Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary			
Company name	Coco Davao Inc.	BRC Site Code	1440886
Site name	Coco Davao Inc.		
Scope of audit	The manufacture of Desiccated Coconut in P.E. liner within Kraft Bag or box and Manufacture of Frozen Coconut Water Concentrate in P.E. liner within Steel Drums or pail.		
Exclusions from scope	None		
Justification for exclusion	None		
Audit Finish Date	2017-05-23		
Re-audit due date	2018-06-08		

Voluntary modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	AA	Previous audit date	2016-05-26		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	5

3.Company Details

Address	Sitio San Jose, Santa Cruz, Davao Del Sur, 8001,		
Country	Philippines	Site Telephone Number	+63822720675
Commercial representative Name	Ms. Fatima Velasco	Email	sales@primexcoco.com
Technical representative Name	Ms. Jocelyn Legaspi	Email	cdi.qualityassurance@gmail.com

4.Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	501-1500	No. of HACCP plans	1-3

Subcontracted processes	No
Other certificates held	Organic, Halal, Kosher, Fairtrade
Regions exported to	Asia Europe Oceania North America Choose a region Choose a region
Company registration number	PH FDA License No. 16461299312
Major changes since last BRC audit	There is no change in product and process since last audit. A new bigger laboratory facility is constructed for accommodating additional customer requirements of testing and new boiler in order to support increased production in future.

Company Description

This company is group company of Primex Coco Products Inc. Factory is located in Davao Del Sur district in Philippines. Company has been established more than 10 years with the capacity of 39000 metric tons of Desiccated coconut per year. There are 3 production lines of Desiccated coconut and 1 production line of frozen coconut water concentrate. The products are mainly exported to USA, EU countries, Japan, Australia etc. 3 shift of operation are carried out with 580 plus employees, handling 450000 coconuts daily. Desiccated coconut 1400 bags per day each bag 45 kgs, Coconut water 24 drums of 265 kgs each of coconut water concentrate with 4% yield. The company owns their own vehicles for transporting raw coconut and finished product. Machineries include the tanks, pasteurizers, evaporators, blenders, aseptic fillers, blast freezers and cold store for Coconut water concentrate and nut opening lines, drillers, shredders, dryers, packing lines and metal detector and magnets for Desiccated coconut. Total site area is 5 acres and built up area is 24678 sq mts.

5.Product Characteristics

Product categories	07 - Dairy, liquid egg 15 - Dried food and ingredients Category Category				
Finished product safety rationale	Desiccated coconut is with low moisture max 3% and sulphited as per customer requirement with shelf life of 12 months and ambient storage. Coconut water concentrate is evaporated to high brix 59-61 brix and frozen at – 16 to -18 deg C. Pasteurized at 92 deg C for 42 seconds, Shelf life 24 months.				
High care	No	High risk	No	Ambient high care	No
Justification for area	Products are ambient stable.				
Allergens handled on site	Sulphur dioxide and Sulphites Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen 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	Yes, organic				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Desiccated Coconut and Frozen coconut water concentrate				

6.Audit Duration Details			
On-site duration	24 man hours	Duration of production facility inspection	12 man hours
Reasons for deviation from typical or expected audit duration	The Site area is below 25000 sq mts for built up area, calculation was done on total land area of 50000sq mts		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2017-05-22	0800	1700
2	2017-05-23	0800	1600

	Auditor (s) number(s)	Names and roles of others
Auditor Number	176173	Sarit Chowdhury
Second Auditor Number	176396	Sirirat Srisawat

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Marlon Brian Si- Plant Manager	√	√		√
Jocelyn Legaspi - QA Manager	√	√	√	√
Yasudhara Evangelin - QA	√	√	√	√
Joann P.Saroongillo – DCO	√	√		√
Caron Sanchez – Stock room incharge	√	√		√
Noemi D Olaer HR, Manager	√			√
Manuel Maleon, Maintenance	√	√		√

Present at audit				
Manager				
Joshua T Calija, CWC QA Supervisor	X	X		X
Elsa B Mejala, Organic Div. Manager	X			X
Sunshine B Elnar, Asst. Plant Manager	X			X

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	**Clause**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Clause**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	1.1.2	Some of the objectives like Nut Opening are not achievable at the present circumstances, some of the objectives fixed do not reflect continual improvement adequately as the targets reflected are same as last year and adequate control	Meeting was conducted for the review of objectives last May 25, 2017. The objectives were revised, all Quality and Food Safety related Objectives retained and the rest not identified were excluded.	***Root Cause:*** The team presumed that all areas should have objectives even if not related to Food Safety and Quality. ***Preventive Action:*** -Ensure all Objectives are SMART. -Review of performances for the previous years as a basis for continual improvement	Revised Objectives	2017-06-20	Sarit Chowdhury

		over the process is not possible, viz, rotten nuts, paring thickness. Some of the objectives were not achieved last year and the root cause of the same were not adequately carried out.		-Objectives set are only related to Food Safety and Quality			
2	2.10.1	The monitoring process of the vibrio shifter in coconut water was found not adequate as it is based mainly on external observation. Internal check of sieve is not done adequately.	Checking of screens / internal check is already implemented starting June 5, 2017. The operators were re-trained and re-oriented on the proper checking of screens.	***Root Cause:*** The operators assumed that by just checking the external ring, the screens inside are also intact. Training was not conducted on the proper checking. ***Preventive Maintenance:*** -Maintenance screen checking every week. –hourly checking of integrity of screens shall be done -re-training and re-orientation shall be done	CCP training record, CCP monitoring record and CCP work instruction	2017-06-20	Sarit Chowdhury
3	3.5.1.1	The raw material risk assessment does not clearly outline a conclusion regarding the category of risk i.e. high or low risk regarding the suppliers.	Risk Assessment of Raw material was conducted and reflected in the Approved Supplier Program. Thus, requirements as per 3.5.1 were translated in the same document	Root Cause: The team did not fully understand the requirements of 3.5 Supplier and Raw Material Approval and Performance Preventive Action: -Understanding deeply the requirements of BRC standards, ask experts e.g. auditor about the	Revised approved Supplier program	2017-06-20	Sarit Chowdhury

				requirement or search to BRC Participate			
4	3.5.2.1	Incoming inspection of pared coconut meat did not include separate pesticide and microbiological monitoring.	Pesticide analysis conducted yearly is the same with the external opening since Coco Davao is the one supplied coconuts to External opening. Nevertheless, microbiological aspect shall be tested every month.	***Root Cause:*** The team assumed that auditing in the External area and monitoring of their white meat were enough without considering verification through microbial analysis of white meat. ***Preventive Action:*** Continuous monitoring of microbiological parameters of coconuts supplied by the external opening. This shall be done in weekly basis. Monthly audit in External Opening shall be continued	Coconut microbiological analysis report	2017-06-20	Sarit Chowdhury
5	4.14.1	The whole site have an effective preventive pest control programme in place to minimise risk of infestation, however during on site verification, spider web was observed on packaging stack, however packaging was closely covered. Dead flies were observed inside insect trap number	-Cleaning and dusting in the packaging section was done, weekly cleaning shall be done in the area, this is verified by the QA / IA. -Additional Light Trap was installed in the Metal detector room -cleaning of insect light trap is implemented during replacement of sticky pad.	***Root Cause:*** -cleaning schedule of the packaging was not properly implemented, the assigned utility resigned. The supervisor forgot to assign it to other person. -cleaning was not included on the checklist, the reason why it is often forgotten.	Insect light trap monitoring checklist	2017-06-20	Sarit Chowdhury

		10 in anteroom of cold store, one fly was observed in the metal detector room of Desiccated coconut section, and however product is enclosed in this area after packing.		***Preventive Action:*** -Cleaning maintenance of the packaging area shall be maintained and checked daily by the Supervisor, thus ensuring dust free packaging materials at all times, cleaning and maintenance shall be done by the regular employee in bag marking. -verification and checking of the cleanliness of insect Light trap after changing of sticky pads, this is done weekly. -random checking of its implementation by the pest control coordinator.			

Comments on non-conformities

Voluntary Modules Non-Conformity Summary Sheet

Critical			
No.	**Clause**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The Quality Policy is established date 29.4.16 and signed by Marlon Brian Si, Plant Manager, is communicated by trainings and display in prominent places.
Function wise measurable objectives is established and monitoring is done monthly and Quarterly, reviewed during OR and MRM meeting in presence management.

Objective for the for the organization is set with timeline January 2017 to December 2017.

Objectives are fixed for reduction of reject, rotton nuts, Paring process control, reduction of foreign matter, reduction of product waste during production and QA objectives related to product conformity. Objectives are getting monitored monthly, verified monitoring record HACCP/ISO 2017 Summary record dated January to April 2017. **Some of the objectives like Nut Opening are not achievable at the present circumstances, some of the objectives fixed do not reflect continual improvement adequately as the targets reflected are same as last year and adequate control over the process is not possible, viz, rotten nuts, paring thickness. Some of the objectives were not achieved last year and the root cause of the same were not adequately carried out. Minor CAR**

Management Review conducted 12 monthly and last management review completed on 7.2.17. Verified action plan of MRM in Minutes of management meeting, attended by Plant manager.
Monthly meeting is conducted every month once for HACCP and once for other criteria's. Verified record for monthly meeting on other issues dated 31.3.17 where issues like PRP monitoring, infrastructure, HR, production etc are discussed. HACCP monthly meeting dated 6.5.17. Monthly meetings attended by Plant manager, HODs and relevant members.
BRC hard copy is available at the site. Registration to BRC participate was done and updates regarding BRC standards and protocol was available.
System is getting updated through Local regulatory and USFDA from website, Legal Networks – Food updated registered from company
Five Minor non conformities were identified last audit and the corrective actions continue to be effective. Audit is happening within renewal timeline. Plant Manager is top management and was present in Opening and closing meetings.

1.2 Organisational structure, responsibilities and management authority

The present site is under direct control Managing Director Mr. Darius Oliver D Sio and he in turn is reported by the Plant Manager of the company. The site has department like Purchase, Production, Quality control, Engineering, Store and Organic. In case of absence of any personal alternate delegation of authority os defined. Organisation chart is updated on 19.4.17 (HRD-OC).

Details of non-applicable clauses with justification	
Clause reference	**Justification**

2 The Food Safety Plan – HACCP

The company's food safety plan is designed as per Codex Alimentarius guidelines and HACCP standard requirements.
Ms. Jocelyn Legaspi is appointed as HACCP team leader. Bachelor of Science with 14 years of experience in same industry, BRC issue 7 trained on dated 10-11.9.15 and also on ISO 22000:2005 awareness, Team is updated on 3.4.17.

The team includes members from Production, Quality, Stores, purchase, maintenance and HR/Admin. Adequate knowledge was seen in team members and all team members were sufficiently experienced. PRP programs are designed as per codex requirements and include all PRP elements viz. surroundings, internal structures and layout, maintenance, cleaning, personnel hygiene, pest control, transportation, prevention of cross contamination etc. Allergen procedure is separately defined.

2 HACCP plans are identified in the present sites which are mainly grouped. Frozen coconut water concentrate and Desiccated coconut. Product description for all of the same was available. Product description includes information regarding product ingredients, physical and microbiological parameters, packing, storage and distribution, shelf life and labelling. Customer preparation is also identified.

HACCP PLAN FOR Desiccated Coconut: Nut opening, paring, sorting of meat, washing, sulphite treatment, blanching, drying, shifting, packing, metal detection, dispatch.

HACCP PLAN FOR Frozen Coconut water concentrate: Storage, pre heating, oil separation, pasteurization, cooling, chill storage, pre heating, evaporation, cooling, filling, blast freezing and storage. Flow diagrams are available for both process. Separate flow diagram for organic and conventional desiccated coconut is available. Verified CDI FSM 01 dated 28.4.17 for DCN and CI FSM CWC 1.0 dated 21.4.17 for Frozen coconut water conc.

The Hazard analysis has been carried out on the basis of knowledge of experienced professionals; recognised guidelines from FDA, Customer requirements as well as scientific institutions information were evident. Physical (physical impurity, metal contamination), chemical (allergen contamination, pesticide residue, cleaning chemical residue, heavy metal) and microbiological (yeast & mould, Salmonella, Listeria, E. Coli.) hazards were identified and control measures are established.

Hazard assessment has included likelihood and severity study. Risk factor more than specified is considered as significant hazard.

Company has identified a set of OPRPs and CCPs. The CCP details are as below. Magnet pull strength

monitoring record was verified CDI-QAOPRP4.0 dated 16.5.17.
1. Desiccated Coconut — CCP identified is Chemical treatment of sulphite with max residual limit as 50 PPM and 100 PPM as per buyer rq. Monitoring hourly. Records verified.

Blanching – Temperature of 90.5 deg C for 9 minutes. Temperature recording hourly. Records verified.

Metal detection – MD 1 – 1.5mm/1.8mm/2.2mm and MD 22mm/2.5mm/2.5mm. Monitoring twice every hour.

Coconut water CCP 1 – Vibrio shifter with mesh size of 200 mesh, monitoring every 30 minutes through visual panel to see if product is clean and intactness of sieve.

Pasteurization of coconut water – Coconut water pasteurized at 92 deg C for 42 seconds. Monitored by operator every 30 minutes.

The monitoring process of the vibrio shifter in coconut water was found not adequate as it is based mainly on external observation. Internal check of sieve is not done adequately. Minor CAR.

Pasteurizations, Sulphite application process has been validated based on the concentration of the soaking loquor and resultant sulphite content of the meat. Verified Validation report of in house validation CDI-VAL-CCP2 dated 4.5.17, Blanching validation based on microbiological testing of end product was seen dated 29.4.17 and Metal detector validation dated 4.5.17 was seen, pasteurization temperature and holding time validation was seen dated 14.2.17. Also external validation of critical process viz. Blanching was carried out.

Frequency of HACCP review is 12 monthly or whenever any significant change. HACCP was last reviewed on 28.4.17 including PRP

Details of non-applicable clauses with justification

Clause reference	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

The company has defined a quality manual for BRC CDI-FSM-01 dated 28.4.17. The quality manual is documented based on the BRC issue 7 requirement. Hard copy was available on site. The distribution of the same document was defined and includes all key personnel's in the organization.

3.2 Documentation control

A procedure for effective documentation and record control is in place CDI PM 01 dated 1.2.17. Document approval, review, amendment, numbering, external and obsolete documents are addressed. Documents approved by the Quality assurance Manager. Distribution list of the document has been prepared, clearly showing relevant documents distributed to relevant staff.

3.3 Record completion and maintenance

A procedure for effective documentation and record control is in place CDI PM 01 dated 1.2.17. Retention time for records is self life + 1 year i.e. 2 years for desiccated coconut where shelf life is 1 year and 3 year for coconut water where shelf life is 2 years as mentioned process wise.

3.4 Internal audit

CDI PM 2.0 dt 5.7.16. The Internal audit frequency has been prepared based on the risk assessment of the processes involved and has higher frequency for higher risk process. Verified document IQA/3.0B dated 20.5.16. Internal audit team comprise of 9 internal auditors, additionally there are 5 field inspectors who are monitoring the farms including the Organic farms. The field inspectors are trained in organic standards. Verified training record for ELSA MEJALA dated 3-4 October 2016 by Ecocert. List of Internal auditors was seen, Internal auditors are trained, verified training record dated March 13 2016.

Last Internal audit is conducted on April 2017. The audit was planned to be carried out on 11.4.17 covered all processes. Verified report for HACCP internal audit by Edna Mamac covering BRC standard requirements. Observations were identified and non conformities raised. One Non conformity raised and reported in separate formats with root cause, corrective action and verification by auditor doe closure. Timelines for closure of non conformities are agreed at the time of audit. CAPA report CPAPCDI dated 13.4.17 was verified.

Monthly housekeeping and fabrication inspection is conducted report was seen in GMP & HK audit checklist, dated 16.3.2017.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

Supplier approval procedure is documented. CDI EVAL ASP 1.0 dated 23.6.16. The Supplier approval procedure indicates the approval procedure based on raw material risk assessment. Risk assessment criteria are defined as Physical, chemical, microbiological, allergen; and substitution criteria are considered in the vulnerability assessment. The raw material risk assessment is reviewed annually, last done on 23.6.16. Approval process of services is also defined. Supplier Audit for all high risk suppliers are carried out and questionnaire for low are defined. The high risk suppliers are separately listed and identified for audit scheduling. Verified supplier list for Davao Plant as well as suppliers approved by the Manila Head Office. **The raw material risk assessment does not clearly outline a conclusion regarding the category of risk i.e. high or low risk regarding the suppliers. Minor CAR.**

The agents and brokers are used fro coconut supply as well as packing material supply and audited with questionnaires. Verified the assessment questionnaire from Sodium Metabisulphite supplier in Germany BASF. The supplier has GFSI certification viz. BRC and FSSC, certificates seen. Verified self assessment questionnaire from Aseptic Bag supplier Goglio (Tanjin) Packaging company, dated 3.6.14, questionnaires are resent every 3 years. Coconut are supplied by traders directly from farms. Coconut supply is subjected to incoming inspections and the same is recorded. Verified Nuts quality performance report for Anifa Bajunaid for year 2016-17. The risk assessment document is seen, it is as a part of HACCP risk assessment. Verified farm audit report of Organic farmer Victoria O Agtarap dated 10.4.17 based on Organic and GAP requirements.

3.5.2 Raw material and packaging acceptance and monitoring procedures

All the material is tested internally. In the incoming materials, sensory, physical will be conducted for chemical and packing material chemical and micro parameters key parameters OR COA.
Verified incoming inspection report for Nuts – CDI NP FORM 4 dated 19.5.17 for H Salem supplier of coconut. Verified incoming inspection report of Sodium Meta Bi Sulphite dated 18.4.17 from Purechem Corp where physical and packaging parameters are checked. COA is received from supplier BASF with same supply where all parameters as per specification are reported. Aseptic bag receiving report CWC Q 013 dated 22.5.17. COA from supplier was seen 21.3.14. Incoming inspection of pared coconut meat CDI EXT Checklist.01 dt 20.5.17. **Incoming inspection of pared coconut meat did not include separate pesticide and microbiological monitoring. Minor CAR.**

3.5.3 Management of suppliers of services

Procedure outlines handling of outsourced services and approval of service providers, same procedure as Supplier approval. Services include transport, external laboratory, security, pest control, workers, canteen, waste disposal etc. Service contract verified with labour contractor dated 3.3.17. Contract with Canteen contractor seen dated 19.1.17. Contract with Pest control services – Chemsol Industries dated 17.2.17.

3.5.4 Management of outsourced processing and packing

No outsource process and packing

3.6 Specifications

Once in three years all the specification will be reviewed and whenever there is change required.
Company has documented specification for all products. Finished product specification verified for Organic Coconut water concentrate CWC PSPEC 2.0 dated 18.2.17, and CWC PSPEC 1.0 for Conventional.
Desiccated coconut specification CDI SPECS QA20A dated 6.5.17 was verified. Raw material specification for Sodium Meta Bisulphite seen dated 29.5.14. Next review is due on 29.5.17. Specification is reviewed every three years.
Specifications for Aseptic bags seen documented. Specifications for Pared coconut meat seen CDI SPECS QA 26.0 dated 7.1.16. Raw coconut specifications are verified. Coconut specifications CDI SPECSNP-1.0. dated 17.2.16.

3.7 Corrective and preventive actions

Corrective action procedure is detailed in CDI PM 4 dated 17.5.17.
Correctives action is detailed, However this unit is recently no major deviation is found. Verified CAPA report from Internal audits where root cause and corrective action along with immediate actions are taken. Discussed earlier. Corrective and preventive action log CAL/5.0 dated 17.5.17.

3.8 Control of non-conforming product

Control of Non conforming procedure is documented CDI PM 3.0 dt 17.5.17 and outlines the segregation, inspection and further action for non conforming products identified.
Procedures are in place to handle the non-conforming product Quarantine area is marked. Identification is done through labelling.

3.9 Traceability

The company has established a traceability system through identification of batch codes, and product codes. Procedure for traceability CDI WI 6.5A dated 30.3.17.
All information are printed on product label as well as a system of recording the same in records and is

available which can be traced whenever challenged. Raw materials, rework materials and packaging materials are included in the traceability loop.

Internal traceability has been conducted for Back word dated 25.3.17 – Desiccated coconut batch number 170180 date of manufacture 18.1.17- Competed in 2.0 hours , product found traceable
Foreword traceability is conducted on 11.5.17 – Incoming Coconut quantity and supplier available in CDI NP form 4 nut receiving report, product found traceable and completed within 2.5 hour.
During audit a batch of Desiccated Coconut batch number 171290 dated 9.5.17 was selected. Total production is 100 bags each 25 kgs. Coconut supplied by Masod, Oden, Estellero, Florentino, Guitillo, Salem and Mukamad, packing material supplied by Innova Plus Davao. Mass balance is justified.
Batch of coconut water organic was tested for traceability. Batch number 171140 production 24.4.17, qty produced 37 drums each 265 kgs. Raw materials supplied by D. Yu from Glan, Mashoo from Maasim, Macana from Jenson, Anutan from Don Marcilino, Aulestis from Mati. All raw materials and ingredients are traceable to their suppliers through GRN numbers. Traceability study was finished within 2 hours in both cases, start time 3.30 Pm and end time 5.30 pm. Organic certificate for farmers are verified during traceability of organic product.

Suppliers approved by questionnaire have had their traceability system verified. Supplier of Soduim Metabisulphite was seen with GFSI certification. Coconut are farmed products and traceability is not applicable till farm level.

Re blanching is done at the Desiccated coconut process. Addition and modification of ingredients during production based on QC check are done at the time of production only.

3.10 Complaint handling

Complaint handling procedure CDI WI 6.5 dated 30.3.17. Total 2 complaints received in 2016 and no complaints YTD in 2017. One complaint is of wrong product code used and other regarding black thread seen in product desiccated coconut.
Complaint data are analysed and results of the analysis are discussed in management review.
Complaint is recorded in the Corrective action/preventive action report, verified format CPAR.CDI dated 9.8.16. Root cause analysis and corrective action were carried out.

3.11 Management of incidents, product withdrawal and product recall

Procedure for recall – CDI WI 6.5B dated 31.3.17. Recall procedure includes classification of recall into mandatory recall and voluntary recall and recall team. Notification to regulatory body defined and notification to certification body is defined within 3 days.

Crisis management procedure includes situations related with Natural disaster, Damaged food products, physical facilities and equipment, pest control and effect on employee. 24 hour contact details of recall team customer and regulatory authority and crisis management team was available. The contingency plan with each emergency was in place. Mock drill for emergency will be conducted once in year. Last conducted 24.4.17.

Mock recall will be conducted once in 3 months, No actual recall is conducted in the last 12 months. Verified Mock recall records dated 27.4.17. The batch selected Desiccated Coconut batch 170181-4 date produced 18.1.17. Mock recall started on 1.30 PM and ended on 4.30 PM, total time 3.0 hrs. All requirements are in place.

3.12 Customer focus and communication

No specific customer policies or requirements in place. Awareness of Labour laws and compliance to importing country regulations were sufficiently in place.

Suppliers are regularly updated on the raw materials requirements as well as some specific requirements of the customer. Supplier acknowledgement from supplier regarding Aseptic bags specification was seen from Giglio dated February 2014.

Details of non-applicable clauses with justification

Clause reference	Justification
3.5.4.1	No outsourced processing and packing
3.5.4.2	No outsourced processing and packing
3.5.4.3	No outsourced processing and packing
3.5.4.4	No outsourced processing and packing
3.12.1	No specific customer policies or requirements in place
3.12.2	No specific customer policies or requirements in place

4. Site standards

4.1 External standards

Local neighbouring activities are communities, land free and food factory – sister company as manufacturing of banana chip. The external area and overall grounds within site was managed and maintained suitable condition. There was no potential contamination risk for the local activities and environment around the factory. Building fabric was maintained to minimize potential for product contamination. Site boundaries were clearly defined and in maintained condition in order to prevent pest ingress.

4.2 Security

Security system was established as CDI-FSP-1.0 (05/03/2017) that based on risk assessment. Access to site of contractors, supplier and visitor has been controlled by registration at security guard at factory gate. Identification card must be tagged at all times in factory. The staff related site security has been trained. Reviewed training records for some staff, records were in place. Water treatment area, chemical storage and others were controlled access by mechanical lock all times. Only authorized person can access to store, warehouse of raw material, packaging material, finished product. Security system was reviewed annually basis and the last review was done on 02/05/2017.

The site has been registered with FDA of Philippines as LICENSE OF OPERATE – LTO no. CFRR-RX1-

FM-1818 valid until 23/09/2021 and US Bioterrorism as registration No. 19210226074 valid until 31/12/2018. Environmental permit number 2013-POA-H-1124-1674 valid until 20/08/2018. Business permit number 0333-2017valid until 31/12/2017.

4.3 Layout, product flow and segregation

Zoning was defied as low risk production area (preparation, blanching), ambient high care area (sorting, filling), Enclosed product area (warehouse) and non-production area which based on BRC zoning decision guild line. Factory zones are separated by physical barrier in different room. Site plans were established to demonstrate movement route of workers, production process, material, air ventilation and waste. Control measures are in place for each factory zone to prevent cross contamination such as control of personal hygiene and cleaning program, etc. Ventilation was appropriated controlled at ambient condition. Temporary structure was not observed during onsite verification.

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

Walls were constructed by concrete that maintained in good condition. Floors were coated by epoxy that maintained in good condition. There was no water stagnant on floor at drying and packing area. Process waste water goes directly to drainages. Drainages were maintained in good condition. Ceiling was constructed by hygienic design that maintained in good condition. There was no mould growth and condensation. Doors were closed fitting and did not open during production.

4.5 Utilities – water, ice, air and other gases

The utility within production line, storage area and other facilities were maintained in suitable condition which carried out maintenance activities by Engineering department. Source of water was deep well that was treated by softener and chlorinated. Water distribution plan was established and updated on 20/06/2016 and sampling plan for water quality inspection was in placed.

Sampling plan for water quality monitoring has been in place. Water quality was monitored by internal and external laboratories. Parameters tested by internal laboratory were TPC, *E.coli, Salmonella* and *Coliforms* as twice a month, chlorine residual as once a day and pH& hardness as 2 times/shift.

- Verified microbiological testing of water on Feb. - Apr. 2017
- Verified chlorine residua, pH and hardness monitoring on Feb. - Apr. 2017

The external testing was conducted according to Philippines Notification standard of drinking water. Verified testing reports as below,

- Full analysis – heavy metal of water as test report no. COA17-13460B (14/02/2017)
- Fully analysis – pesticide of water as test report no. 17CB-0384 (03/04/2017)
- Fully analysis – microbiological of water as test report no. WA-091-2017 (13/02/2017)
- Full analysis – heavy metal of steam condensate as test report no. COA17-13462B (14/03/2017)
- Fully analysis – microbiological of steam condensate as test report no. WA-09-2017 (13/02/2017)

Chemical agents as chemical no. ZI-CHEM 1221, 1670 and 1630 were used for anti-scaling and oxygen scavenger in boiler and these chemical complied with 21 CFR 173.310 to ensure that steam quality that directly contact with material during process was suitable for food used.
Compressed air was used for pneumatic control and used for cleaning process at DC production line. Air filter was changed annually basis as defined in maintenance plan and the last changing was done on 07/05/2017.

4.6 Equipment

Equipment were appropriately designed such as drilling machines, filtering equipment, pasteurization unit, packing machines, etc. The equipment has been specified prior installation and the commissioning has been done by engineering and related department. All equipment were located in proper position that enable access for maintenance and cleaning. Certificates of conformity related to food contact materials were observed such as belt conveyor as C22CF that complied with EU 10/2011, flexible rubber hose that complied with 21 CFR 177.2600 and stainless steel for mixing tank and other equipment.

4.7 Maintenance

The preventive maintenance and breakdown maintenance procedure was established, implemented and maintained. Preventive maintenance plan was established covering all equipment and machines that defined frequency as monthly, quarterly, every 6 months, annually and others and records were seen such as pasteurization unit for CWC, blanching machine, dryer and filter, sewing machine, metal detector, water treatment system, air compressor, boiler and others. Some machines were verified record such as machine no. OPS-CSC1, no. OPS-EBC, WGB-B2ST1-4, no. WGB-GR5, no. WGB-ULF4, DRS4-CF17, no. PKS6-BC, etc., the results found satisfy. All equipment and machines were located in proper position which easy to access and cleaning. Hygiene clearance procedure was in place after maintenance work and record were maintained. Engineering workshop was located on outside production area to prevent contamination risks to the product. Food grade lubricant was used for maintenance activities such as OMEGA 58 NLGI2 (NSF registration no. 132439) and non-allergen status were seen.

4.8 Staff facilities

Onsite verified staff facilities, they were maintained suitable condition and sufficient for all staff, e.g. toilet, canteen, hand washing station, locker, etc. Changing facilities were provided to all staff and visitors, e.g. hair cover, gown, mask, and footwear. Street clothes and protective aprons were found stored separately in the change rooms. Separate lockers and hangers were provided for the same. Hand washing facilities including liquid soap, hand drying facilities, alcohol spraying and washing instruction were sufficient provided at every access point. Toilets were located separated from production and storage areas. Designated smoking area was provided separately from production area and warehouse area. No evidence of smoking was observed out-of-designated area. Appropriate canteen was provided to staff's food storage to avoid the product contamination. Canteen building was separated building from production area.

4.9 Chemical and physical product contamination control

Raw material handling, preparation, processing, packing and storage areas

Chemical and physical contamination control were in place to manage the use, storage, and handling of non-food chemicals and others physical risks to prevent product cross contamination.

4.9.1 Chemical control

Chemical control procedure as QA-WP-A6.0 (20/03/2017) was established and maintained. Chemicals were listed and approved. They were stored in lockable area and identified by tag to prevent misuse and security purpose. Trained staff was responsible for control this room. MSDSs were available at chemical storage room. Verify some chemical agent such as sodium metabisulfite, detergent (Soilax), hand soap, isopropyl alcohol, etc.

4.9.2 Metal control

Metal control procedure CDI-WP-CP (19/05/2017) was implemented in processing area were registered and check for in-out daily basis to prevent contamination such as knives, sawing needle and others. Metal control policy was established and reviewed.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass policy and breakage control procedure was established, implemented and maintained as CDI-WP-CP (19/05/2017) that defined instruction for handling by registration, protection, and inspection weekly basis. Inspection records during Feb. – May 2017 were verified and no breakage issue were seen. Glass control instruction was established covering action to be taken in case of breakage of glass such as changing of work wear and inspection of footwear, inspection of area, and control of nonconformity products to ensure the product safety.

4.9.4 Products packed into glass or other brittle containers

N/A – No product packed into glass or other brittle containers.

4.9.5 Wood

Wood Policy has established, implemented and maintained as defined wooden material was not allowed in processing area. Wooden pallet was limited acceptable area such as storage area that products are enclosed in order to prevent contamination. During assessment, broken or damaged wooden pallet was not observed.

4.10 Foreign-body detection and removal equipment

4.10.1 Foreign-body detection and removal equipment

The foreign body detection equipment were metal detectors, magnets and sieves according to risk assessment as defined in hazard analysis.

4.10.2 Filters and sieves

Sieve has been used for sorting after drying step. Daily monitoring for its condition was carried out and recorded.

4.10.3 Metal detectors and X-ray equipment

Metal detectors were defied as CCPs of each product. Metal detectors were installed incorporate with machine stop, light and noise alarm. Sensitivity of detection was monitored and recorded. They were located at the end of the process after products are packed into primary packaging. 3 test piece types as ferrous, nonferrous and stainless steel were used for challenge test. Details of validation parameters for metal detector detection were considered and defined in validation report such as test piece size, sensitivity and rejection system. Relevant staff demonstrated understating of their task and procedure related to metal detector including corrective action plan.

4.10.4 Magnets

Magnets have been used. Their performance was monitored once a shift. Intensity of them has been monitored quarterly.

4.10.5 Optical sorting equipment

N/A – No optical sorting equipment in place

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

N/A – No container cleaning equipment used.

4.11 Housekeeping and hygiene

Cleaning programs were established for all areas such as production area and warehouse area (raw materials and finished products) include the surrounding area and cleaning equipment as defined in CDI-CLP-1.0. Programs have been specified covering the areas, items of equipment to be cleaned, responsibility, method/ chemical used and cleaning frequency. Cleaning staff were trained cleaning program and chemical used as plan. Cleaning equipment were stored in designed area. Cleaning records during Feb. - May 2017 were verified. Swabbing for cleaning effectiveness verification was carried out that covering equipment and machines as weekly as defined in CDI-QA-NPEM.1.0 Verified swabbing records on Feb. 2017 – present.

4.11.7 Cleaning in place (CIP)

CIP instruction has been implemented for cleaning in storage tank and piping system of coconut water concentrate line. Updated CIP schematic plan. CIP control parameters were established and monitored covering CIP schedule, cycle time, temperature and chemical concentration. Layout of CIP unit was observed such as pasteurization unit, blending unit, storage tank and others. pH of final rinse water was verified chemical residue after CIP process and to ensure in effectiveness of rinsing, Sampling checked the CIP record during March – May 2016, they were compliance with plan and specification. CIP validation was done on 14/02/2017.

4.12 Waste / waste disposal

Procedure of waste management was established and implemented covering general waste, recycle waste and hazardous waste. All waste types were segregated and disposed by authorized service provider such as Narcisso cubillo. Substandard trademark was destroyed by internal user before removed to third party. During onsite assessment, it was found that the waste collection container was clearly identified, well maintained, and cleaned as appropriate.

4.13 Management of surplus food and products for animal feed

Management of surplus food procedure was established and implemented as CDI-CPM-1.0. In case of surplus and out of specification of customer-branded products, customer brand name was removed and products inside was treated according to rework and reprocess handling procedure according to the nature of problem. There was no by-products and downgraded/ surplus products intended for animal feed.

4.14 Pest Control

Pest control procedure was established, implemented and maintained as CDI-PCP-2.0 (01/02/2017). Pest control service was performed by Chemsol Industries (service period 1 Feb. 2017 – 31 Jan. 2018) covering target pest as ants, cockroach, rodent, insect and others. Pest service and inspection was performed by trained staff of service provider as plan. Updated maps of baits, glue trap and insect light trap were available as in CDI-PCP-RBS1.0 (01/02/2017). Service reports in 2017 were verified with service details. Training records of service providers were maintained such as Alex B. Astchalian. Using of pesticide complied with local regulation and MSDS was provided, e.g. Klerat; Brodifacoum (registration no. HSR-5805), etc. Pest inspection results were analysed and identified trend. In depth pest survey was done yearly basis by service provider and the last survey was done during Jan – April 2017 by Alex B. Astchalian. Recommendation from expert was consider to correct problem and improve pest control program. All factory staff were provided training on GMP on 22.4.17 where they were informed about pest sighting and subsequent reporting to nominated personnel.

1 minor CAR was raised – see CAR attachment.

4.15 Storage facilities

Raw material, packaging material and finished product were clearly kept in segregate building area as ingredient store, packaging store and finished product warehouse to prevent cross contamination. Material was stored off floor and easy access to cleaning and cleaning records during Feb. – May 2017 were verified. Some finished products as frozen coconut water concentrate were stored under temperature control $\leq$ -18 ^{o}C and temperature record was performed by production staff hourly basis. Storage procedure has been established, implemented and maintained. The scope of procedures was defined covering cleaning storage areas and vehicles, avoid cross contamination or taint uptake, FIFO system. Identification of each item was attached in each material the labelling tag to indicate item name, receiving lot no., supplier, item's manufacturing lot and quantity. Incoming materials were inspected by Store and QA staff which inspected in the quantity and quality of materials as the requisition specific. Verified material storage onsite, e.g. packaging storage room, raw material storage including finished product in cold storage, they were maintained suitable condition.

4.16 Dispatch and transport

Procedure of finished product dispatching and transportation was established and implemented as defined in CDI-WP-WH5.0 (16/03/2017). Transportation was carried out by service provider and contract were seen covering BRC requirement clause 4.16. Container was checked condition, cleanliness, pest and temperature (for frozen product only). Receipt document, product identification label on pallet, stock card, order sheet were facilitated for traceability and transportation. Delivery records was detailed the container inspection, lot number of finished product, product quantity, container and seal number. Record of transportation was maintained. Instructions in the case of vehicle breakdown, accident were defined in transportation control procedure.
Sampling delivery record, such as

- Contract no. 4500329107, loading on 2 March, 2017 export to USA for product coconut water concentrate (organic) Lot no. 163470-4, total 837 bags, container no. CMAU 831844-0, seal no. FG 285717
- Contract no. 038C, loading on 17 May, 2017 export to Japan for product desiccated coconut (sulfited free) Lot no. 171240-4, total 520 bags, container no. NYKU 973453-4, seal no. PH 1073342
- Contract no. M8024, loading on 18 May, 2017 export to UK for product desiccated coconut

(sulfited 50 ppm.) Lot no. 171290, total 285 bags, container no. TEMU 020719-0, seal no. YMLL 409524	
Details of non-applicable clauses with justification	
Clause reference	**Justification**
4.2.3	No external storage tanks, silos or intake pipes with external opening.
4.3.5	No high-risk areas defined
4.2.3	No external storage tanks, silos or intake pipes with external opening.
4.3.5	No high-risk areas defined
4.3.6	No high-care areas defined
4.3.7	No ambient high-care areas defined
4.3.9	No temporary structures constructed
4.4.4	No high-risk / high-care areas defined
4.4.6	No suspended ceilings or roof voids present
4.4.13	No high-risk areas defined
4.5.3	No legislation that specifically permits the use of water which may not be potable for initial cleaning.
4.5.4	No air, other gasses used in direct contact, or as ingredient in, products. No compressed air used directly in contact with the product.
4.8.4	No high-risk areas defined
4.8.5	No high-care areas defined

4.10.5.1	No optical sorting equipment in place
4.11.7.1	No CIP
4.11.7.2	No CIP
4.11.7.3	No CIP
4.13.1	No customer branded products made
4.13.2	No customer branded products made
4.13.3	No products intended for animal feed
4.14.3	The site doesn't undertake its own pest control
4.15.3	No temperature control is required
4.15.4	No controlled atmosphere is required

5. Product control

5.1 Product design/development

New product development procedure: CDI-FSM-01 (28/04/2017) has been established as guideline for restrictions to scope of new product. Hazard analysis and related regulations review were conducted and considered by QA. However there was no new product during 2016-2017. Shelf life study of new product will be studied that covering safety such as microbiological, quality and sensory evaluation as defined in CDI-SLP-10.

5.2 Product labelling

Product labelling including allergen information has been reviewed by QA to confirm all information that presented on labels to meet legal requirements for the designation country of use. However there were no retailed packed products in this site. Allergen information were identified on packaging for communication to their customers. Individual lot has been identified on each packaging for traceability supporting. There was no any claim regarding nutrition and others.

5.3 Management of allergens

Control of allergen has been identified in CDI-WP-A1.0 (27/04/2017). Risk assessment was analysed covering allergen. Allergen information was provided by questionnaire that carried out by suppliers. Allergen list was in place. Allergens at this site were coconut and sodium metabisulphite (sulphur dioxide). Training of allergen knowledge was provided to all concerned staff.

5.4 Product authenticity, claims and chain of custody

Documented of vulnerability assessment has been in place as CDI-PAVP (05/05/2017) that conducted on 05/05/2017 for coconut and sodium metabisulphite. Potential risk of adulteration or substitution was identified based on historical evidence that get from web site and news, economic factors that considered from raw material costing, ease of access to raw materials through the supply chain, testing method and natural of raw materials. All of raw materials were determined to low levels of adulteration or substitution.

Traceability with mass balance was carried out for organic product every lot of production. Summary of it was maintained. Organic certificate was found valid, verified PH-2016-119094-Z-40-903-2016 valid upto 6.6.17.

5.5 Product packaging

Product packaging and contracted sheets were inspected before receiving. Testing report was available for plastic bags and aseptic bags which primary packaging. Verified testing reports as test report no. PHL16-08952 (07/10/2016) for plastic liner (LDPE) for chemical migration of plastic bag and test report no. FDD01G00872.9001 (26 /09/2014) for aseptic bag (laminated PE) for chemical migration of aseptic bag. A part-used packaging material suitable for use was protected by plastic bags from contamination and clearly identified before return to storage.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Inspection and testing schedule for all process steps has been in place and recorded such as % moisture, particle size, FFA, % residual oil of finished products. Verified testing records of finished product on Feb.-Apr. 2017.

Finished products were sampled to verify against their specifications and related regulations by external accredited laboratory as below,

- Pesticide of white meat as test report no.COA17-13324 on 09/02/2017
- Pesticide of desiccated coconut as test report no.COA17-13324 on 09/02/2017
- Heavy metal of desiccated coconut as test report no. PHL17-00600-01 on 31/01/2017
- Microbiological of desiccated coconut as test report no. PHL17-00600-01 on 31/01/2017
- GMO of desiccated coconut as test report no. PHL17-00600-01 on 31/01/2017
- Mycotoxin of desiccated coconut as test report no. PHL17-00600-01 on 31/01/2017
- Pesticide of coconut juice concentrate as test report no.COA17-13613A on 28/02/2017
- Heavy metal, Microbiological of coconut juice concentrate as test report no. PHL17-01023 on 16/02/2017
- Patulin of coconut juice concentrate as test report no. PHL17-01023 on 16/02/2017
- Nutrition testing of desiccated coconut as test report no. CQ1703-2050-01 on 02/03/2017

- Nutrition testing of coconut juice concentrate as test report no. CQ1702-1632 on 21/02/2017

All results of testing complied with their specifications.
Ongoing shelf life was implemented according to procedure: CDI-SLP-10. Sensory and microbiological was carried out at starting and end of shelf life.

5.6.2 Laboratory testing

Internal laboratory building has been located separated from production and storage area for chemical and physical check. There was no contamination risk from chemical which used. Good laboratory practice has been applied for internal laboratory. Procedure of hygiene control, access movement, and waste management of internal laboratory is in place for implementing as defined in CDI-M-ML1.0 (02/01/2017). Recognized methods have been used for testing such as BAM online for microbiological and AOAC for chemical testing.

Ring test has been conducted with their customer for lab staff evaluation. Verified ring test report on 31/03/2017 for Salmonella, 09/03/2017 for E. coli. Accredit external laboratories have been used for testing such as heavy metal of water analysis, heavy metal and microbiological testing of finished product such as F.A.S.T Laboratories, SGS Laboratory.

5.7 Product release

Product release procedure: was in place for implementing. Final inspection was performed by organoleptic, chemical and microbiological test for every production date of each product. The results of them were verified and signed off for release by QA manager. Verified release records of products which loaded for contract no. Contract no. 4500329107, for product coconut water concentrate (organic) Lot no. 163470-4, Contract no. 038C, for product desiccated coconut (sulfited free) Lot no. 171240-4, Contract no. M8024 for product desiccated coconut (sulfited 50 ppm.) Lot no. 171290.

Details of non-applicable clauses with justification

Clause reference	Justification
5.2.3	No claims made to satisfy a consumer group (no nutritional claims)
5.2.4	No customers or nominated third party responsible for label information
5.3.5	No rework used or reworking operations carried out
5.2.3	No claims made to satisfy a consumer group (no nutritional claims)
5.4.5	No claims made about the methods of production

6. Process control

6.1 Control of operations

All parameters and CCP that defined in procedures and HACCP plans were monitored and recorded such as metal detector, pasteurization temperature/time, blanching temperature/time etc. Records were maintained and verified by supervisors. Process parameters were validated to confirm quality of product had been met to specifications. Records of correction when the process control parameters deviated were maintained and verified by supervisors and food safety team.

6.2 Labelling and pack control

Documented procedure for labelling and pack control was in place as CDI-WP-PMP. Packaging type was specified in ordering. In addition, there was a system to verify packaging type before using. The packing process was verified by QC and production to ensure the products were packed into correct packaging and correct label, in good appearance, correct product coding, MFG and expiry date as specification or customer required. Package clearance was implemented and packaging was moved out before start the new product or formula and check by production and QC. Verify some product such as desiccated coconut Lot 170090-4, desiccated coconut “Organic” Lot 163470-4, Desiccated coconut SO2 free Lot 171240-4.

6.3 Quantity, weight, volume and number control

All products were packed in bulk pack which controlled by weight as defined on packaging regarding customer requirements. Product weight was verified at starting of operation for 3 bags. The weighting inspection records were maintained in CDI-QCP-BTWC. Sampling some product such as desiccated coconut Lot 170090-4, desiccated coconut “Organic” Lot 163470-4, Desiccated coconut SO_2 free Lot 171240-4.

6.4 Calibration and control of measuring and monitoring devices

Calibration plan and procedure: CDI-WP-A7.0 of measuring devices which impacted to product safety and quality was in place. Permitted error was identified for acceptable. Calibration status was identified by tag that placed on equipment. Calibration was performed by external laboratory. Calibration reports/ certificates were maintained. Verified calibration reports/certificates of measuring devices as below,

- Moisture analyzer of desiccated coconut
- Thermometer, report no. 0317PPM1204 on 14/03/2017
- Thermometer, report no. 0317PPM0976 on 13/03/2017
- Digital balance, report no. 0317PPM1198 on 14/03/2017
- Digital balance, report no. 0317PPM1199 on 14/03/2017
- pH meter, report no. 0317PPM1221 on 14/03/2017
- Analytical balance, report no. 0317PPM1213 on 14/03/2017
- Incubator, report no. 0317PPM1234 on 15/03/2017
- Water bath, report no. 0317PPM1236 on 15/03/2017
- Auto clave, report no. 0317PPM1247 on 15/03/2017

Details of non-applicable clauses with justification

Clause reference	Justification
6.2.4	No on-line vision equipment used to check product labels and printing

7. Personnel

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

Training plan was established covering OJT, food safety awareness, food defence procedure and others based on training need survey and updated yearly basis and provided for concerned staff carrying out the tasks critical to the effective implementation of the BRC Global standard for Food Safety issue 7 and the maintenance of food safety, regulatory requirements, and quality. It was outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with food safety and quality system. Qualification and experience were defined in Job description, including training need. Yearly program for Food safety and Hygiene course including on the job training was established and maintained based on training need survey. Records of training course contained name of trainer, name of trainee, content, training date with duration. Methods of evaluation were examination test, interview, and observe work performance. Training evaluation was conducted and record was maintained. Verified training record according to yearly training plan, e.g. Site security on 29/04/2017, allergen awareness on 25/03/2017, GMP and HACCP on 22/04/2017, etc.

Refresher training was provided to all staff as defined in Yearly Training Plan such as HACCP System and CCP monitoring refresher training courses that were provided to all staff who were relevant to CCP point. HACCP training was provided for all staff who involved in developing and maintaining food safety plans and food quality plans and refreshed training was done annually basis.

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

Hygiene requirements was established and implemented as CDI-CM-02 covering standard required for all employees, visitors and contractors. Compliance with hygiene rule was checked by sanitation staff prior entering in production line and storage area. Hand washing program established is before entering production area and leave the toilet. All cuts and grazes on exposed skin was covered by blue metal detectable strip that the last lot 256AE was tested with metal detector record was maintained. Personal medicine as placed in personnel locker.

7.3 Medical screening

Medical screening policy and procedure were implemented and maintained throughout the organization covering all employees, visitors and sub-contractor. Medical check-up was conducted annually and illness of operator has been controlled by HR department. In case of infectious disease, staff was moved to work in low risk area and re-screening was required. Refer to procedure, a system for the notification by employees, including temporary employees, of any relevant infection or disease was established and maintained. Employees must notify their supervisor about illness. Personal hygiene and medical screening was applied for all staff in production, storage area and also visitor who have to filled-in the health questionnaire prior entry production and storage area.

7.4 Protective clothing: employees or visitors to production areas
Company provided protective cloth for staff, contractor and visitor before entering to process area and removed when leave the processing area and storage area such as hair cover, plastic apron, plastic glove, plastic boot which apron and boot were in-house laundry. Laundering of protective clothing was done by in-house according to written guidance as CDI-WP-QAH2.0 (04/05/2015) and verified effectiveness of cleaning by visual inspection and swabbing. The verification of cleanliness was conducted by production leader daily as well as swab regarding plan.

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.4	No high-risk / high-care areas defined
7.4.7	No items of personal protective clothing that are not suitable for laundering are provided.