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

1. Audit Summary			
Company name	KUIBURI FRUIT CUP CO., LTD.	Site code	5092614
Site name	KUIBURI FRUIT CUP CO., LTD.		
Scope of audit	Manufacture (blanching, filling, sealing, sterilization) of tropical fruit, pineapple, mango and aloe vera packed into plastic cup.		
Exclusions from scope	None		
Justification for exclusion	None		
Audit start date	2023-12-14	Audit finish date	2023-12-15
Re-audit due date	2025-03-23	Head office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Meeting FSMA requirements for Food	Passed	Manufacture (blanching, filling, sealing, sterilization) of tropical fruit, pineapple, mango and aloe vera packed into plastic cup.	None
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	A+	Audit programme	Unannounced – mandatory 1 in 3 years
Previous audit grade	A		Previous audit date	2023-03-20	
Certificate issue date	Select a date		Certificate expiry date	2025-05-04	
Number of non-conformities			Fundamental	0	
			Critical	0	
			Major	0	
			Minor	8	

3. Company Details			
Site address	1 Moo 7, Petchkasem-Yangchum Road, T. Kuiburi, A. Kuiburi, Prachuap Khiri Khan 77150		
Country	Thailand	Site telephone number	+ 66 32 681 578-9
Commercial representative name	Mr. Puvadol Thanyodom	Email	puvadolth@kuiburifruit.co.th
Technical representative name	Mr. Kongkiat Muangsong	Email	kongkiatmu@kuiburifruit.co.th

4. Company Profile					
Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3

Shift pattern	Single shift (08:30 am – 05:30 pm)	
Seasonal site	No	
Seasonal opening times (Start/end date)	Click or tap to enter a date.	Click or tap to enter a date.
Other certificates held	GMP/HACCP, ISO 9001:2015, KOSHER, ISO 14001:2015	
Outsourced processes	No	
Outsourced process description	None	
Regions exported to	North America Choose a region Choose a region Choose a region Choose a region Choose a region	
Company registration number	10769129160	
Major changes since last BRCGS audit	None	

4. Company Profile

Company Description

KUIBURI FRUIT CUP CO., LTD. was established in 2010, located in Prachuap Khiri Khan province which 100% privately owned. The production working shift was 1 shift on Monday - Saturday (8.30 – 17.30 p.m.) and total staff 43 persons with maximum production capacity 60,000 cups per day.
Main raw materials were pineapple, aloe vera, citric acid, sugar, etc. Main products were tropical fruit, pineapple, mango, aloe vera packed into plastic cup which sold in domestic (1%) and export market to USA (99%).
Equipment includes mixing machine, filling machine, cooker, metal detector which appropriately criteria inspection and maintenance. HACCP plan was 1 plan for sterilization of acidified fruit product in plastic cup.
Factory located in the same fence with Kuiburi Fruit Canning Company Limited which produced canning product, aseptic juice and dehydrated fruit and supplied some utilities and facilities with KUIBURI FRUIT CUP CO., LTD. i.e., water treatment, canteen, waste control, security guard, boiler, laundry, microbiological laboratory, etc.
There was 1 building which clearly separated for low care area and enclosed product area. Low care area was covered receiving area of fresh material from Kuiburi Fruit Canning, preparing and filling area.
Enclosed product area was covered sterilization area, labelling area, store of raw material, chilled room, store of packaging and store of finish product.

5. Product Characteristics

Product categories	11 - Low/high acid in cans/glass Category Category Category Category Category Category Category
Finished product safety rationale	For sterilization product, packed in plastic cup with sterilization process P value > 0.1, storage at ambient condition and long shelf life 12 - 24 months.

High care	No	High risk	No	Ambient high care	No

Justification for area	Based on decision tree for production risk zone, there was no applicable for high risk, high care and ambient high care area. Product can store at ambient condition for long shelf life.
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen

5. Product Characteristics	
	Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	Gluten free, lactose free, vegan
Product recalls in last 12 months	No
Products in production at the time of the audit	Pineapple tidbits in pineapple juice packed in plastic cup.

6. Audit Duration Details			
Total audit duration	24 man hours	Duration of production facility inspection	12 man hours
Reasons for deviation from typical or expected audit duration	Variety of products and included FSMA		
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 and closing meetings (ref: clause 1.1.11)

Name	Job title	Opening meeting	Site inspection	Procedure review	Closing meeting
Kongkiat Muangsong	QMR	onsite	onsite	onsite	onsite
Worasiri Mekniti	Production manager	onsite	onsite	onsite	onsite
Suwannee Ngam-on	QA manager	onsite	onsite	onsite	onsite
Sakwit Sootapativej	WH manager	onsite	onsite	onsite	onsite
Pattama Janhom	Assistant QA manager	onsite	onsite	onsite	onsite

Apaporn Petchaudsorrn	Assistant ST manager	onsite	onsite	onsite	onsite
Prayute Engont	Assistant MT manager	onsite	onsite	onsite	onsite
Matee Seangyai	Assistant safety manager	onsite	onsite	onsite	onsite
Suleerat Sa-Ngounchiam	QMS supervisor	onsite	onsite	onsite	onsite
Wilai Changkeian	Purchase supervisor	onsite		onsite	onsite

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/Unannounced	Pass/Fail
2021-03-15	BRCGS Food Safety Issue 8	Announced	Pass
2022-03-11	BRCGS Food Safety Issue 8	Announced	Pass
2023-03-20	BRCGS Food Safety Issue 9	Announced	Pass

Document control			
CB Report number	3765414		
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
2.7.1	By review the hazard assessment, there was no included some step as; - rework process of pineapple in cup, Aloe Vera in cup e.g. cup/plastic film, waste from rework. -Paper sheet that use at crating step 19 after cooling process.	Update and amended the process flow diagram of HACCP in detailed every step.	Review process flow diagram at on–site following the process step every year or once any process change.	Lack of reviewing the flow diagram in-detailed and incompletely the hazard assessment in some step.	2024-01-09	Phakham T.
4.4.1	During on site at media preparing room found peeling paint at the wall near water boiling tank.	Repair the peeling paint at the wall and cover the wall with stainless steel sheet.	Monitoring and maintained to prevent the accumulation of dirt and minimise of condensation by operator regularly.	It's caused by the deterioration from heat and steam exposed at the water boiling tank and poor maintenance in good condition.	2024-01-09	Phakham T.
4.6.3	There was found improperly for newly machine control as below ; -There was no procedure for	1. Amended the documented procedure to include the commissioning newly machine and equipment. 2. Provide the commissioning checklist	Provide training for technician or operator who responsible for machine installation at least once a year.	The technician who responsible for the machine installation are not understand the hygienic clearance and related requirements.	2024-01-09	Phakham T.

Minor						
	commission newly machine -During on site found newly machine (made machine) for unloading machine, installed in year 2023, However there was no commission report.	to ensure that food safety and integrity is maintained during the installation of new machine and equipment.				
4.7.2	During on site found some part of filler machine was crack but no evidence for check and correction.	Change a new one spare part to replace the damaged part of plastic cup filler machine.	Amended the maintenance checklist to increase the frequency of filler machine inspection from monthly to be daily basis.	Due to the deterioration from long time operation and also poor maintenance to properly condition.	2024-01-09	Phakham T.
4.11.6	During on site found improperly for cleaning equipment by found damage dishwashing sponge at cleaning equipment storage area.	-Establish a document work instruction for inspection the cleaning equipment and tools used. -Provide a cleaning checklist to monitoring and ensure that appropriate standards of hygiene.	Provide training for responsible person to acknowledge the method of cleaning including records for completion.	There are some worker not awareness to maintain an equipment in clean and hygiene condition.	2024-01-09	Phakham T.
4.15.2	By onsite audit the temporary storage area of plastic cups before sending them to the production area. Found an area with dust and	Provide the suitable storage area and bring an ingredients from the temporary area to the appropriate storage condition.	Does not storage any ingredients or packaging outside the warehouse and ensure that the storage location are	Due to the factory rescheduling and reduce the production capacity, so that the storage area are not sufficient.	2024-01-09	Phakham T.

Minor						
	dirt accumulated on the floor.		properly condition regularly.			
4.15.6	By review the inventory control of N2 gas, there was no FIFO use during onsite audit; seen use of lot 23/11/2023 before lot 13/9/2023.	-Create additional identification tag to clearly define a differentiated between old and new nitrogen. Provide training for operator to understand and awareness the correct stock rotation.	Monitoring and recheck the operation practice daily basis by supervisor.	The operator lack of recheck the correct stock rotation of N2 gas due to an ineffectively tag identification.	2024-01-09	Phakham T.
7.2.1	During on site at production line found some staff long fingernails.	Re-training and emphasize the staff to awareness of the personal hygiene practice.	Monitoring and recheck the personal hygiene of staffs before working by daily basis.	The staff lack awareness of the personal hygiene practice.	2024-01-09	Phakham T.

Comments on non-conformities
Click or tap here to enter text.

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**
21871	Phakham	Thaemhong

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
Phakham	Thaemhong	21871	Lead auditor	2023/12/14	09:00	18:00	Physical	NA
Watchara	Ponrong	20761	Second Auditor	2023/12/14	09:00	18:00	Physical	NA
Phakham	Thaemhong	21871	Lead auditor	2023/12/15	08:30	14:30	Physical	NA
Watchara	Ponrong	20761	Second Auditor	2023/12/15	08:30	14:30	Physical	NA

1. Senior management commitment

There is a documented food safety policy (QMPTC-07 rev. 5 update on 11 Feb 2023) which is signed by managing director effectively communication to all person in company board, training and inform during staff orientation. The policy notices on 13 March 2019 in Thai and Myanmar language that covers food safety, quality, legality and authenticity and the responsibility to meet specifications and quality as customer requirements and continuous improvement including food safety and quality culture and is supported by a number of objectives implementing at all levels.
Key performance indicator clearly set up to review on Jan -November 2023 such as.
%NC < 0.10%; 0.06% achieved
Defect rate <0.60%; actual 0.96% not achieved, found root cause analysis and action taken related the review % defect condition and improve for the sealing machine.
Complaint <= 1 case/ year; 1 case achieved.
Withdrawal 0 case; 0 achieved.
CAR minor from 3rd party <=8, 1 minor CAR from 2nd party.
Recovery (Yield) > 96.90 % / month 97.61 % achieved.
KPI monitoring and reporting on monthly basis to steering committee and top management, the KPI that no achieve target have taken corrective action plan and follow up by QMR.

Managing director attended management review meeting on twice a year and all monthly meetings. Last management review meeting on 27/7/2023 found all agenda was reviewed such as policy, KPI, food safety and quality culture, customer complaint, internal audit result, progressive and action plan of each KPI, HACCP plan update, Legal and regulatory and shown output from management review and production review with details of responsible persons, time, and conclusion, and monitored, etc.

Recorded minutes of monthly meeting were kept on file that last reviewed record is available, last monthly meeting report e.g., 23/11/2023, 19/10/2023, 28/9/2023, 20/8/2023, 20/7/2023 included KPI, food safety and quality NC, customer compliant, food safety and quality culture, KPI, updated of legal requirement, fraud, and integrity, etc.

By interview with the managing director and management representative. Food safety and quality culture was in place, channel to food safety and quality culture action plan to food safety and quality culture development. There was set the culture plan timescale on January to December 2023 onward in topic reduce physical contamination control and pest infestation. There clearly set activities in 2 phases included Phase 1: awareness training of all staffs by clearly and open communication with staff by meeting, board, and morning talk for feedback to employee, performance measurement on activities related to the safety, authenticity, legality, and quality of products by review one a month and review effectiveness twice a year and communicate in monthly meeting and management meeting. Phase 2 to review measuring by monthly GMP audit on January to November 2023, average 96.67% for production line and labelling/warehouse and 100% for store (target more than 85%), and data contamination form QA inspection (W/H), set target < 0.1 %, found actual 0.06%.

The whistle blowing system set in WI-HR-26, Site and all its employees will have visible access to a clearly displayed, in local languages; channel for whistle blowing included hotline and e-mail of managing director, production manager, HR manager and QMR, suggestion box which located in canteen; HR manager was responsible to collect the suggestion report and review by ethical team; investigation and feedback by food safety team and managing director. This could be in relation to food integrity, quality, and safety. Since the previous audit, there was no issue about food safety and other cases.
QP-MR-09 channel e.g. suggestion box, e-mail, letter to MD, hot line.
FSTL representative has set the system to ensure that the company was kept information of scientific and technical development, industry codes of practice and all relevant legislation applicable in the country of raw material supply and the country where the products are sold.

The current issue of the Global Standard for Food Safety Issue 9 is presented during this evaluation in PDF file.

Due date and activities of FS and QMS was planned and follow up by FSTL, the root cause of all audits was review and handling by QMR as corrective and preventive action procedure to prevent reoccurrence of nonconformity. All nonconformity from previous audit was implemented and found the effectiveness by seeing the corrective action.

BRCGS logo used was appropriate and not found on the primary packaging or label. For this BRCGS audit, managing director has been attended in both opening and closing meeting.

There was found clearly defined line of command which updated and presented in the organization chart include QA manager, Production manager, QMS manager, QC team and document team reported to managing director. QA manager acted as food safety team leader.
Work instruction and procedures are part of the quality manual and jobs description properly documented. Absence of the responsible persons included food safety, legality and quality has been allocated and understood by manager define in Job description (SD09-HR-55). Each department was responsible for update the legal and requirement.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
None	

2. The Food Safety Plan – HACCP

Team still made form multidisciplinary from 22 employees such as production, QS manager, QA, product development, warehouse, purchasing which Ms. Suwannee served as FSTL and PCQI. All persons have education, experience, training, and knowledge as shown in announcement on 27 Jul 2023.

Good maintained on environmental and operational programs, suitable of controls measure for all hazards were documented. PRPs maintained as cleaning and sanitizing, pest control, preventive maintenance, waste management, personal hygiene, chemical and physical control, etc.

Product description was indicated as: pH < 3.9, brix depends on product, shelf life 12 months at ambient temperature, 15 months at 4 - 18°C, 18 months at 1 - 4°C, packed in PP cup with PP lid and flushing mixture of nitrogen gas and carbon dioxide gas.

Product description included chemical/biological characteristic, packing size, label defined, storage condition, manufacturing and expiry date and destiny country and product refer to local and customer's country requirement, MoPH 416, etc.

Process flow diagram of pineapple in syrup/ juice in plastic cup (SDPTC07-QA-01 rev.24), aloe vera in syrup in plastic cup (SDPTC07-QA-04 rev.12), tropical fruit in syrup/ juice in plastic cup (SDPTC07-QA-02 rev.26), mango in syrup in plastic cup (SDPTC07-QA-03 rev.21) was verified onsite annually by food

safety team, found evidence record review available on file, latest on 15 February 2023. Mainly the process was raw material, blanching/ soaking hot water, sorting, filling with media, flushing gas, sealing, passing metal detector, sterilization, storage, labeling and transport. Reprocess and intermediate process were included in the process flow diagram. However there was found the flow diagram was not cover some step. (Seen as NC)

A review of HACCP analysis work sheet indicated that hazard analysis considers both severity and likelihood of the hazard occurrence. Microbiological, physical, chemical, radiological, food fraud hazards included pesticide and heavy metal and allergen was determined in each production step such as microbiological hazard (*Salmonella spp., B. cereus, E.coli, S. aureus, B. coagulants, C. perfringens,* coliforms), chemical hazard e.g. pesticide, heavy metal (cadmium, lead, mercury, arsenic), patulin, herbicide, physical hazard form foreign mater contamination e.g. glass, breakable plastic, metal fragment, stone, allergen from coconut, etc. For food malicious has also assessed in each process properly. A review of CCP monitoring records indicated that, the monitoring procedures were implemented at required interval.

CCPs from justification by decision tree
Critical limit and monitoring were defined in pineapple in syrup/ juice in plastic cup (SDPTC07-QA-01), aloe vera in syrup in plastic cup (SDPTC07-QA-04), tropical fruit in syrup/ juice in plastic cup (SDPTC07-QA-02), mango in syrup in plastic cup (SDPTC07-QA-03), aloe vera in syrup in plastic cup (SDPTC07-QA-04) validated and agreed by team. And information was from historical process data i.e.

- CCP1: blending media process, CL is equilibrium pH < 3.9: monitoring every batch by QC and recorded in FMPTC-QA-19. Correction: adjusted pH and rechecked and holded product.
- CCP2: passing metal detector step, CL is control physical hazard by use test pieces (Fe < 1.5 mm., non Fe < 2.5 mm. SUS < 3.0 mm.) check before, end of production and every 2 hours by PD and recorded in FMPTC-PT-14. Correction: when found deviation, hold product, adjusted the machine and rechecked product.
- CCP3: sterilizing process, CL is cooking temperature and cooking depend on number of cooker, type of product and packaging size; monitoring temperature every hour by QC and at the beginning and every 4 hours for time and recorded in FMPTC-QA-11. Correction: when found deviation, increased cooking time and temperature and hold product.

Validation was conducted as planned by the production department. Records were maintained. The most recent validation was conducted as followed:

CCP1 and CCP3 referred reference to temperature distribution i.e., cooker 2 on 3 November 2022 (2 year) and heat penetration study i.e., tidbits pineapple at cooker 2 on 14 February 2023, aloe vera at cooker 2 on 11 March 2023, etc. All product has P value > 0.1 refer to microbiological and engineering of sterilization process edition 11 2003.

CCP2 on 7/6/2023 for metal detector no.2 (for product code ZCTJ and ZFSDJ1) by testing of metal detector with test piece for all program by internal and calibrated by external provider with test pieces Fe < 1.5 mm., non-Fe < 2.5 mm. SUS < 3.0 mm. on 1 September 2022.

Documented monitoring, corrective action procedure is in place and implemented when the critical limits are not met. An interview with person in charge of CCP monitoring indicated that, the procedure is implemented. Review of records and interviews with processing staff showed that they were aware of the CCPs and the actions to be carried out.

Verification and validation of CCP and critical limit were effectiveness by product testing, internal audit, calibration and HACCP team meeting. For the new HACCP plan, there has to be a validated HACCP plan before it is implemented. However, since the previous audit, there was no new HACCP plan. For all existing plans, there is verification plan properly.

Reviewed and updated HACCP and GMP in monthly meeting and HACCP meeting or change in suppliers, ingredient, or raw material. HACCP review has been conducted on 25/1/2023.

Related legal, requirement updated on monthly meeting.

A Minor Non-conformance has been raised against 2.7.1
By review the hazard assessment, there was no included some step as;
-Rework process of pineapple in cup, Aloe Vera in cup e.g. cup/plastic film, waste from rework.
-Paper sheet that use at crating step 19 after cooling process.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
None	

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 – QMPTC-07 rev. 5, on 11 Feb 2023. The organization food safety and quality management were documented, implemented, and updated which state the food safety system, HACCP, Quality requirement, operating procedure manual and hygiene manual comply with new versions of BRCGS food V9. The Quality manual was implemented and maintain in Thai version and distributed to key staff such as QC, Production, Engineer, etc. During onsite verification, it was observed that work instructions in each area were updated such as production control process, quality control process.

The documentation control procedure (QP-DC-01 rev.11) is available. All documents were controlled under documentation control procedure by sampling documents on master list FM-DC-01 indicated the current version, found effectiveness of approved on Document action request (FM-DC-05). All sampling documents were updated and provide adequately.

Review SDPTC07-QA-02, 03 rev. 26, 21 effective date 17/11/2023 DAR 527/2023. SDPTC09-QA-18.1, 18.2, 18.3, 18.4 effective date 12/12/2023 as DAR 577/23. QMPTC-07 effective date 11/02/2023 as DAR 057/23.

The records control procedure is available as procedure in QP-DC-02 rev.06. All records were control as procedure; retention time for record keeping was 36 months. By verification observe during onsite audit and document audit seen the records were maintained in good condition, legible and retrievable such as raw material preparation record, weighting record, inspection record, water analysis report, cleaning record, personal hygiene inspection record, etc.

During onsite verification, it was observed that work instructions, process control, external document and HACCP plan in each area were updated. Control of document is implemented with all documents. Back up of electronic file has been done automatically on daily basis. WI-IT-01, WI-IT-02, authorize control for access.

3.4 Internal audits

Internal audit process was established and maintained in procedure QP-MR-02 that set at least four different audit dates throughout the year to audit in all activities with different 4 times which schedule based on risk assessment from performance, key process, and activity for fundamental requirement

(SD09-MR-03 update on 11 Mar 2023 and SD09-MR-01). In year 2023 on February, May, August, and November 2023. Internal audit team update on 27 July 2023, The internal auditor team training for BRCGS Food v.9 and Internal audit technique on 12-13 January 2023.

The last audit was performed on 30/11/2023 – Production/QA/Planning/Plastic cup, HACCP team , Recall of plastic cup – 1 NC as IPT040/23. 1/12/2023 – Utility (no NC), 22/8/2023 for procurement (no NC), 25/8/2023 procurement of RM (no NC), 28/8/2023 for RD (no NC), etc.
All corrective action for non-conformity was set the root cause and set the corrective action by owner area within time frame and followed up by internal auditor team. To sample the corrective action in CAR no. IPT040/23, IPT024, 009/23 found root cause analysis, corrective action, preventive action undertaken.

Monthly inspection conducted on factory environment and processing equipment and recorded in Monthly Factory Environment, Processing Equipment and Hygiene Inspection Record FM-PA-125. It included inspection at external building, drainage, structure, opening product area, equipment, food contact surface, toilet, water supply, hand sanitizing, sewage disposal system, lighting protection, hygiene facilities, etc. To review latest conducted on 31/10/2023, 24/11/2023, 4/12/2023.
The corrective actions for each NC found during the internal audit have to be completed within a time frame. Reviews of the corrective action found are closed out completely. The root cause and corrective action are defined clearly.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

All raw material, ingredient and packaging were undertaken the risk assessment (SD09-PM-01) and significant outcome. This was undertaking as a part of hazard analysis, potential hazard (chemical, biological, physical, allergen, food fraud, malicious, variety, legality, customer requirement) were identified and considered when established specifications and supplier approval procedure., latest reviews on 25/03/2023 and reassessed annually.

A review of purchasing order and the relevant records indicated that, all raw materials, ingredients and food contact packaging were purchased by specific company and manufacturing location. Raw material and ingredient assessments at intake, Certificates of analysis and laboratory analysis form part of the on-going review of supplier performance. Packaging suppliers were approved in a similar way, including compliance with food contact regulations, specification, self-audit questionnaire or GFSI certificate.

The company was assessed the risk as a part of hazard analysis, potential hazard was identified and considered when established specifications and supplier approval procedure.
The risk assessment was undertaken a documented risk assessment of each raw material e.g., pineapple, concentrate juice, refine sugar, citric acid, ascorbic acid, flavour, etc. were controlled and define in hazard analysis with the biological, chemical, physical, allergen and substitution or fraud of raw material and packaging. For low-risk raw material, the approval process was on self-audit questionnaire (FM-QA-259) which has been sent to supplier at the first approval and reviewed every 3 years. The questionnaire was covered detail of GMP, HACCP and traceability process and has been review by competent staff before approved in AVL. For medium risk, the approval process was on onsite audit by competent auditor or GFSI certificate. For high-risk raw material, the certification of BRCGS or GFSI audit has been requested from supplier and conducted supplier audit by competent auditor. From risk assessment, there was only low and medium risk raw material some raw material such as White Grape juice concentrate and White sugar.
Ongoing supplier performance review has been conducted through supplier evaluation every 6 months which concerned in quality, price, certificate, coordinate, and delivery issued, Latest evaluation supplier on 26/7/2023.

Approved vendor list has been updated every changing time on FM-PM-09 which covered list of suppliers of raw material, ingredient, packaging, and service provider, latest updated on 26/7/2023.

Review supplier evaluation report, supplier questionnaire and GFSI certificate or supplier audit report e.g.
Sugar Mirtaroonlarp (A); Kaset Thai International FSSC22000 certify valid date 2/5/2025.
,Ruamkaset (A) , Medium – United Farmer and Industrial FSSC certify valid 13/3/2024.
Jamon (new supplier), Medium – Sunshine Biotech International BRCGS certify valid 12/1/2024.
Trail report for citric acid monohydrate as request no. 016/66, test date 15/7/2023.
Thai Citric acid (A), Medium – FSSC certify valid 18/6/2024.
EKA Global (Suzhou, China) (A), Low – FSSC certify 3/7/2026.
VEXCEL (Thailand) (Visy pack) , Low – BRCIOP 10/5/2024.
PT DNP Indonesia (A), Low, FSSC22000 valid 14/7/2025.
Dominant (A), Medium – FSSC22000 valid 28/3/2025, Luwei Pharmaceutical Group
Sensient (A) , Medium – FSSC22000 valid 9/3/2026.
N2, CO2 gas – United Industrial Gas (A), Low – supplier audit on date 28/8/2023 checklist FM-QA-329. Scoring 72% grade B.

Some raw material has been purchased from agent which are known for the last manufacturer and can get information about GFSI certificate such as Citric acid from Jamon (supplier questionnaire FM-QA-259 date 23/6/2023, scoring 93% grade A, sign agree specification on 17/7/2023) which traded from Sunshine Biotech Co., Ltd. (BRCGS certified valid until 12/1/2024).

Traceability of each raw material has been tested by the company with supplier at the first approval and every 3 years to confirm the effectiveness of traceability system for low-risk raw material.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

The company maintained the system to control and ensure that the raw materials, ingredients, and packaging complied with the safety, legality, and quality of product as appropriate. The company has a documented procedure for acceptance and release for use of raw materials, processing aids and packaging to receipt based on the risk assessment and exist on AVL.

The raw material, processing aids and packaging material were sampling and testing based on risk assessment, records of testing and CoA shown accepted and complied with specification. Risk assessment of raw material and packaging were controlled and define in hazard analysis with the biological, chemical, physical, allergen and fraud. Certificates of analysis/conformance were required for relevant materials. Specification (SD05-QA-01, SD-QA-02, SD-QA-13, SD-QA-07) was review and updated on at least 3 yearly.

Raw material was monitor and confirm by QC complied with company standard before receiving such as brix, pH, acidity, foreign matter, defect, chemical and microbiological parameter and provided the CoA before approved for ingredients and packaging.
Sampling the testing report as;
-Packaging cup -Eka-global (Suzhou) packaging, test report on 18/5/23,(PP/tie/EVOH/Tie/PP) for over all migration , Migration of BPA , migration of heavy metal, Restricted substance, comply with EU 10/2011, and 2011/65/EU and its latest version (EU) 2015/863

-Lid film (PET/Nylon/PP), testing report on 23/9/2021, DOC for BPA free

-Citric acid lot 23027044 receiving on 19/4/23 review testing report on 3/2/23 , report no. 549000
-Vitamin C lot 3220123076, receiving on 24/5/23, testing report QDF23-023048-16 on 27/4/23,
-N2 99.5 % receiving on 13/5/23, review COA, Testing on 24/9/23
-CO2 99.5% receiving on 13/5/23, Testing report on 8/2/23.

3.5.3 Management of suppliers of services

Documented procedure for approval and monitoring of supplier of service is in place. Supplier services were maintained and controlled as contract agreement e.g. laboratory service, calibration service, pest control service, waste management service and transportation service. Found evaluation report complied with planned latest on 26/07/2023 for Pest control from Advanced Group Asia Co., Ltd.=B, calibration service from Tomco Automatic machinery Co., Ltd.= A, SGS =A and Kuiburi Fruit Canning Co., Ltd. for laboratory = A, Kuiburi Fruit Canning Co., Ltd. for laundry service= A, Better World Green for waste management = A grade etc. report was maintained.

There are contracts/formal agreements of supplier of service were available maintained and controlled as contract. The contract was clearly defining the condition and service expectation include ensure to prevent and control potential risk i.e. transportation service and pest control service company as below: Advanced Group Asia Co., Ltd. (Pest service) contract agreement number CT23-0000614 during 1 January 2023 – 31 December 2023, KT transport (2015) Co., Ltd. (Transport service) contract agreement on 4 January 2023.

3.5.4 Management of Outsourced processing

There was no outsourced process.

3.6 Specifications

Specifications were included for raw material and packaging, process specification and product specification. The specifications were clearly defined for acceptable levels included for microbiological, chemical and physical, allergen and substitution or fraud.

Sampling specification of raw material SP-IRRD-01-xxx, process specification SDPTC09-QA-15, SDPTC09-QA-02, product specification SD-FGRD-07-0001 which has been agreed with customer, etc.

The specifications were review and approved together between company and supplier or customers and updated every 3 years or change on specification.

3.7 Corrective and preventive actions

Corrective and preventive action procedure is in place in QP-MR-03 was established and detail covering the process steps and handling for customer complaints, quality and food safety management system, internal audits, and external audit.

The corrective and preventive action are effective implemented as root cause analysis, correction, corrective action and follow up effectiveness by competence operator and review by FSTL. Internal audit CAR and customer complaint CAR were closed status and effective follow up action to prevent recurrence. Verification of the effectiveness of the corrective actions is monitored via on-going QM and process check. They are formally verified by the QMR to ensure satisfactory completion.

Sampling CAR no. 009/23 – no training record for de bag root cause and corrective action and follow up, closed 26/6/2023.

024/23 – no flow for product rework root cause and corrective action, closed 25/9/2023.

040/23 – cobweb on ceiling of the mix gas root cause and corrective action, closed 8/12/2023.

3.8 Control of non-conforming product

Non-conforming product procedure QPPTC-QA-05 was established and implemented which defined non-conforming product management by accept (release as normal), exceptional release hold, reject, re-process, down grade which approved by QA.

Clearly identify and reported of potential non-conformity and segregated area in storage area. The non-conforming products (raw materials and packaging, work in process and finish products) will be segregated and identified by HOLD tag and placed into the designated area or return to suppliers if possible. QA manager is response to assign as the authorised person to release, rework or dispose of non-conforming material.

By onsite audit found designated area for quarantine non-conforming product. Sampling NC no. HB001/23 product ZCTL and HB002/23 product Z18ACUELF1 which found release/ disposition record FMPTC-QA-45 by QA manager.

Reprocessing procedure as WIPTC-PT-36 and indicated in food safety plan SDPTC07-QA-04 date 2/5/2023, review reprocess report BKPTC-PT-06 of HB002/23 product Z18ACUELF1 lot 7/7/2023 total 6,429 cups, reprocessing date 14-15/7/2023 total 6429 cups product Z18ACUELF1 lot 14-15/7/2023, total 81,922 cups and 49,665 cups. seen test report for release product after reprocessing.

3.9 Traceability

Traceability procedure is in place which allows the organization to trace all raw material product lots including primary packaging from their suppliers through all stages of their process until one step out of their responsibility and vice versa. All supplier raw materials, ingredients and packaging will be traced via their batch code details. Finished products will be given a lot of nos. of product identifies in product and carton.

The traceability exercises are carried out for backward and forward testing once a year within 4 hours period time and 100% mass balance which has been achieved.
-Backward traceability tested combine with mock recall. The backward procedure was reviewed the effectiveness after test in meeting. Regularly test once a year and found effective test. Last backward test on 9 March 2023 for product pineapple choice tidbit in pineapple in plastic cup 4 oz ZTCJ order no. 2210039 total 63,056 cups, best by May 29, 2024, that effectiveness recall 100% and trace back within 1.50 hours.

-Forward traceability tested on 17 Mar 2023 for plastic cup size 4 oz. lot CPP348-07-230-TR received on 11 Feb 2023 from EKA Global quantity 806,400 Pcs, used on 20 Feb 2023 to 1 Mar 2023 , that mass balance 100% and trace back within 2.0 hours.

Auditor random and trace back product code ZFSDJ1 (Tropical fruit salad in pineapple juice 4.5 oz) MFG 30/8/2023 load on 14/9/2023 , 296 CTN, Container no. HLXU3504835 , Seal no. HLC 1410696 ,export to USA , which the process control such as labelling on 12/9/23 ,Thermal process set 93.5 C , time actual 20.15 min 9 spec > 17 min (CCP record) , Packing on 30/8/23 check sealing property (Peeling , bursting , Residue Oxygen < 2%) , Code date check, weighting test (Fill weight : 62-66g) Max = 75 g , , net weight = 127-137 g. used raw material such as corrugated box lot on 26/8/23, sticker lot receiving on 28/8/23, lid lot 23/6/22, spoon lot 22/6/22, Film lot 23/9/21, Cup lot XR 20218-4100 received on 1/3/2023 , Pineapple lot 30/8/23, which can trace back within 4 hours, mass balance 100 %.

Manage and trace back was effective by seen the evidence of loading WH record, production monitoring record, receiving record, preparation record, sterilization record, passing metal detector record, packing record, laboratory testing report and test conducted backward including quantity check of raw material and packaging and then found to be effective within 4 hours. And show that if any rework or any reworking operation can be traceable by seen the production form for the detail of rework.

3.10 Complaint-handling

There is a procedure QP-QA-11 in place for customer's complaint handling. The complaint procedure includes internal communication and investigation, and timely response. Records show compliance to the

procedure. In year 2022, company has 2 complaint which about quality i.e., found mould external cup and damage carton. In year 2023, there was trend analysis and reduce the customer complaint only 1 customer complaint. Customer complaint in 2023 related leakage cup and damage carton, complaint 002/23, root cause incomplete seal cup., damage box from gluing too short. Corrective action by adjust the seal inspection by visual 1 hour by QA, added 2 hours check by operator; change the pattern of glue flap on long side of outside carton instead of inside. Increase the length of glue flap on log side.

Customer complaint was analysed in order to assess customer complaint trend. All customer complaint was closed that report to top management and food safety team through monthly meeting and management review both complaint status and trend.

3.11 Management of incidents, product withdrawal and product recall

The incident management was maintained as procedure QP-QA-10 date 8/3/2023 and QP-OH-06 date 20/9/2022 included the effective to manage incidents and potential emergency situation that impact to food safety, legality or quality was provided for all potential risk to organization and business included bioterrorism, electric breakdown, lack of steam, flood, fire, transport breakdown, cyber security, product contamination indicating a product may be unsafe or illegal, Covid-19 situation (QP-OH-08), contaminate of water and product, lack of staff, lack of raw material, etc.

The procedure was existing to manage to the raw material, work in-process, finish product which may impact to food safety, legality, and quality. Evidence showed that the procedures are maintained. If the incident was occurring, the food safety team will call the meeting to manage to these products.

There was no incident in 2022 to present. List of key contact person as notice documented that covered all key contact (SD09-BI-01 updated on 13 Mar 2023) such as Certification body, customer, consignee and emergency service company, government (local market), etc. that telephone number, e-mail address and business recovery by managing director making decision. There was found mock test of incident response on 8 December 2023 for fire extinguish, chemical leakage and boiler explosion and 21 December 2022 for flood report were maintain.

Recall and withdrawal procedure GP-QA-03 Rev.24 implemented and maintained. The procedures exist for the return, receipt, storage, and control of products. Evidence showed that the procedures are maintained. Once the incident was found, the food safety team will call team meeting to trace back to the relevant information. If there is any serious issue impact to public health and products recall needed. Managing director is an authorized person to approve the recall.

The company team will contact marketing to inform the customer for recall the concern products to recall or destroy at the destination, when the returned goods arrived at the factory, QA will be checking these products again. The unsafe return goods will be disposed under provision of the FST. Key contact list (SDPTC09-QA-01 date 14/2/2023)

There was no product recall occur in 2022 to present. The recall procedure was reviewed the effectiveness after test in meeting. Regularly test once a year and found effective test. Last mock recall on 9 March 2023 for product pineapple choice tidbit in pineapple in plastic cup 4 oz ZTCJ order no. 2210039 total 63,056 cups, best by May 29, 2024, that effectiveness recalls 100% and trace back within 1.50 hours.

The certification body “BSI group (Thailand)’’ was defined in procedure to contact 3 working days after decision for recall or notify by government and feedback for corrective action to CB within 21 working days.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.4	There was no outsourced process.

4. Site standards

4.1 External standards

Size, location, construction, and design to facilitate maintenance, prevent contamination. The site stayed inside with the Master factory as Thai coconut public company limited and use some facility together such as Laboratory, Water treatment plant, Boiler plant, Waste storage area, Canteen and separated building for Plant based food production. There was not any potential contamination risk for the local activities and environment around the factory. The external area and overall grounds within site were managed and maintained even during preventive maintenance period. Condition of site was verified in internal audit process. Drainages were installed, adequate drainage was observed.

External traffic routes are on maintenance and construction, there were plastic cover used for prevention of dust and any contamination. The building fabric was maintained to minimize potential for product contamination. Site boundaries were clearly defined and in good condition to prevent pest ingress. No potential contamination observed during assessment.

HR staff was good trained to control visitor, subcontractor, employees who access to the area by HR approval. Visitors and contractors were required to contact to responsible person before entrance to the site, the responsible person will be pick up them at the entrance and sign in at time of arrival. The external storage tank e.g. potable water tank was closed and locks. There was installed CCTV inspection in restrict area and inspected on daily. Security inspection every 2 hours by security guard.

4.2 Site security and food defence

Food defence procedure is in place (QP-ADCT-002 rev 00), the risk assessment was done by food defence team last reviewed on 11/03/2023 by managing director. The internal and external threat was assessed and define the control measure to control such as outside security measure (physical security, shipping / receiving security, main handling security), internal security measures (general inside security, processing area security, storage security, ingredients water security, chemical/hazardous material control, information security, non-employee security, employee security).

PCQI / food defence Qualified individual were notifying by managing director on 16 May 2023, training date 17/12/2023, 7/7/2020 FSPCA certificate of training and Food defence awareness training 8/12/2561.

Food security/risk assessment as SD09-BI-09 and SD09-BI-06, last updated 11/3/2023 was done by safety team and security guard that covered all potential risk area as documented self-inspection checklist of food defence planning e.g., production area, raw material receiving area, finish product loading, staff control, and visitor control and check staff history. Reviewed plan on monthly, last review on 23/10/2023 by TACCP team found effective control and implement. Monitoring of food defence plan on monthly, last updated 19/7/2023, 18/2/2023, 27/1/2023, 18/10/2023.

CCTV monitoring by security on daily and record in FM-WH-52, FM-HR-26. Security inspection every 2 hours by security guard record in FM-HR-105. All staff has been trained in site security procedure and food defence as plan. The external storage tank e.g. potable water tank was closed and locks. Access

control procedure as QP-BI-05; area security was controlled by HR staff, which was trained for area access, visitors have to stay with authorized person all the time including fill the questionnaire.
Review training record of security guard, training date 28/8/2023 food defence, 12/09/2023 CT-PAT, emergency training date 8/12/2023. Annually refresh training food defence and security plan for all staffs (see detail in req. 7.1)

4.3 Layout, product flow and segregation

The site has factory lay out, process and product flow suitable segregate to prevent the contamination of product. The site lay out was define access points for staff, raw material, ingredients included packaging, location of toilets and changing facilities. During onsite seen good maintain. The movement of personnel, raw materials, ingredients, packaging, rework, waste from production was clearly to define in flow and layout.

This site can separate zone to low-risk area as opened product area such as preparing area, mixing area, filling area and enclosed product area as passing metal detector area, sterilization area, storage area, cold room and loading area. Layout of premise and process flow diagram has been defined risk zone clearly. The manufacturing site was no part of high-risk area, high care area and ambient high-care area. The premises and plant were well designed, constructed and maintained. The work area had sufficient working space and appropriate to control hygienic condition of all areas by cleaning schedule. Found all work area was cleaned and effectively control of hazards. There were no temporary structures constructed or evidence of cross contamination during onsite audit.

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

The site fabrication, building and facilities was suitable and good maintained. The concrete walls for production area, and ISO wall for cold room and PU floor were maintained with good condition to prevent contamination from environment. Ingredients and packaging were kept in bags, debag store in closed container. During onsite found all area suitable to produced safe product. The roof and ceiling were cleaned and maintained in good, repaired condition; insect-o-cutter has been installed at the entrance. The manufacturing site was provided suitable and sufficient light. All lights were protected against breakage with the plastic coverage. Mechanical air extraction is provided in processing areas; there was no evidence of pooling water and condensate seen during the site inspection. There was no elevated walkway. Doors and windows are fitted and maintained in good condition. However during on site found improperly wall condition.(Seen as NC)

Air intake is no filter required. Production risk zone was clearly indicated for enclosed and low risk area. This site was no include high-risk area, high care, and ambient high-care area.

There was no elevated walkway, access step or mezzanine floors. Plastic strip has been installed at each entrance which suitable for intend use.

A Minor Non-conformance has been raised against 4.4.1
During on site at media preparing room found peeling paint at the wall near water boiling tank.

4.5 Utilities – water, ice, air and other gases

The control of water has been defined, implemented, and maintained to control and monitor soft water and potable water which has been supplied from Kuiburi Fruit Canning Co., Ltd. Steam has been used indirectly contact with product which has been supplied from Kuiburi Fruit Canning Co., Ltd. There was no use of ice. Nitrogen gas and carbon dioxide gas have been used at filling process to remove the excess air in packaging. The system of water has been defined and updated for each point of use, which is used as sampling basis.

Sufficient quantity and potable quality are at the point of use and there is no risk of contamination. The potable water and soft water were testing annually as ssampling plan SD09-QA14 date 24/11/2023, by external laboratory included physical, chemical, and microbiological such as pH, hardness, total solid, As, Pb, Phenol, nitrate, Cd, Cu, Odour, Colour, *E. coli*, Coliform against Thai FDA standard for water that last tested by SGS (ISO 17025 accreditation). Review test report of underground water , test 24/3/2023 Test report 5526931 comply with EU council directive 98/83/EC of November 1998; soft water test date 16/3/2023 report 5519098 comply with MoPH 61, 135.
Condensate steam test date 16/3/2023 report no. 5519101 complies with MoPH 61 and 135.

For routine inspection of soft water, potable water and cooling water, criteria and sampling plan as SD09-QA-33 date 12/5/2023; there was found testing of appearance and chemical parameter every 3 hours, microbiological parameter (TPC, Coliform) every week by Kuiburi Fruit Canning Co., Ltd. Review test report e.g. 25 September, 9, 16, 23 October, 7, 14, 21, 28 November 2023, 5 December 2023.
Nitrogen gas and carbon dioxide gas has CoA for purity > 99.5% every lot which received from United Industrial Gas Co., Ltd.

Air compressor no 2, change air filter 2000 hours, oil filter/oil (Lubricant P/N SR46), last 9/9/2023, daily check, cleaning filter on weekly. Mainline filters install with filter (filter 3-micron, 0.3-micron, 0.1 micron) before use, cleaning on 29/8/2023.

4.6 Equipment

All food-processing equipment is suitable for intended use. The preventive maintenance procedure set in QPPTC-PT-03 , All equipment, which uses direct contact to food, was made by appropriate material such as stainless steel and kept cleaned in suitable condition. Preventive maintenance included critical production equipment, the frequency and accountability for maintenance exists such as sealing machine, conveyor, metal detector, cooker, blending tank , etc. To sampling the preventive maintenance , repaired machine record on 6/3/2023 for N2 gas filter , found record for control tooling bring into and out form production line record in FMPTC-PT-16 and hygiene , line clearance check record in FMPTC-PT-15 record were maintain.

For any new equipment, there was found procedure for purchasing equipment and assess hazard by food safety team before approval. At the commissioning process was not define in procedure (Seen as NC) , there was found procedure including hygiene clearance record, inspected by food safety team before accepted into production line and defined relevant program i.e., maintenance, cleaning, training of used. However, since the previous audit, there was not found purchase new equipment, only site made machine (unloading machine) has been tested and still in commissioning process. However there was no commission report during audit.(Seen as NC)

The procedure of movement static equipment set in procedure, there was no movement of static equipment since the previous audit.

Some unused equipment has been stored in the production area, however, there was in good condition and clean which will clean before used.

There was no use of mobile equipment and battery-charging equipment in the open product area.

To sampling the material to contract for food safety such as plastic piping (Toyosilicone hose) , review certification refer No.AA14-13-00879 on May 27, 2014 , and No.AA12-13-01682 , the material comply 21.CFR.177.2600 and notification No.595 (Issued in 2012) to the Food sanitation Law of ministry of health, Labor and Welfare.

A Minor Non-conformance has been raised against 4.6.3

There was found improperly for newly machine control as below ;
-There was no procedure for commission newly machine
-During on site found newly machine (made machine) for unloading machine, installed in year 2023, However there was no commission report.

4.7 Maintenance

The maintenance control procedure (QPPC-PT03 rev, 5 24 March 2021), machine list (SDPTC09-PT-02), preventive maintenance plan (FMPTC-PT-09) were implemented and maintained to ensure the effective to control machine and equipment condition and prevent risk to cross contamination to product, process. The preventive maintenance program was established, implemented and maintained for each machine and equipment which cover to all concern machine and equipment within factory which define frequency and item to PM by monthly, quarterly and annually.

The details of machines and time frame for preventive maintenance are clearly defined by area i.e. boiling basin on 30/11/23, conveyor on 30/11/23, metal detector on 18/9/23, cooker on , mixing tank on 30/11/23, filling machine ,(Shinwa 2 , sealing cup) on 30/11/23, cold room, cooling tower, air compressor, inkjet machine on 18/12/23 , Metal detector, on 18/9/23 , gas mixer on 12/12/23 etc. The inspection record was available in FMPTC-PT-28. The production line will be stop during maintenance process.

All the repaired machines will be cleaned and approved by the production, QA and engineer before start running in FMPTC-PT-15 and FMPTC-PT-16. This manufacture was using food grade lubricant oil and grease to maintenance machine “AUSBOND AA-20 food grade lube oil NSF. No.138812 , and AA-2 Food grade grease NSF No. 138810” comply with FDA approved grease and oil and allergen free status certificate. A review of maintenance records indicated that the procedure is implemented. The maintenance workshop kept clean and located outside the production area. Onsite audit observed, there was no temporary repair of machine.

A Minor Non-conformance has been raised against 4.7.2:
During on site found some part of filler machine was crack but no evidence for check and correction.

4.8 Staff facilities

The staff facilities were sufficient to number of employees, designed to minimise the risk of product contamination and maintained in good and clean condition such as toilets, hand washing station, personal locker both for personal belonging and food, and the personal locker was located at canteen.

The changing facilities was provided for all staff and visitors e.g., hair cover, clothes, mask, gloves and footwear. Hand washing facilities (foot tap) including liquid soap, hand dryer, alcohol spraying and washing instruction with the picture and translate to appropriate language at all access point and at the entrance of production lines. Toilets were located separated from production line and provided sufficient facilities as washing basin with soap, hand dryer and washing instruction are provided and hygiene by housekeeper.

Designated smoking area was observed out-of-production area at the designated area in front of factory. Canteen located out of production area and warehouse. All food has been stored in designated area in canteen. Eating and drinking were not permitted inside production, store and warehouse area. Only drinking water at specific area has been allowed. There was no vending machine.

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

4.9.1 Chemical control

The chemical control procedure is in place to control the non-food chemicals used in the facility to prevent chemical contamination. The procedure was included identification label of chemical container, approval of chemical list for purchasing such as NaOH, Super Fresh, chlorine, ethanol 75%, etc. and availability of MSDS, chemicals storage control with restricted access and to be used by trained personnel only. On-site verification and interview with the assigned person indicated that, the procedure is strictly followed. The employees were trained to control the use of chemical. Good identification for chemical in store area, production area including cleaning chemical.

Procedure for chemical spillage has been established. Empty chemical container included obsolete chemical has been controlled properly by stored at specific area waiting to return back to supplier or sold to service provider.

4.9.2 Metal control

There is documented policy to control foreign matters and prevent cross contamination in WIPTC-PT-42 rev. 1 18 March 2023. The inspection records are maintained. Non-production blades, equipment and tools shall not be left in a position that allows a risk of product contamination. The snap off blade was not allowed to use.

Metal was controlled and found record of inspection equipment before bringing in production line such as knife, scissors checked in condition and quantity and inspected before and after work and recorded in FMPTC-PT-96 and FMPTC-PT97.

There was not found used of staples on ingredients and packaging. Staples, paper clips and drawing pins were not allowed to be used in production area.

4.9.3 Glass, brittle plastic, ceramics and similar materials

The documented glass control, glass breakage protocols (GP-QA-02 rev.16 19 September 2022) were also included in the program and instructions for line stop, quarantine the defected products and product area, cleaning, and re-inspection of equipment prior to start-up. Areas were required to be cleaned, product controlled, and area cleared by the production staff. Employee protective clothing was changed after breakage and shoes inspected.

Glass and hard plastic layout and list (SDPTC09-QA-04) was developed listing location of item and condition of item during inspection. The layout of glass matter detailing location, number, type and condition in the production lines is in place. The inspection records are maintained, 100% checked all the glass and brittle plastic such as light bulb, window, clock, emergency light, CCTV, etc. and recorded in FMPTC-PT-31 daily and FMPTC-QA-26.x twice a month.

There was no breakage that occurred during onsite audit and document review. The system in place to handle in case of breakage will be report and record. Interview staffs were good understanding to manage when glass breakage occur.

4.9.4 Products packed into glass or other brittle containers

There was no product packed into glass or other brittle containers.

4.9.5 Wood

Wood not used in open product areas, use for pallet wood in warehouse of raw material, ingredient and product. All pallet has been inspected before used and recorded in FM-ST-21, review date 1/12/2023-13/12/2023, 1-31/11/2023.

4.9.6 Other physical contaminants
Debag and de-box procedure is in place (WIPTC-PT-46) and trained to operator to protect the contamination. Portable equipment was indicated the designed that pens were register and inspect by production staff and record in FMPTC-PT-96 and FMPTC-PT-97 daily check. All pens can be detectable by foreign-body detection equipment. Based on risk assessment, other foreign body has been controlled and reduced as defined in hazard analysis.
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment
There is system in place which design and maintain to reduce product contaminated by foreign body detection and removal equipment. Base on risk assessment the site was used metal detector installed after sealing process, then monitoring by PD before started and after finish production line and every 2 hours. Filter has been used for filtering media after mixing sugar and before filling media which has been inspected condition before and after production. Magnet has been installed before filtering process of media which has been inspected daily. X-ray equipment and optical sorter were not applied in the factory.
4.10.2 Filters and sieves
Filter has been used for filtering hot water for soaking pineapple process, filtering media after mixing sugar and before filling media which has been inspected condition before and after production.
4.10.3 Metal detectors and X-ray equipment
There was installed metal detector after sealing of product, the metal detector type is light alarm and rejection system; the metal detecting was indicated as CCP and test the effectiveness prior end of use and every 2 hours. The critical limits are monitored as various sizes of test pieces; Fe < 1.5 mm., non-Fe < 2.5 mm. SUS < 3.0 mm. The working instruction for provided metal detection and standard for setting program (sensitivity / phase) was indicated and defined method for testing at least sensitive point of metal detector. Failsafe system has been tested before work by close air pressure and open the reject box. Last verify the effectiveness of metal detector provided by external service provider on 1 September 2022. By onsite audit, test and interview the metal detector operator that shown effective control of metal detector, found metal detector monitoring on record FMPTC-PT-14 complied with HACCP plan. There is no use x-ray detector.
4.10.4 Magnets
Magnetic bar has been used which fixed on filling machine before filtering process, to control metal contamination products, which found list of magnets that covered the type, location and the strength of magnets. Documented procedures of magnet inspection are in place. Verified of magnetic bar has been done every day and tested by gauss meter every 6 months which > 8000 gauss.
4.10.5 Optical sorting equipment
Based on the risk assessment, there was no applicable for optical sorting equipment.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers
Product packed in rigid PP plastic cup, based on risk assessment, there was no need for cleaning before filling. However, there was found verified of cleanliness of PP cup every week through swab test and inspected before filling process.
4.10.7 Other foreign-body detection and removal equipment
There was no other foreign-body detection and removal and equipment.
4.11 Housekeeping and hygiene
The housekeeping and cleaning system are in place to ensure appropriate to maintain the hygiene standard to minimise the risk of product contamination. The documented cleaning procedure is implemented and maintained cover for all building and equipment. The documented master sanitation program is in place and implemented for all areas in the plant including all equipment and areas such as production area (receiving raw material area, preparing raw material area, mixing area, filling area, sealing area, sterilization area), store of ingredients, store of finish product, cold room, etc. The master sanitation program SDPTC09-PT-01 includes the responsible person, area, or equipment to be clean, frequency, method, chemical, material to be used. The responsible person such as QA and production chief will be inspected and verified after start production run, the inspection record was available for all concern equipment such as table, conveyor, mixing tank, filling machine, metal detector, sealing machine, cooker, etc. On-site inspection and a review of some records indicated that the cleaning program was followed, and the level of housekeeping was appropriate for the facility which recorded in FMPTC-QA-27 for before production and FMPTC-PT-01 for cleaning record. Sampling record on Sep - Nov 23. The verification of the cleanliness was done by swab test and air test as plan against to microbiological criteria. The swab test report and inspection record shown complied with specification and has been conducted trend analysis. All cleaning equipment has been stored in good condition and has been cleaned properly. However during on site found improperly cleaning equipment control. (Seen as NC) **A Minor Non-conformance has been raised against 4.11.6** **During on site found improperly for cleaning equipment by found damage dishwashing sponge at cleaning equipment storage area.**
4.11.7 Cleaning in place (CIP)
CIP was implemented for cleaning in pipe system. Frequency of CIP has been defined as daily for mixing vat and filling media machine and define in cleaning program work instruction (WIPTC-PT-24 rev.8 28 May 2018), chemicals used as NaOH in daily CIP. All parameter of schedule control such as temperature, time for contact, chemical concentration was controlled. Checking of pH on rinse water on last step has been tested for ensure not found the residue of chemical. Schematic of CIP has been defined in WIPTC-PT-24. Validation of CIP has been tested before approved CIP method and retested annually which tested on 24 February 2023 for 80 °C and concentrate 1.0% and 3 March 2023 for 80 °C and concentrate 1.5% and tested for TPC, Coliform, yeast and mould report were maintain by internal lab record in FM-QA-53. Sampling CIP record on Oct -Dec 2023 in FMPTC-PT-43 report were maintain, found check
4.11.8 Environmental monitoring

The environmental monitoring program was established based on risk assessment SDPTC09-QA-22 to SDPTC09-QA-25 17 March 2023 as define on swab test and air test plan; the risk assessment was defined 4 zones of risk. Zone 1 and open product area has been tested weekly such as filling head, conveyor, filling machine, filling table, basin, sorting table, stainless box, weight balance, melting tank, juice pipe including plastic cup, film, clothing, gloves, and hands and zone 1 with enclosed product area has been tested monthly for cooker. Swab test conducted for TPC, yeast and mould, Coliform , E.Coli comply with standard SD09-QA-33, latest on 11/11/23 , 8/12/23 , and 1/12/23. Air test has been conducted for open product area, enclosed product area and non-production refer (plan SD09-QA-90) area such as filling room, preparing syrup room, changing protective clothes and blowing room for TPC and yeast and mould which comply with SD09-QA-33, latest on17/11/23, 24/11/23, 1/12/23, and 8/12/23 , Pass all area.

Environmental monitoring program has been reviewed annually and when have any changed which may affect to cleanliness.

4.12 Waste and waste disposal

Waste disposal was managed in accordance with legal requirements and to prevent accumulation, not risk of contamination and the attraction of pests.

The waste and waste disposal procedure are implemented in QP-HR-06 and maintained to control waste which removed from the production process to the central waste collector area. Process waste has been destroyed at wastewater treatment area. General waste and hazardous waste have been stored in the cage. The waste from the production process will be eliminated to the waste storage area and separate for each type of waste such as packaging to prevent and reduce risk of the cross contamination. The responsible staff shall be destroying the packaging before transfer by supplier of service. The trademark logo for packaging set disposal instruction in WIPTC-WH-05.

The hazardous waste has been destroyed by Better World Green Co., Ltd. and packaging waste has been provided by Chalermpong which found contract agreement.

Plastic cups recycle waste by Sor Kit Charoen PVC registration no. 10743103625652 valid 10 August 2024. Registration valid until 31/12/2023.

4.13 Management of surplus food and products for animal feed

There was the indicated procedure the control the handling and storage of surplus food and by-product. There was no by-product for animal grade. A review of customer's contract and relevant records indicated that, the procedure is strictly followed.

Surplus customer-branded products waste disposed of in accordance with customer-specific requirements. Customer brand names were removed from packaging and were damage before removed.

4.14 Pest management

The pest control procedure is in place in QP-QMS-01, the preventive pest control program is implemented and maintained to minimize the risk of infestation and product target. The pest control sub-contractor is Advanced Group Asia Co., Ltd., contract agreement number CT23-0000614 during 1 January 2023 – 31 December 2023 which included service for termite, cockroach, ants, rodent, insect a current license according to Thai FDA is available such as Fipronil, Cypermethrin, Deltamethrin, Stun Pro. The pest

control schedule was defined service monthly for spraying and fumigation chemical in external area. To sampling training for staff of pest control service training for pest management on 4 January 2023.

On-site verified indicated that the current schematic accurately reflected to placement of pest control devices. The poison baits only used outside the buildings and glue trap used in storage area of packaging and raw material with identification tag on the baits (60 stations) and glue containers (120 stations), lizard trap 30 stations.

The location of pest control devices is defined in the pest control layout. For flying insects, the company installed EFK (5 stations) which has been inspected the quantity of any insect by service provider monthly. To review the catch analysis for insect latest July – September 2023.

Review of the record provided by sub-contractor, indicated that the certified chemicals are used, concentration and amount of the chemicals used are recorded. Last service on 11/11/2023, 9/12/2023, seen the result of pest control inspection was assessed and analysed for trend analysis by quarterly basis.

The documented pest control survey was undertaken by pest control expert. By interviewed the staffs was found understanding and aware the signs of pests and action to be taken. In-depth survey provided on quarterly by expert pest control (Biologist), FDA registration no. 2048/2562 valid 13/6/2024, last date 11 November 2023; actions taken were identified, evaluated, and recorded when found evidence of infestation. Training of pest control inspector (training date 19, 29/09/2023 by supplier of service). Inspection record in FM-QMS-09 on daily.

4.15 Storage facilities

The documented procedure is implemented and maintained the product safety and quality during storage raw material, ingredients, packaging, and finish product were developed which clearly included kept packaging and chemical in segregate area, raw material and finish product in dry storage which clearly identified and segregated to prevent cross contamination.

On-site verification the raw material, finish product, packaging at store and chemical in control room, it was appropriated maintained in clearly segregated to protected contamination between raw material, work in process, finish product and effective inventory control.

The storage conditions are raw material at ambient condition, finish product at ambient condition and cold room at chilled condition. The cold rooms were controlled by the temperature below 5 degrees Celsius and monitored and recorded every 4 hours. The identification tag was attached to indicate for each item which includes name, receiving date, lot no., quantity, and inspection status, etc.

Incoming materials were inspected by warehouse and QC staff in quantity and quality of materials as the requisition specific and raw material specification. Verified material storage onsite and receiving-storing-dispatching records of raw materials, ingredients, and packaging, e.g., citric acid, plastic cup, sugar, aloe vera in syrup in plastic cup, etc. found compliance with procedure and FIFO/FEFO practice. However during found some raw material was improperly for storage control. (Seen as NC)

Review stock e.g.
Refine sugar: receiving 29/8/2023 lot 10/01/2023, 11/01/2023, 12/01/2023. 4/10/2023, 6/10/2023.
Citric acid: receiving 25/7/2023 lot 131111, MFG 11/05/23. Receiving 25/10/2023 lot 15/09/2023.
Ascorbic acid: receiving 11/11/2023 MFG 16/06/2023 EXP 15/05/2025.
Tropical flavour: receiving 17/8/2023 EXP 17 Dec 2023.
Grape flavour: receiving 17/8/2023 MFG 19/5/2023 EXP 17/5/2024.
Plastic cup 4.0 oz receiving 27/10/2023 MFG 05,06,07/09/2023.
Film receiving 2/6/2023 lot 179002, 009, 001, 008 0523, 1450050523.

There was no external storage.
There was no require to atmosphere storage.

A Minor Non-conformance has been raised against 4.15.2
By onsite audit the temporary storage area of plastic cups before sending them to the production area. Found an area with dust and dirt accumulated on the floor.

A Minor Non-conformance has been raised against 4.15.6
By review the inventory control of N2 gas, there was no FIFO use during onsite audit; seen use of lot 23/11/2023 before lot 13/9/2023.

4.16 Dispatch and transport

The dispatch and transport documented procedure is implemented and maintained to ensure that the management to prevent risk to the product safety, security and quality of dispatch, vehicle and containers used for transport product from the site. The loading inspection record was maintained to confirm of product at storage, loading, transport was maintained in good condition.

Dispatch-receipt as packing list and which identified batch no. of product, production date, customer name and delivery date clearly. And found product dispatch within shelf life and then effective.

The contract and services agreement are clearly defined the specific requirement include good hygiene practice, cleanliness's of carriers, containers integrity and delivery performance as contract. The delivery service provider evaluation results are in place and found record of monitoring shown effectiveness of controlling.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.4.6	There were no elevated walkways, access steps and mezzanine floors.
4.6.6	There was no mobile equipment used in open product area.
4.6.7	There was no battery-charging equipment used in open product area.
4.9.4	There was no product packed in glass or brittle containers.
4.10.3.5	There was no used of X-ray machine.
4.10.5	There is no optical sorting equipment applied for physical contamination control
4.15.4	There was no require to atmosphere storage.
4.15.5	There was no external storage.

5. Product control

5.1 Product design/development

Product development has been established, implemented and maintained in procedure (QP-RD-01 rev.5 1 September 2021). Consideration of quality, product safety and legality issues were demonstrated throughout all product development stages such as risk assessment of raw material, chemical (contaminant, allergen), process, etc. Hazard analysis study was considered during the product development including the legislation consideration. Information changed from product development including formation a process will be revised and distributed new document version to all concerned department. New product development procedure was established covering approval step from HACCP team leader or HACCP committee team member prior to production trial.

To sampling the new product development for product code : ZFSDJ1 (Mix pineapple and papaya) , Tropical fruit salad in pineapple juice , size 4.5 oz , start project on 15/11/22 , There set trail production on 13/2/23 , and found the process validate by internal process authorities by study Heat Penetration test on 13/2/23 , Cooker temperature 93.0 C , process time 17 min , Found micron test by SGS latest on 13/2/23 , The product specification was set and send to customer , found customer approved informal by email on 8/12/22 , found first production on 2/3/23 found quality check pass under specification.

Validations of shelf life were conducted as shelf-life protocol, covering formulation, process including there was any change in term of quality, safety and legality of product. Shelf life has been planned and tested covering shelf-life period covering storage condition. Testing parameters were covered chemical, microbiological, and sensory evaluation. Shelf-life testing records for all products group were maintained.

RD department responsible for regulation update and verify labelling against destination country regulation. Sampling shelf life study record of new product development for product code : ZFSDJ1 which covered sensory, brix, pH, acidity, vitamin C, drain weight and micro as TPC, yeast and mould, Coliform, aciduric spoilage and flat sour bacteria., recommended shelf life 15 month 4.5-18C , study at ambient , 5 c and 18 C report were maintain.

Since previous audit, there was no new product.

5.2 Product labelling

The product labelling was controlled, the label to meet customer requirement and legal requirement of use and include information to allow the safe handling, display, storage, preparation, allergen caution and use of the product by customer.

To sampling the labelling as;
-tropical fruit salad in pineapple juice (ZFSDJ1) , were reviewed and verify the composition and nutrition fact is correct based on product recipe and ingredient specification , Nutrition test on 26 Dec 2022 , testing report no. 5448068, found labelling claim as the non GMO ,and BPA free packing , found the testing GMO testing on 7/6/2023

-Pineapple Tidbit in extra light syrup (ZSTEL), were reviewed and verify the composition and nutrition fact is correct based on product recipe and ingredient specification, review Nutrition test report no. 3760906 on 18/12/2017, found labelling claim as the Gluten free , Lactose free, found the testing report gluten free report no. 5224181 on 25/3/2022 and lactose testing report no. 5226309 on 1/4/2022.

There is system in place to ensure that the label information from customer or nominated third party provided the accuracy label information and to be check the label information whenever change occurs which may affect the label information by product development manager to ensure that all labels comply with regulation and customer requirement.

Procedure for approved artwork has been defined in QP-QA-14 rev. 4 December 2022. This manufacturing site has only OEM brand. Seen sampling label was comply with legal and customer request. The label was control in warehouse where labelling activities was done prior to ship out the finished product.

5.3 Management of allergens

Allergen control procedure (GP-QA-06 rev. 14 , 5 July 2022) was established and maintained to minimize the risk of allergen contamination of product such as control the incoming material for process to be not cross other product i.e., identified by allergen tag, separate store and keep in the closed container, the equipment which use for allergenic materials were identified for used.

All raw material and ingredients were assessed risk assessment for allergen contamination form supplier by issue the questionnaire. Documented risk analysis was set in all HACCP plan.

The raw material assessments were presence and likelihood of contamination by allergen and include review of raw material specification.

Allergen control policy and updated allergen lists will be communicated to related function if any. The allergen control which separated to each physical characteristic of allergen as liquid and powder.

The allergen list (SD09-QA-62) was review and update covered coconut which refer to client as USA, Japan, etc. Staffs were trained and good understand to handling the allergen. There was found some claim for food sensitivity i.e., gluten free and lactose free, which found verification testing product pineapple in syrup, test report on 1/4/2022 report no. 5224181 for gluten allergen (ND) and 4 April 2022 test report no. 5226309 for lactose (ND) , report were maintain.

The site controls allergen cross contamination by production planning, segregated operation area, dedicated utensils, and cleaning programme when product change. Documented allergen verification procedure is in place, by test allergen after cleaning the processing which contain allergen every changing product from allergen to non-allergen and validate the cleaning programs at start up the program or any change or new machine as define on risk assessment.

5.4 Product authenticity, claims and chain of custody

The documented procedure QP-QA-01 was maintained to assessment of adulteration or substitution of raw material which use in the facility. VACCP team last updated on 1/7/2021. Documented vulnerability assessment SD09-QA-09 as was provided to cover all raw material, ingredients, and packaging to assessment the potential risk of adulterer or substitution that covered for historical evidence of substitution or adulteration, economic factor, ease of access to raw materials through the supply chain, sophistication of routine testing and nature of the raw material. The reassessment was provided on at least annually that last on 8/3/2023. There was found only low and medium risk which has been controlled as procedure. Medium risk raw material such as citric acid (certified BRCGS), ascorbic acid (certified FSSC 22000).

Food safety team leader was monthly review fraud news in website e.g. www.foodfraud.org, etc. last review on 23/11/2023.
For the mitigation plan set medium level by supplier audit or questionnaire and GSFI certification, high risk level set supplier audit and GSFI certification. Review risk assessment on 8/3/2023 e.g.
Sugar, citric acid = Medium (BRCGS, FSSC certify)
Ascorbic acid, flavour = Medium (FSSC certify)
Plastic cup, film = Low
Gas N2, CO2 (process aid) = low
Pineapple, passion fruit juice = low
White grape Concentrate juice = Medium – review International Beer Breweries (Israel) – Thai American Food Co., Ltd FSSC certify, valid 4/11/2026.
Lemond juice concentrate juice = Medium - review SVZ Tomaszow Sp. Z.o.o (Poland) (DKSH) BRCGS certify exp. 27/11/2024.

There was no claim of product and about method of production.

5.5 Product packaging

Product packaging e.g., plastic cup, plastic film is kept was kept in ambient room temperature that separated area from raw material and non-food chemical and in a good condition controlled by the hygiene program such as pest control, etc.

Specifications for packaging are established by quality control department and made agreement with suppliers. Results of verification as;

-Packaging cup -Eka-global (Suzhou) packaging, test report on 18/5/23,(PP/tie/EVOH/Tie/PP) for over all migration , Migration of BPA , migration of heavy metal, Restricted substance, comply with EU 10/2011, and 2011/65/EU and its latest version (EU) 2015/863

-Lid film (PET/Nylon/PP), testing report on 23/9/2021, DOC for BPA free were maintain.

During on site, there was no evidence the risk of handling packaging materials. It was controlled according to GMP system. For obsolete packaging i.e., label, has been destroyed before removed.

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

The inspection/testing infrastructures area was in good condition and well maintained which separated from production area, the sampling channel was prevented from cross contaminate. There is a procedure in place for product inspection and testing which includes heavy metals, pesticide 4 groups, microbiological (APC, yeast and moulds, Coliforms, *E. coli*, *Salmonella spp., C. perfringens, B. cereus*, thermophilic anaerobic spore formers, *S. aureus*, flat sour producing mesophilic bacteria, flat sour producing thermophilic bacteria).

The external laboratory for finished product testing and release. The external laboratory accredited ISO 17025 such as SGS with accreditation no. 1007/43. The test and inspection results recorded are reviewed by QA. A review of management review meeting report indicated the compliance with the requirement included trend analysis.

Testing program has been defined which covered microbiological, pesticide, heavy metal for each product based on risk, the finished goods testing plan set in SD09-QA-14 update 24/11/2023.

The finished product last tested for Pineapple in juice, mango in syrup, aloe vera in syrup, tropical fruit cocktail in syrup tested on 24 February 2023 for Cd, Hg, Cu, As, Fe, Zn, Pb, Sn, APC, yeast and moulds,

Coliforms, *E. coli*, *Salmonella spp., C. perfringens, B. cereus, Listeria spp.*, thermophilic flat sour, *S. aureus*, mesophilic flat sour thermophilic anaerobic spore formers to complied with MoPH 414, MoPH 416, EC 1881/2006, Codex STAN 193-1995.

Fresh pineapple tested on 7/3/2023, Fresh papaya on 8/3/2023 , fresh mango tested on 28/2/2023, fresh aloe vera tested on 14/3/2023 for pesticide by OMIC with accreditation no. 1066/48. Fresh papaya tested on 7/6/2023 and Pineapple on 7/6/2023 for GMOs screening, result ND.

Shelf life on going was tested for physical, organoleptic and microbiological (TPC, yeast and moulds, Coliform, *E. coli*), sampling shelf life study record of
-Pineapple Choice tidbits in pineapple juice started on 20/1/21 to on 28/2/23 (end shelf life) for 25 months at 18 °C, 5°C, etc.
-Tropical fruit salad in light sweetened pineapple juice, started on 31/11/23, study 19 moth (shelf life 15 month) at 5 , 18 and ambient
-Mango choice diced 15 mm in a natural flavoured light syrup, started on 18/2/23, study 19 moth (shelf life 15 month) at 5 , 18 and ambient
-Aloe vela cubes in extra light syrup with natural white grape flavour, started on 25/7/23, study 25 moth (shelf life 15 month) at 5 , 18 and ambient

PT test at site for qualification internal staff was established. There have internal laboratory such as microbiological such as TPC, Yeast and mould ,Coliform, E.coli bacteria. And chemical test such as brix , pH, acidity etc. Sampling the PT test as below ;
-Yeast and mould (CFU/g) , Sample No.NFI-PTM-31-2023 in corn powder on 30/11/2023 , Z score = 1.13
-TPC (CFU/g) , Sample No.NFI-PTM 08-2023 on 17/5/23 in Freeze dried shrimp , Z score = -2.49
-E.coli (MPN/g) , Sample No.NFI-PTM 47-2023 on 12/4/23 in Kratom powder , Z score = -0.05
-Coliform (MPN/100 ml) , Sample No.NFI-PTM 31-2022 on 14/12/2022 in Potable water , Z score = -0.47
-Acidity (g/100g) , Sample No.NFI-PTC 06-2023 on 30/5/23 in Canned food (pineapple in syrup) , Z score = -0.96.
-pH and brix, sample No.NFI-PTC 05-2023 on 29/5/23 in Canned food (apple juice), Z score = 0.27(pH) and 0.00 (brix)

5.7 Product release

The product release process is in place to ensure that the positive release of finish product comply with this clause as seen evidence during onsite audit.

The QA manager was authorized person who release the finished product. The System in place fully practice comply with this clause as seen evidence during onsite audit on product release base on parameters as organoleptic, appearance, chemical test, and microbiological test.

Positive release is implemented for the finished products by cut off test result and incubation test at 37°C for 7 days and 10 days ambient condition. The sample of records that were assessed showed that the inspection and test results have been reviewed and release was approved by authorized personnel (QA manager). NCs products are identified as hold product, destroy, reject and pass, decision making by factory manager.

5.8 Pet food and animal feed

There was no production of pet food and animal feed.

5.9 Animal primary conversion

There was no animal primary conversion process.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.8	There was no production of pet food.
5.9	There was no animal primary conversion process.

6. Process control

6.1 Control of operations

The operation control procedure is maintained to control and ensure that consistently of production of the product safety and legality with desired quality characteristic and fully compliance with the HACCP plan such as incoming, preparing raw material, filling, sealing, thermal processing, packing process, etc. Documented work instruction and process specification available for key process. All the measuring instruments were calibrated periodically. The program of the cooker has been set up and changed by authorized person only i.e., retort supervisor which has been controlled as password protected.

Temperature distribution of cooker has been validated annually and heat penetration has been studied for new product or every 3 years for HP and 2 years for TD.

Product monitoring were carried out every batch of production. The production supervisor and production manager are response for review the production records regarding to HACCP plan and work instruction. QC supervisor and QA manager is response to review the quality control record of the products to ensure that, the product quality and safety are complied with the specification.

There were no in-line monitoring devices.
There was no by-product outside the scope.

6.2 Labelling and pack control

The label and packing control procedure and packing operation control was available to ensure the products will be correctly labelled and coded. The site was in-line and off-line coding of plastic cup and carton box. Product has been coded on primary packaging for product code, MFG date and EXP date.

There was no in-line vision equipment. The coding machine is separated from the open-product area to make sure no contamination from the ink.

Inspection record during labelling process has been covered inspection of date coding, batch coding, barcoding, allergen information, type of packaging which has been checked at the start of packing, during packing, changing batch and at the end of production at labelling process and packing process.

During onsite audit, there was found changing lot of products from VCTJ02-BD79A to VCTJ02-BD79B which found clearance record properly.

6.3 Quantity, weight, volume and number control

Weight was check and control as customer requirement that indicated in product specification, recorded on weigh inspection record and checked by QC inline at start production, every hour and finish of product to complied with specification. Records of quantity verification indicated satisfactory control.

There was no auto-check weight.
There was no bulk quantity.

6.4 Calibration and control of measuring and monitoring devices

A calibration plan was established and implemented and calibration procedure set in QP-MS-02 , that covered all measure devices both use in processing and laboratory room. Seen list of measure devices document plan FM-MS-43 update in 2022 - 2023.

Sampling calibration report e.g.

-pH meter CKL-T255 calibrated on 9/9/2023 ,
-Peel strength tester CKL-T270 internal calibrated on 30/6/23 , by use standard weight calibration on 5/9//2023
-Bursting test CKL-T161 internal calibration on 29/6/23 , by use master pressure gauge with calibrated on 23/3/2023
-Thermometer CKL-T144 , CKL-T148, internal calibration on 29/6/23 , by use master digital thermometer with calibration on 11/9/23
-Thermometer CKL-T016 , internal calibration on 29/6/23 , by use master micro bath with calibration on 19/9/22
-Balance PA-T560 , internal calibration on 29/6/23 by use standard weight with calibration on 5/9/2023
-Metal detector CKL-T130 , CKL-T266 , calibration on 18/9/2023 , review test piece certification as Cert-0047692 (Fe1.5 , Non Fe 2.5, SUS 3.8 mm.)
-Thermometer Cooker (RTD) CKL-T56 ,CKL-T157 internal calibration on 4/8/23 , by use master micro bath with calibration on 19/9/22
-MIG CKL-T220 internal calibration on 19/2/23 , by use master micro bath with calibration on 19/9/22
-Stop watch CKL-T242 internal calibration on 25/11/23 (every 3 month)
-Thermometer Cold room No. 5 CKL-T56 internal calibration on 19/2/23 (at -1C , 3 ,6 C), by use master micro bath with calibration on 19/9/22

All device which have been calibrated that calibration result was accepted and in range of used.

Calibration procedure was in place to ensure the out of limit measuring and monitoring devices were effective controlled.

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

6.1.4	There were no in-line monitoring devices.
6.1.7	There was no by-product outside the scope.
6.2.4	There was no online verification equipment.
6.3.3	There was no auto-check weight.

7. Personnel

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

The company has a comprehensive training procedure in place which is undertaken according to defined procedure and programme as training program SDPTC09-HR-02 in year 2023 approve on date 7/7/2023. Training is undertaken in accordance with defined procedures and is administered by the HR department.

An overall annual training plan is established centrally and each of the factories develops its own programme for on-the-job training according to the need. Levels of training include orientation training, job training against specific work instructions and specialised training for relevant personnel. This may be provided by suitable external agencies. Training evaluation system was conducted after end of course to ensure their competency for relevant staff with evaluation of training by observing from actual operation, interview or examination, etc.

Full training records were available for all staffs requested. Seen training records for example,
Allergen/Fraud control procedure – 13 June 2023 13 July 2023 and 10 August 2023
Food security/ food defence – 4 September 2023 , 13 July 2023, 24 January 2023 for QC
HACCP/Food safety - 9 November 2023 for production, 24 January 2023 for QC
glass, and breakable control program date 3 February 2023
GHPs – 3, 24 February 2023 for QC , 3 March 2023 for production.
OJT training e.g. sorting operation training date 15/11/2023, labelling and pack control procedure training date 1, 27 September 2023, metal detecting operator 7/11/2023, CCP metal detector 9/11/2023, sealing inspection procedure 3/11/2023 ,CCP (SD09-HR-31) training date 24/01/2023 ,BRCGS Food V.9 (requirement and internal audit) on 12-13 Jan 2023.
During onsite audit, from interview staff, there was found good understanding of staff for their roles and responsibilities.

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

The staff personal hygiene procedure set in GP-QA-01 rev.18 was effective controlled such as jewellery policy state in questionnaire and during site tour and production inspection, and not found operator worn watch, jewel, and ring as hygiene policy as define on company rules.

The changing room administrator was supervised. For the belongings that are not allowed into the workshop, they must be store in locker at the entrance of production area and make confirmation when in and out of the workshop. The staff enter to the workshop will be through the changing room were supervised and monitor for any jewellery, personal medicine, etc. To sampling personal hygiene check in daily by leader (FMPTC-PT-21) on August 2023- November 2023 and recheck by QA. in every week latest sampling record before working and during work on 18 August 2023

Personal medicine has been stored at locker. All staff will be checking personal hygiene staff at the entrance when in and out of the processing area. Hand washing has been installed at the entrance of production line which covered hand dryer and liquid soap. The blue strip plaster will be use in case of cut and grazes together to gloves which has been inspected condition and quantity. Blue strip plaster has been tested through metal detector daily sampling record for tested on 11 Feb 2023 by lot 21043906 receiving on 27 May 2022 report were maintain.

During on site at production line found some staff long fingernails.
A Minor Non-conformance has been raised against 7.2.1
During on site at production line found some staff long fingernails.

7.3 Medical screening

The company was good maintained the medical screening procedure by seen questionnaire to screen personal health for visitors and contractor before entering to the workshop which control by HR department and all concern department. The procedure set in WI-OH-04 rev.01.

Annually for medical examination included item of Spirometry, stool culture which report shown passed for all staffs last on 13-14 December 2022, 14-15 December 2023 (waiting report) Follow as rule of hygiene and HR staff inform about when infection or disease, person have to report to supervisor.

New employees and contractual workers have medical screening before entering production line. Not allow illness person entry processing, visitor or contractor must be approved before entry.

7.4 Protective clothing: employees or visitors to production areas

The company maintains the documented rules to control the employees, contractors, and visitors regarding the wearing of protective clothing in specified areas as procedure.

The audit overview in this section found system to control protective clothing of all employees, contractors and visitors were maintaining for example it was system in place to change clothes before entry the production process, separate by designate area and color differentiate. The instruction for laundry instruction set in WI-HR-24 rev.09, date 4/4/2023. Temperature 60 degree Celsius ,59 mins, drying 60 degrees Celsius, 25 mins. The laundry record as FMPTC-HR-17, record date 8/12/2023, 14/12/2023.
Training record for laundry process on 4/4/2023 WI-HR-24 for Housekeeper.
Verification of laundry on weekly included KFCU protective closing included TPC <= 500 cfu, coliform bacteria, YM, review the record of 8/12/2023, 24/11/2023, 17/11/2023, 11/11/2023, 3/11/2023.
Validation of launder process, 28/04/2023, 9/10/2023, test for laundry machine (rinse water after laundry of the dehydrate protective closeting (product dehydrate SO2 300 ppm) shown Not Detected SO2.

The disposable gloves were available for product handling duties and were controlled appropriately.
The responsible staff will be monitoring the cleanliness of protective clothing before entry processing line.

Swab tests weekly on sampled clothes by QC. For laundry process sampling record latest on 8/12/2023, 24/11/2023, 17/11/2023, 11/11/2023, 3/11/2023, etc. for TPC, Coliform bacteria, Yeast and mold, there was found provided by Kuiburi Fruit Canning Co., Ltd. which has been controlled laundry process such as temperature and time for laundry process and found internal audit as plan.

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

None	

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	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	
11.3 Raw material receipt and inspection	
Click or tap here to enter text.	
11.4 Management of cross-contamination between species	
Click or tap here to enter text.	
11.5 Product testing	
Click or tap here to enter text.	
11.6 Training	
Click or tap here to enter text.	

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)

Preventive control was established and implemented for process control plan and supply chain preventive control plan. Process control plan has been integrated with HACCP plan which clearly defined 3 CCPs i.e., blending media, passing metal detector and sterilization process.

Monitoring activities has been clearly defined for each control plan i.e.

1.Process control plan has been monitored through CCP monitoring which referred to HACCP plan i.e., blending media, passing metal detector and sterilization process. Sampling food safety plan of aloe vera in plastic cup defined in SDPTC09-QA-18.3 rev.3 update 12/12/23 and pineapple in syrup/ juice in plastic cup defined in SDPTC09-QA-18.1 rev.5 update 12/12/23, Tropical fruit in SDPTC09-QA-18.2 rev.5 update 12/12/23 , and Mango in plastic cup in SDPTC09-QA-18.4 rev.2 update 12/12/23 etc.

2.Supply chain control plan has been monitored through incoming inspection record of each raw material, ingredient and food contact packaging and CoA including guarantee letter or statement of compliance for allergen and radiation status. Sampling allergen status and irradiation status from Eka Global Co., Ltd. for plastic cup, filled on 8 March 2022, vitamin C from Shandong Luwei Pharmaceutical Co., Ltd., white sugar from United Farmer and Industry Co., Ltd. on 26 April 2022 and radiation statement on 28 February 2023., Sunshine Biotech International Co.,Ltd supply citric acid , found COA , testing report on 3/2/2023 , Non GMO status on 27/2/2023 , radiation statement , allergen status on 10/1/2023.

Corrective action procedure was established and implemented in documented Hazard Analysis and Critical Control Points (HACCP) for process control plan. For the supply chain control plan, there has been established corrective action in work instruction and procedure.

Validation methods of process control have been planned through TD verification every 3 years and HP study verification every 2 years included blending of media process and metal detector verified by external calibration every year.

For supply-chain control has been validated through testing of finish product, packaging, ingredient and raw material as plan.

There was found all record for preventive control plan has been reviewed and signed by PCQI within 7 days.

Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)

There was no production of animal food.

Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)

USFDA registration no. 10769129160 which valid until 31/12/2024.

Food security risk assessment was done by food safety team, which covered all potential risk area e.g. production area, water tank, laboratory, maintenance shop, packing room, raw material storage, finish product storage or chemical storage. Area security was controlled by HR staff and security guard, which was trained for area access, visitors have to stay with authorized person all the time including fill the questionnaire.

The site was maintained security system as appropriated to ensure that product is protected from theft or contamination while under the site control such as 24 hours CCTV operations, security guard at entry area. The security program was documented in SD09-BI-06 and updated on annually included for all area, latest updated on 11 Mar 2023. There was found registered of key handling for each area has been defined in SD09-HR-74. Security guard will monitor around the factory every 2 hours and recorded in FM-HR-105. CCTV has been inspected condition daily by each authorised person and recorded in FM-HR-26. Monitoring of food defense plan on monthly, last updated 19/7/2023, 18/2/2023, 27/1/2023, 18/10/2023. Security guard monitoring for restrict area every 2 hours.

Security guards were good trained to control visitor, subcontractor, employees who access to the area by HR approval. All staff has been trained in site security procedure and food defence, latest trained on 8 Mar 2023.

Visitors and contractors were required to contact to responsible person before entrance to the site, the responsible person will be pick up them at the entrance and sign in at time of arrival. There was no external storage.

Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)

Vehicles and transportation equipment was maintained and store in sanitary condition. There is hygiene inspection record to check the cleanliness of vehicles and transportation equipment. All shippers and carriers to USA has been selected by customer which comply with FSMA's Sanitary Transportation rule. Contract has been clearly defined sanitary specifications of vehicles for the loader and carrier. There was no controlled-temperature loading. All records have been kept at least 3 years and can be retrievable within 24 hours.

Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)

The company has a comprehensive training procedure in place which is undertaken according to defined procedure and programme as training program SDPTC09-HR-02 for year 2022 – 2023 which included Principles of food hygiene and food safety, Produce safety standards. Training is undertaken in accordance with defined procedures and is administered by the HR department.

An overall annual training plan is established centrally and each of the factories develops its own programme for on-the-job training according to the need. Levels of training include orientation training, job training against specific work instructions and specialised training for relevant personnel. This may be provided by suitable external agencies. Training evaluation system was conducted after end of course to ensure their competency for relevant staff with evaluation of training by observing from actual operation, interview or examination, etc.

PCQI has been assigned such as Ms. Suwannee trained for FSPCA on 10 December 2016, Ms. Pattama and Ms. Worasiri which has been trained for FSPCA on 12 June 2016, Mr. Tanadech and Ms. Jiraporn trained for FSPCA on 3 September 2018.

14.1 Additional Specifier Requirements
14.1 Traceability
Click or tap here to enter text.
14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.

Certificate of Registration

BSI Group ANZ Pty Ltd #0723 certifies that:

KUIBURI FRUIT CUP CO., LTD.
Site Code: 5092614
1 Moo 7, Petchkasem-Yangchum Road, T. Kuiburi, A. Kuiburi,
Prachuap Khiri Khan 77150 Thailand

Has achieved:	**Grade A+**
To the requirements of the:	**BRC Global Standard for Food Safety Issue 9: August 2022**
Audit programme:	Unannounced – mandatory 1 in 3 years
Scope of activities:	Manufacture (blanching, filling, sealing, sterilization) of tropical fruit, pineapple, mango and aloe vera packed into plastic cup.
Exclusions from scope:	None
Product categories:	11 - Low/high acid in cans/glass
Certificate number:	BRCFD 764546
Auditor number:	21871
Certificate issue date:	20 January 2024
Audit date(s):	15 December 2023
Re-audit due date:	From 23 February 2025 to 23 March 2025
Certificate expiry date:	04 May 2025

For and on behalf of BSI:

Todd Redwood
Global Food and Retail Supply Chain Operations and Compliance Director

Auditor number(s): 21871

BRCGS Site code: 5092614

KUIBURI FRUIT CUP CO., LTD.
1 Moo 7, Petchkasem-Yangchum Road, T. Kuiburi, A. Kuiburi, Prachuap Khiri Khan 77150
Thailand

In conjunction with an Unannounced – mandatory 1 in 3 years audit for

Global Standard Food Safety, Issue 9

HAS SUCCESSFULLY PASSED THE BRCGS MODULE 13 (FSMA Preventive Controls Preparedness)

For the scope of activities: Manufacture (blanching, filling, sealing, sterilization) of tropical fruit, pineapple, mango and aloe vera packed into plastic cup.

Product categories: 11 - Low/high acid in cans/glass

Date(s) of audit: 15 December 2023

Certificate issue date: 20 January 2024

Re-audit due date: From 23 February 2025 to 23 March 2025

Certificate expiry date: 04 May 2025

Certificate issue number: FSMA 764547