assure conformance to finished product specs. Test results are reviewed daily to identify trends and confirm finished product conformance to customer requirements. Any non-conforming results are reviewed for significance and responded to with appropriate action to protect customer confidence and product integrity.

Reviewed finished product testing (brix, citric acid, pH, color, viscosity) from 6-9-2023 with satisfactory results.

The facility has an in-house laboratory capable of confirming product safety, legality and quality. There is a well-documented laboratory manual that controls procedures and standards, to assure product testing is reliable and accurate. Lab procedures are documented in controlled procedures.

Testing is done prior to product release. Based on customer requirement, this may require microbiology tests. The in-house laboratory had documented procedures, used recognized test methods and trains its technicians thoroughly and effectively for their jobs. Organoleptic testing is done daily for flavor and aroma. The results of this testing are recorded. The site's in-house microbiological testing is limited to coliforms and Y & M; any test for pathogens is contracted to outside laboratories which are ISO 17025 accredited.

The company has an ongoing laboratory analyst proficiency program. They have 5 technicians, they did in-house round robin comparison proficiency tests on 10-03-2024. The tests include identical samples for the routine testing done in-house. All results have been reviewed and found to be in compliance. In addition, there are proficiency samples provided by the Juice Processors Association (JPA). They again are common physical and chemical tests, the samples have been purchased and registration was completed, pending the receiving of samples and completion of the test for 2023. For 2024 there have been problems with JPA, which lead to the site implementing their own comparison tests.

**Shelf-Life Assessment:**
The site's products are generally single ingredient items, and they follow the established industry standards for declared shelf-life so ongoing shelf-life determination is not deemed necessary. The current shelf life of products is up to 36 months. Retention samples are kept for all lots and are available should a question on a lot arise. That shelf life is based on industrial norms, product history and in-house shelf-life study conducted, comparing with similar products in the market, scientific literature, and evaluation of retention sample.

Shelf-life studies may be performed at a customer's request, but this is an unusual situation.

## 5.7 Product release

The methods and responsibility to release products for sale are documented; *Product Release* M-QA-PRO-016 reviewed 2024-07-24. All results must be entered into the electronic inventory control system and these results verified as in conformance to specification requirements before a CoA can be finalized. CoA's must be completed before the product is loaded for shipment to customers. The contract cold storage is not to release any product prior to receiving the completed CoA. Only QA personnel may authorize the release of product into commerce from this plant.

## 5.8 Pet food and animal feed

N/A

## 5.9 Animal primary conversion

| |
|---|
| N/A |

| Details of non-applicable clauses with justification | |
|---|---|
| Clause/Section Ref | Justification |
| 5.2.4 | The site does not provide any cooking instructions |
| 5.3.6 | The site does not utilize the “may have been produced” warning label |
| 5.3.7 | The site does not make any claims regarding the suitability of any of its products for food allergy or sensitivity |
| 5.5.2 | The site does not purchase any bags of liners for ingredients or work-in-progress items |
| 5.8 | The site does not produce pet food or animal feed |
| 5.9 | The site is not involved in animal primary conversion |

## 6. Process control

### 6.1 Control of operations

**Process specifications/instructions:**
Documented production procedures, operator training programs and effective monitoring systems are used to maintain control of operations undertaken by the plant. Records to demonstrate process control are included in paper based operational records and in the electronic database recorded in test results and process parameters.

Work instructions and process specifications are in place for key processes. These include recipes, blending instructions, equipment settings, processing times and temperatures, and load out procedures. In line flow meters and temperature monitors are in place and linked to alarms that show on video monitors in the processing control room. The actions to be taken when equipment fails or deviates from nominal operations are documented in the non-conforming product procedures discussed earlier in this report. Preoperational sanitation checks are performed before each run.

Most of the site’s products are naturally High Acid and are not required to be registered with the FDA. For the few items which are acidified the company’s Process Authority has provided the minimum processing requirements as well as the thermal process details.

**Process control and Monitoring:**

The equipment is PLC controlled. All information in the process and filling processes are electronically monitored using a Software program. The computer settings are password protected; most can be modified by authorized members of the engineering staff; however, some adjustments are limited to the equipment manufacturer. The temperature control on the cooking is alarmed, there are low temperature dump valves which activate should the product temperature drop below 197° F. The product flow goes into a recycle mode until the proper temperature can be met and the process restarted.

Operators use the displays to get information to report on the production records. Any adjustments are reported on the production records.

## 6.2 Labelling and pack control

**Labelling system:**
All finished packages packed are in non-printed bulk containers. The same packaging materials are used for all finished products.

The product labels are site printed and provide basic information including the plant identity, the product name or description, storage information, production date, use by dates where appropriate and weight. Only the necessary quantity of labels is printed for each production batch. Labels are delivered to the packaging line only after the labels from the previous batch are removed. The accuracy of labels on products is checked against purchase order information prior to loading shipment for delivery. The labels are generally generic but may be customized per customer request. Packaging Instruction and labels included item code to ensure correct label usage.

**Line clearance:**
There is a documented checklist which includes confirmation that the date code, proper label and correct box are all checked. There is a line clearance procedure to verify that the correct product is packed into the correct shipper. Leftover labels at the end of a run were destroyed by the operator.

**Checks in place for pack/labels:**
The filler operators are responsible for making checks are the start of each run to confirm that the proper labels are being applied. In addition, Quality Technicians periodically go through the area and verify the correct information is being used for the product currently under production. A copy of the label is retained.

As a change in product requires a major line clearance and CIP procedure, the site attempts to only run one product a day. The site was only running the same product all day each day of the audit and there was no opportunity to observe a product changeover.

## 6.3 Quantity, weight, volume and number control

The site's equipment is designed to produce containers which conform to legal requirements and customer requirements and the quality control programs are designed to confirm that compliance. Packaging operators are responsible for assuring correct weights are maintained for the product. All the finished products are packed in commercial rather than retail sized packaging, 5-gallon pails, 55-gallon drums, 275-gallon totes and bulk tanker trucks; the pails, drums and totes are filled on a scale. As such there are few regulatory requirements. The tankers are weighed before and after filling to determine the product weight. For the pails deviations from specified weight requirements are adjusted as necessary to maintain conformance with package declarations and/or product specifications. Each pail is filled manually to a net weight by the operator.

All package weights are verified for conformance to specification before shipment to customers.

## 6.4 Calibration and control of measuring and monitoring devices

A policy defines the methods and responsibilities for calibrating measuring, testing and inspection equipment and has been implemented. The facility has developed a calibration schedule (Calibration Program and Master schedule) with all devices listed.

Equipment Calibration Program is in place. Deviations for malfunctioning equipment/instruments require product needs to be isolated, re-tested/rechecked and corrective action procedure is followed for handling the affected product.

The following calibration records were reviewed:

- Drywell calibration reference (used to calibrate RTDs – annual – external service – 2024-03-25
- RTDs – internal against Drywell reference – frequency varies with the individual unit from monthly to quarterly; for example, the aseptic filer RTD – done monthly – most recently 2024-09-19
- Scales – every 6 months – external service – 2024-08-26

The policy includes the procedures to address the disposition of any affected product should inspection equipment be found to be out of calibration. Inspection and testing equipment is protected from damage or unauthorized use by authorized use. Equipment is calibrated against national or international standards.

| **Details of non-applicable clauses with justification** | |
|---|---|
| Clause/Section Ref | Justification |
| 6.2.4 | There are not any on-line vision systems used in the plant for packaging label verification. |
| 6.3.2 | The site does not pack products in sizes which are governed by legislative regulations. |

## 7. Personnel

### 7.1 Training: raw material handling, preparation, processing, packing and storage areas

The company has systems in place to ensure that all personnel who perform work that affects product safety, legality and quality are competent to carry out that activity, through training, work experience or qualification. The company has a training policy that covers staff orientation, SOP training, contractors, Food Hygiene and refresher training. All employees go through an orientation session when they are hired.

New employees undergo job specific documented induction training. Training is administered per the requirements and is effective. There is formal annual training required (safety, GMP's, SOP's). Temporary employees were also trained for GMP's.

The plant uses the “Alchemy” commercial computerized training program to perform training and to maintain their records. All training records are maintained in the Alchemy database. Sign-ins for training done through Alchemy is electronic. The employees are provided a list of training required on Alchemy, the individuals are required to complete the training for all the topics in 2 months; if they do not complete it, the system highlights the variance. All other training is documented on a manual sign-in sheet that lists the trainer, the topic and the attendees. Training effectiveness is assessed through tests or documented observations.

In response to issues raised in the review of the plan to improve the food safety culture the site has implemented a program of group training on a different topic every 2 weeks. The topic schedule is developed and maintained by the Vice President of Operations. This is over and above the Alchemy training program.

## 7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

**Personal Hygiene:**
The site’s personal hygiene standards have been developed to minimize the risk of product contamination from personnel and are appropriate to the products produced. All personnel are required to follow these rules when in the production areas of the facility. Jewelry and body piercings are not allowed in the plant. Plain wedding bands are the only exception. Fingernails are to be kept short. Strong perfumes and colognes are not allowed. Personnel practices are verified daily by Supervisors’ observations as well as during the monthly GMP/Safety/Security Inspections.

Per the GMP Policy (Plant and Equipment reviewed 2024-04-12 and GMP for Staff reviewed 2024-04-12), medicines are not allowed in the plant. Personal lockers are available to all employees for storing any medications.

**Hand washing:**
Movement of personnel, visitors and contractors through areas is controlled and does not compromise product safety. There is a floor plan which shows sensitive areas, staff facilities and personnel foot travel routes. Employees entering the plant during this audit were observed to have stopped and washed their hands.

The First Aid cabinets contained blue metal detectable bandages which were tested through the metal detectors. Samples for each lot of bandages are passed through the opening of the in-line metal detectors at the time of the reception of the lot and periodically thereafter. The Quality Lead keeps records of the tests. Records reviewed included:

- Knuckle – Lot 94390 – tested 2024-10-08
- 1” X 3” – Lot 2014110 – tested 2024-10-08

Neither inbound nor outbound vehicle drivers are allowed into the plant’s production and storage areas. When access through production areas is required, personnel are guided so as not to risk product quality or personal safety. Visitors are always accompanied.

## 7.3 Medical screening

Medical screenings, as allowed by state law are conducted prior to employment. Full-time employees were offered annual check-ups. The GMP policy requires employees to notify their supervisor in the event of an infectious disease or if they are suffering from a medical condition; the employees are trained in the requirement to report any potentially infectious condition to supervision for assessment and action if necessary. Contractors and visitors sign a document attesting to the fact that they are free from contagious illnesses as a condition of entry into the facility.

Supervisors and managers are trained to recognize risky medical conditions and to reassign or send home any employee suffering from any such affliction. Employees must have a doctor's clearance prior to returning to work after being sick for three days.

### 7.4 Protective clothing: employees or visitors to production areas

The Plant has assessed the risk of clothing to the product. The plant has been identified as enclosed product areas. There is no company required protective clothing. There is a dress policy to control the condition of clothing worn by personnel in processing areas. Clothing must be clean, suitable, no loose threads, etc., sleeves and pants are required, steel toed shoes (these are issued).

Employees were observed in reasonable clean attire. Individual uniforms are not issued to employees at this facility. Clothing procedures are presented to employees in training and to visitors and contractors in documentation they receive prior to entering the plant address clothing requirements. Contractors wear company approved clothing but are monitored and restricted in their movement around active production areas.

Plant GMP's require that suitable footwear to be worn by all persons entering production and storage areas of the plant.

There is very limited handling of the ingredients as they are batched and almost none of the finished products; there are not any requirements for employees to use gloves when handling the product. Single use blue nitrile gloves and disposable white smocks are made available to employees at filler stations most commonly when producing pails. Per the GMP policy, they must be clean, intact and sanitary for use in the production area.

**Details of non-applicable clauses with justification**

| Clause/Section Ref | Justification |
|---|---|
| 7.4.6 | There are no clothing items that are not suitable for laundering |

## 8. Production risk zones – high risk, high care and ambient high care production risk zones

### 8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones

Not applicable

### 8.2 Building fabric in high-risk and high-care zones

Not applicable

| 8.3 Equipment and maintenance in high-risk and high-care zones |
|---|
| Not applicable |
| 8.4 Staff facilities for high-risk and high-care zones |
| Not applicable |
| 8.5 Housekeeping and hygiene in the high-risk high-care zones |
| Not applicable |
| 8.6 Waste/Waste disposal in high risk, high care zones |
| Not applicable |
| 8.7 Protective clothing in the high-risk high-care zones |
| Not applicable |

| **Details of non-applicable clauses with justification** | |
|---|---|
| Clause/Section Ref | Justification |
| | |

| **9. Requirements for traded products** |
|---|
| 9.1 The food safety plan - HACCP |
| Not applicable |
| 9.2 Approval and performance monitoring of manufacturers/packers of traded food products |
| Not applicable |

| 9.3 Specifications |
|---|
| Not applicable |
| 9.4 Product inspection and laboratory testing |
| Not applicable |
| 9.5 Product legality |
| Not applicable |
| 9.6 Traceability |
| Not applicable |

| **Module 11: Meat Supply Chain Assurance** | |
|---|---|
| **Scope** | **Not applicable** |
| **11.1 Traceability** | |
| Not applicable | |
| 11.2 Approval of meat supply chain | |
| Not applicable | |
| 11.3 Raw material receipt and inspection | |
| Not applicable | |
| 11.4 Management of cross-contamination between species | |
| Not applicable | |
| 11.5 Product testing | |
| Not applicable | |
| 11.6 Training | |

| |
|---|
| Not applicable |

| **Module 13: Meeting FSMA Requirements for Food – July 2022** |
|---|
| Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33) |
| **Not applicable** |
| Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1) |
| **Not applicable** |
| Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11) |
| **Not applicable** |
| Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9) |
| **Not applicable** |
| Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18) |
| **Not applicable** |

| **14.1 Additional Specifier Requirements** |
|---|
| 14.1 Traceability |
| Not applicable |
| 14.2 Environmental Monitoring |
| Not applicable |
| 14.3 Product inspection and laboratory testing |

| |
|---|
| Not applicable |
| 14.4 Protective clothing: Employees or visitors to production areas |
| Not applicable |