Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary			
Company name	Primex Coco Products Inc.	BRC Site Code	1435598
Site name	Primex Coco Products Inc.		
Scope of audit	The Manufacture of Desiccated Coconut, Coconut Milk Powder, Low Fat Desiccated Coconut, Coconut Flour in PE liner within kraft bag and box, Virgin Coconut Oil in PE liner within Paper IBC and Steel Drums and Frozen Coconut Water Concentrate in PE liner within steel drum and in PE liner within pails, Coconut Butter Paste in PE liner within pails, Coconut Butter Spreads, Creamed Coconut in PE liner within pail, Virgin Coconut oil in glass jar.		
Exclusions from scope	None		
Justification for exclusion	None		
Audit Finish Date	2017-05-25		
Re-audit due date	2018-05-28		

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	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2016-05-23		

Number of non-conformities		
	Fundamental	0
	Critical	0
	Major	0
	Minor	9

3.Company Details

Address	Bo. Mangilag Sur, Candelaria, Quezon, Philipines		
Country	Philippines	Site Telephone Number	+63425858764
Commercial representative Name	Ms. Fatima Velasco	Email	sales@primexcoco.com
Technical representative Name	Ms. Melba C.Garcia	Email	qualityassurance@primexcoco.com

4.Company Profile

Plant size (metres square)	>25K sq.m s	No. of employees	51-500	No. of HACCP plans	>8

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. CFRR-RIV-FM2222
Major changes since last BRC audit	There is no major change in process since last audit. Two new products have been added in the scope, coconut butter paste/ creamed coconut and virgin coconut oil in glass jar. New cold storage constructed for Coconut water line, infrastructural improvements like flooring, laundry and magnets installation was done.

Company Description

Company has been started 1991 with the capacity of 7500 metric tons of desiccated coconut.Currently its one of the leading of desiccated coconut brand in the world having 25000 MT capacity. Factory is located in Candelaria, Quezon. The products are mainly exported to USA, EU countries, Japan, Australia etc. Currently they have 9 factories in Philippines for oils and coconut and Banana. The equipments include nut breakers, grinders, dryers, coconut milk extraction units, metal detectors, oil extraction units, dumping trucks for raw coconut carrying. Total approximately 450 workers are working in 3 shifts. Site area is 5 acres and built up area for manufacturing is 30900 sq mts.

5.Product Characteristics					
Product categories	07 - Dairy, liquid egg 15 - Dried food and ingredients 18 - Oils and fats Category				
Finished product safety rationale	Desiccated Coconut moisture 3.7-4.5% with shelf life of 6-8 months, Coconut milk powder moisture 2.5 % with shelf life 18 months, Coconut Flour Moisture below 3%, Concentrate: Coconut water concentrate pasteurization (temperature > 92 deg C, time 42 seconds) and keeping frozen condition (-18 deg C). Coconut oil and coconut butter paste is with low moisture max 2% and inhibit bacterial growth, creamed coconut with 2% moisture content and 1 year shelf life.				
High care	No	High risk	No	Ambient high care	Yes
Justification for area	Products are Ambient stable.				
Allergens handled on site	Sulphur dioxide and Sulphites Milk Other 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, coconut oil, coconut butter paste and creamed coconut				

6.Audit Duration Details			
On-site duration	32 man hours	Duration of production facility inspection	16 man hours
Reasons for deviation from typical or expected audit duration	None		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2017-05-24	0800	1700
2	2017-05-25	0800	1700

	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
Topi U.Mali - Plant Manager	√	√		√
Melba C.Garcia - QA Manager	√	√	√	√
Michael D Prado– DCN production Manager	√	√		√
April Bantucan, Internal Audit Incharge	√		√	√
Hernani M Malabanan, HR Coordinator	√			√
Rodrigo A Castillo – CMP Production Manager	√	√		√
Arnold B Patelot, CWC Production manager	√	√		√

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 SO2 Non Conformity is not seen with appropriate target set, some of the objectives are not realistically set viz. foreign matter contamination target zero and Customer complaints target zero. SO2 non conformity objective target is set to**	A management meeting was done, discussed criteria of the Food Safety and Quality Objective to verify need to change and improve.	**Root Cause:** The FS team did not consider all targets to be measurable and specific. **Preventive Action:** - The HACCP team shall convene a meeting to assess and revised the objective criteria to	• Revised Food Safety and Quality Objectives • HACCP Team attendance Sheet of the meeting regarding Food Safety and Quality	2017-06-20	Sarit Chowdhury

		0.2%, however the system did not provide for control of the same by volume.		be more measurable and specific. **Target Date: May 31,2017**	Objectives		
2	2.7.1	**The hazard analysis does not adequately address hazards related to organic production of coconut, e.g the receiving of coconut is 7nalysed for conventional and not for organic coconuts.**	The HACCP team did a meeting conducted hazard analysis of organic coconut for organic production including documentation for organic production.	**Root Cause:** The HACCP team failed to include the hazard analysis of the organic coconut and its process. The current system is the organic receiving is written in the organic documentation program. **Preventive Action:** - Shall conduct Hazard Analysis of organic coconut including its process to address the cleaning of equipment prior to organic production and to incorporate documentation in the existing Food Safety system. **Target Date: June 1,2017**	• Organic Desiccated HACCP Manual that includes the hazard analysis for organic coconut • HACCP Team attendance Sheet of the meeting regarding Hazard Analysis of Organic Coconut	2017-06-20	Sarit Chowdhury
3	3.4.1	**The program of BRC audit does not define 3 monthly audits as the risk**	- Renewal of subscription to BRC participate	**Root Cause:** The subscription on BRC participate has already	• Internal Audit Plan aligned with BRC	2017-06-20	Sarit Chowdhury

		assessment is based on 6 biannual or annual audits.	and align the internal audit frequency based from the BRC participate IA Memo was done	expire. **Preventive Action:** - Shall check the validity and renew the subscription at least one month prior to expiration date. **Target Date: June 5,2017**	Participate Memo • Verification Plan		
4	3.6.1	**Documented specification for Metal closures for Virgin coconut oil in glass jars was not available.**	- Specification for Virgin Coconut Oil metal closure of glass jar was established.	**Root Cause:** There was a failure to establish company's own specification for the metal closure of glass jar. **Preventive Action:** - Shall establish final specification of the metal closure. **Target Date: June 1,2017**	• Revised Glass Jar with Metal Lid Specification Sheet that includes specification for the metal closure.	2017-06-20	Sarit Chowdhury
5	4.6.1	**The Product Virgin coconut oil in glass jar has been newly added to scope, however during audit, adequate provision of sealing and ink jet printing of jars after filling was found not available.**	- Completed sealing and printing set up in VCO in glass jar production.	**Root Cause:** There was some delays on the receiving of the additional set up prior to the audit. **Preventive Action:** - Shall make a follow up in the purchasing	• Copy of invoice (as proof of purchase) of the Ink jet labelling machine and Automatic Shrink Sleve Applicator (Sealing).	2017-06-20	Sarit Chowdhury

				department to expedite the order of ink jet printing and sealing. **Target Date: June 12,2017**			
6	4.9.1.1	**Processes have in place to manage storage and handling of chemical agent to prevent contamination, however some chemical storage such as sodium meta bisulphite in Desiccated Coconut production line and boiler chemical near stockroom found not locked during on site verification which was not in compliance with the control procedure QA-SP-01B(13/06/2016)**	- Padlock for Sodium Metabisulfite and Boiler chemical storage were provided.	**Root Cause:** There was a failure of the personnel in-charge to lock the areas of chemical storage. **Preventive Action:** - Re-training shall be conducted to all personnel in-charge in all chemical storage. **Target Date: June 2,2017**	• Photo of Sodium Metabisulfite Storage in Desiccated Coconut production line, with pad lock. • Photo of Boiler Chemical Storage with pad lock • Retraining attendance sheet of the personnel in-charged in chemical storage.	2017-06-20	Sarit Chowdhury
7	4.14.1	**The production and storage area have an effective preventive pest control programme in place to minimise risk of infestation, however some pest sighting like dead cockroach on the floor of**	- Cleaning in the CMP area was done and pest control provider were informed to install insect light trap in the	**Root Cause:** - Lack of installed glue traps in the CMP ingredient room. - The pest control provider failed to	• Photo of additional Sticky Glue Trap in CMP Ingredient Storage • Photo of newly installed Insect	2017-06-20	Sarit Chowdhury

		CMP ingredient room was evident. **However all materials were fully covered to prevent contamination. Provision of insect killer in loading bay of coconut water concentrate was not seen.**	loading bay of Coconut Water Concentrate	assess the needs of installing the insect killer in loading bay of coconut water concentrate. **Preventive Action:** - Shall installed additional glue traps in the CMP ingredient room. - Shall installed insect light trap and a plastic curtain in loading bay of coconut water concentrate. **Target date: June 1,2017**	Light Trap (ILT) and plastic curtain in Coconut Water Concentrate loading bay.		
8	5.2.1	**The label design of Organic coconut oil in glass jar has not been finalized yet. Completion of approval process was on going at the time of audit.**	- The label for organic coconut oil in glass jar finalized.	**Root cause:** There was a failure to complete and have the final approval prior to the audit process of the label design of the Virgin Coconut Oil in jar. **Preventive Action:** - The FS team shall finalize the labelling and shall process the approval prior	• Copy of Finalized Organic Virgin Coconut Oil in Glass Jar label	2017-06-20	Sarit Chowdhury

				to the final printing. **Target Date: June 5,2017**			
9	6.2.2	**Change over process between coconut butter paste and creamed coconut which are made on the same line are not adequately defined. No change over checklist has yet been defined.**	- Changeover process procedure and checklist between coconut butter paste and creamed coconut established and implemented.	**Root Cause:** The change over procedure and checklist is not yet fully establish and implemented prior to the audit. **Preventive Action:** - The QA and production team of Coconut Butter Paste and Creamed Coconut shall convene a meeting to establish the procedure and full implementation shall follow. **Target Date: May 31,2017**	• Changeover Process Procedure • Change over Process Awareness meeting attendance sheet	2017-06-20	Sarit Chowdhury

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 30.1.16 and signed by E M Umali, Plant Manager, is communicated by trainings and display in prominent places. Quality and Food Safety Policy is reviewed annually, last reviewed on 11.1.17. Verified review records.
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 organization is set with timeline January 2017 to December 2017.

Objectives are fixed for receiving of husked nuts, volume, rotten nuts %, for opening section foreign matter presence in the product, wet section SO2 non conformity, Total production in the dryer section, reduction of bag damage, pest infestation at warehouse, Microbiological criteria's, customer complaint reduction and product quality related objectives. Objectives are getting monitored monthly, verified monitoring record PCPI-FSQC-1.0 Summary record dated January to April 2017. **Some of the objectives like SO2 Non Conformity is not seen with appropriate target set, some of the objectives are not realistically set viz. foreign matter contamination target zero and Customer complaints target zero. SO2 non conformity objective target is set to 0.2%, however the system did not provide for control of the same by volume. Minor CAR**

Management Review conducted 12 monthly and last management review completed on 5.5.17. Verified action plan of MRM in Minutes of management meeting, attended by Plant manager and Managing Director. Action plan for MRM was seen with status of the projects and completion timeline.
Monthly meeting is conducted every month for HACCP and other criteria's. Verified record for monthly meeting on issues like Updates, Food Safety objectives and Hygene and fabrication on 13 march 2017 and 10.5.17 been most recent after April meeting. 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
08 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 is defined. Organisation chart is updated on 12.5.17 (PCPI-HR-OC). Organization job responsibility for Production supervisor JDM 13 and DCN Production manager JDM 3 and spray dryer operator CMP JDM 3 was verified.

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. Melba C Garcia is appointed as HACCP team leader. Bachelor of Medical Technology with 25 years of experience in same industry, BRC issue 7 trained on dated 10-11.9.15 and also on ISO 22000:2005 awareness, Team members are trained in various related topics including food safety. Verified Food Safety training record of Consuelo B Salas dated 21.11.13.

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.

9 HACCP plans are identified in the present sites which are mainly grouped. Frozen coconut water concentrate, Desiccated coconut, Coconut Milk Powder, Low fat Desiccated coconut, Organic Virgin Coconut oil, Organic coconut flour, Coconut water concentrate, Organic Coconut Butter Paste, Organic Creamed Coconut, Virgin coconut oil in Glass jars. 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. Intended use of product is indicated for general population and sensitive population.

Flow diagram Desiccated Coconut/ low fat Desiccated Coconut: Nut opening, paring, sorting of meat, washing, sulphite treatment, blanching, drying, shifting, packing, metal detection, dispatch.

Flow diagram Frozen Coconut water concentrate: Storage, pre heating, oil separation, pasteurization, cooling, chill storage, pre heating, evaporation, cooling, filling, blast freezing and storage.

Coconut milk powder - Extraction of milk, pasteurization, cooling, storing, reheating, blending, filteration, reheating, homozenization, spray drying, fluid bed drying, sieving, packing and dispatch.

Organic virgin coconut oil /Coconut oil in glass jar– Desiccated coconut as raw material, expelling, screening, Sharplex filtering, polishing, oil separator, polisher 5 microns, packing dispatch. For Glass jar, same goes for another polishing 5 microns, filled in glass jar, capping, packing, labelling and dispatch.

Coconut flour – Oil cakes from Desiccated coconut after oil extraction – pulverizing, shifting 2mm mesh, filling and packing, metal detection dispatch.

Flow diagrams are available for all process. Verified document PCPI-FSM/BRC-01 addendum 1-7. Flow diagram verification was last done on 10.3.17.

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. **The hazard analysis does not adequately address hazards related to organic production of coconut, e.g the receiving of coconut is analyzed for conventional and not for organic coconuts. Minor CAR.**

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.

Coconut water

1. In line Vibrio filtration – CL – as per CPG sec 555.425 of USFDA, mesh size is 200 mesh
2. Pasteurization – CL 92 deg C for 42 seconds

Desiccated Coconut (sulphited)

1. Blanching – CL 190Deg F, 9 minutes, monitored hourly.
2. Product instection for physical hazards – CL absense of foriegn matter, monitored 2 hourly.
3. Metal detection Fe 1.5mm, NFe 1.8 mm and SS 2.0mm. Monitored hourly.
4. Sulphiting – CL sulphite levels as per customer requirements or between 50 ppm as per granule size., monitored every 30 minutes.

Virgin Coconut Oil

1. Final Polishing (SS Filter, Cloth) – CL absence of metal and injurious fragments in ginished product VCO

Coconut Milk Powder

1. Pasteurization – CL 72 deg C for 15 secs monitored every 15 minutes.
2. Metal detection – CL Fe 2 mm, NFe 2.5 mm and SS 2.5 mm. Monitored every 30 minutes

Coconut Flour

1. Metal detection – CL Fe 2 mm, NFe 2.5 mm and SS 2.5 mm. Monitored every 30 minutes

Coconut butter paste and creamed coconut

1. Metal Detection- CL Fe 2 mm, NFe 2.5 mm and SS 2.5 mm. Monitored every 30 minutes

CCP monitoring is done as per plan and record maintained, these dated, signed and verified. Verified Process log for Coconut Oil, Coconut milk powder, desiccated coconut and coconut water dated 24.5.17.

Pasteurizations, Sulphite application process has been validated based on the concentration of the soaking liquor and resultant sulphite content of the meat. Verified Validation report of in house validation PCPI VRS-01 dated 15.5.17, Blanching validation based on microbiological testing of end product was seen dated 26.4.17 and Metal detector validation dated 7.11.16 was seen, Validation of stainless screen filter dated 13-17.3.17 for Coconut oil polisher was seen. Also external validation of critical process viz. Blanching was carried out. Verified validation report by Campden BRIdated 16.11.16, Report number MB/REP/137393/Candelaria/2.

Frequency of HACCP review is 12 monthly or whenever any significant change. HACCP was last reviewed on 6-10.3.17 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 PCPI-FSM-BRC/01 dated March 2017. 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. Relevant SOPs have been translated in local language and displayed in prominent places.

3.2 Documentation control

A procedure for effective documentation and record control is in place DDC SP 02 dated 18.11.16. 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 DDC SP 02 dated 18.11.16. 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 concentrate where shelf life is 2 years as mentioned process wise. Record correction is mentioned, where signature to be included in order to authorize a correction of record.

3.4 Internal audit

Internal audit procedure QA SP 09 dt 10.6.16. The Internal audit frequency has been prepared based on a risk assessment of the processes involved and has higher frequency for higher risk process. Verified document QA SP 03 dated 8.3.16. **However the program of BRC audit does not define 3 monthly audits as the risk assessment is based on 6 biannual or annual audits. Minor CAR**. Internal audit team comprise of 18 internal auditors, additionally there are 7 field inspectors who are monitoring the farms including the Organic farms. The field inspectors are trained in organic standards. Verified training record for Roseanne Salamat dated 29-30 September 2016 by Ecocert. List of Internal auditors was seen, Internal auditors are trained, verified training record dated March 15 2017, by April D Bantucan. The auditors do not audit their own work. Internal auditor training of April D Bantucan seen dated 1-2-12-2016

from external.

Last Internal audit is conducted on 6 April 2017. Covered all processes. Verified report for Quality Assurance internal audit by Temberly Queto dated 29.3.17 covering BRC standard requirements. Observations were identified and raised non conformities. 12 Non conformities raised and reported in separate formats with root cause, corrective action and verification by auditor for closure. Timelines for closure of non conformities are agreed at the time of audit. CAPA report CPAP/5.0 dated 6.4.17 was verified. CAR no. KDM17-001.

Monthly housekeeping and fabrication inspection is conducted report was seen in GMP & HK audit checklist, dated 26.4.2017.

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. 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 Primex Plant. Exceptions are addressed. Coconut being a bulk agricultural product has been considered under exception and the compliance of the raw material is mainly determined at the time of receiving through incoming inspections and sorting.
Raw materials are Coconut, organic coconut, sodium metabisulphite, sodium caseinate, maltodextrin. The agents and brokers are used from coconut supply as well as packing material supply and audited with questionnaires. Verified the assessment questionnaire from Sodium Metabisulphite supplier in Germany BASF dated 3.3.17. The supplier has GFSI certification viz. BRC and FSSC, certificates seen. Verified self assessment questionnaire from ZPK Agrocomplex Poland for Caseinate supply dated 28.1.17. Kraft paper supplier Soligbag Packaging audited 24.3.17 and questionnaire filled March 2017. Coconut are supplied by traders directly from farms. Coconut supply is subjected to incoming inspections and the same is recorded. Verified farm audit report of De Torres dated 10.1.17. Verified farm audit report of Organic farmer ROmel De Vera dated 13.1.17 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 Sodium Caseinate – PMX DCNC P65 dated 22.5.17, COA from supplier dated 9.3.17 and heavy metal report 30.1.17, Kraft paper incoming inspection report PCPI CH WH01 dated 28.2.17, COA from supplier dated 28.2.17. Conventional coconut receiving report – PCPI DNRR 01 dated 18.4.17, external laboratory test report for raw coconut for Aflatoxin report number PHL1702258-13 dated 19.5.17. Organic coconut receiving report PCPI DNRR 01 dated 11.5.17. Organic material is received along with a transmittal checklist signed by the Field inspector. Verified report dated 10.5.17.

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, waste disposal etc. Service contract verified with labour contractor Peshimel Manpower services dated 2.2.17.

Contract with Pest control services – Chemsol Industries dated 10.4.17.

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 QA PS 02 dated 29.1.16 was verified, reviewed 20.3.17. Virgin Coconut Oil QA PS 11 dt 20.3.17. Organic coconut flour QA PS 12 dt 29.1.16, reviewed on 20.3.17, Coconut water concentrate QA PS 13 dt 20.3.17, Specifications for Coconut milk powder seen documented QA PS 15 dt 29.1.16. Specifications for Coconut butter paste QA PS 19 dt 20.3.17, Organic creamed coconut QA PS 20 dt 20.3.17.
Specification for Sodium Caseinate QA TS 01 dated 29.1.16, last reviewed 20.3.17. Specification of Kraft paper QA TS 07 dated 29.1.16, reviewed on 20.3.17. Specification of raw coconut PD DP -01 dated 28.1.17.
Last review of specification on 20.3.17, reviewed every 3 years or as required. **Documented specification for Metal closures for Virgin coconut oil in glass jars was not available. Minor CAR.**

3.7 Corrective and preventive actions

Corrective action procedure is detailed in QA SP 05 dated 29.7.16.
Correctives action is detailed, However this unit is recently no major deviation is found. Verified CAPA report from Internal audits and customer complaint addressing where root cause and corrective action along with immediate actions are taken. Discussed earlier. Corrective and preventive action log CPAR/5.0 dated 18.1.17. The CAPA raised out of In process insection.

3.8 Control of non-conforming product

Control of Non conforming procedure is documented QA SP 04 dt 10.6.16 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. Hold products are classified into category 1 hold with major food safety risk and category 2 hold with minor food safety risk.

3.9 Traceability

The company has established a traceability system through identification of batch codes, and product codes. Procedure for traceability QA SP 23 dated 29.7.16.
All information are printed on product label as well as a system of recording the same in production logs 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 162313 date of manufacture 18.8.16- Competed in 2 hours 30 minutes , product found traceable
Foreword traceability is conducted on 14.5.17 – Incoming Sodium Metabisulphate quantity 1500 kgs and supplier Will Ann International, product found traceable and completed within 1.5 hour.
During audit a batch of Desiccated Coconut batch number 1713501920 date of production 15.5.17 was selected. Total production is 1564 bags each 100lbs. Coconut supplied by Roxas from Bicol, Magpantay from Tagkawayan, Segui from Lopez, Remegio from Bicol, Vivas from Bicol, Sodium Meta Bi Sulphite

supplied by Will Ann International, Kraft Paper bags by Duche Bags. Mass balance is justified.

Batch of coconut Butter Paste was tested for traceability. Batch number 1714420 production 24.5.17, qty produced 52.03 kgs. Raw materials supplied by – Desiccated Coconut Medium by company's sister plant at Legaspi, Coconut flour own house production and Virgin coconut oil own house production. 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. Certificate Organic no. #PH-2016-140741-Z-44717-2016. Valid upto 31.3.18, certificate for Primex Legaspi.

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. BRC certificate of Baolingbao, China, supplier of maltodextrin was verified.

Re blanching in Desiccated coconut process, re centrifugation in virgin coconut oil process and re blending and re drying in case of Coconut milk powder are reworks defined. Rework procedure defined QA DP 08 dt 10.6.16.

3.10 Complaint handling

Complaint handling procedure QA SP 06.5 dated 19.12.16. Total 3 complaints received since last audit YTD in 2017. One complaint is of wrong product grade found in desiccated coconut bags, one about paint flaking in Coconut water drums and other regarding red 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.5.0 dated 16.8.16 and dated 3.12.16. Root cause analysis and corrective action were carried out.

3.11 Management of incidents, product withdrawal and product recall

Procedure for recall – QA SP 08 dated 28.4.14. Recall procedure includes classification of recall into mandatory recall and voluntary recall and recall team. Recall process defined with responsibilities defined. Notification to regulatory body defined and notification to certification body is defined within 3 days. Contact details of the customers and regulatory bodies are available.

Crisis management procedure QA DP 52 dt 15.3.16 includes situations related with Natural disaster, like fire, typhoon, chemical spill, earthquake, bomb threat etc. Separate Food Security plan QA SP 01B dt 13.6.16 was seen where sabotage, and failure of services are identified and contingency plans were defined. 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 25.4.17.

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 Virgin Coconut oil batch 160360 date produced 5-6.2.16. Mock recall started on 8.30 AM and ended on 10.30 AM, total time 2.0 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. Company has a Ethical sourcing policy and the same requirements are covering ethical

standards and sourcing. Policy HR-SP-06 dated 25.4.16. The requirements are communicated to vendors and agreed upon. CSR statement forms are filled by vendors and communicated. Verified from Solid Bag Packaging – supplier of Kraft bag and Agro Complex – supplier of Sodium Caseinate.

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
3.9.4	No rework used or reworking operations carried out
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 and land free. 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 QA-SP-01B (13/06/2016) 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 13/06/2016.

The site has been registered with FDA of Philippines as LICENSE OF OPERATE – LTO no. CFRR-RIV-FM-2222 valid until 19/02/2020 and US Bioterrorism as registration No. 13309371574.

4.3 Layout, product flow and segregation

Zoning was defied as low risk production area (preparation, cooking), ambient high care area (sorting, filling, packing), Enclosed product area (warehouse) and non-production area which based on BRC zoning decision guild line. It was defined in QA-SP-33 (24/03/2017). 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

Overall buildings and facilities were appropriately designed and maintained in suitable condition to prevent contamination such as wall, floor, drainage, ceiling and others. There was no stagnant water on the floor. No suspended ceiling used. All window, glass and plastic were protected against breakage. Doors were in good condition and closing fitting to prevent pest ingress. Sufficient lighting was observed during assessment in processing and inspection areas. All lightings in production and store were covered and registered in glass control program including electric fly killer were protected by screen. Ventilation system was adequate.

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 as EM-WD-L003 (24/03/2017) 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* and *Coliforms* as weekly and chlorine residual as 2 times/day.

- Verified micro testing of water on Feb. - Apr. 2017
- Verified chlorine residual 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. CL1702-0443 (20/03/2017) and microbiological of water as test report no. CL1702-0444 (25/02/2017)
- Fully analysis – pesticide of water as test report no. COA17CB-0321 (09/03/2017)
- Full analysis – heavy metal of steam condensate as test report no. CL1702-0445 (22/03/2017)

Chemical agents as chemical no. Zi-Chem 1630, 1221, 1670 were used for anti-scaling 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 14/04/2017.

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 ESPOT 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 as 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 and CMP, spray drying machine and filter, separator and polisher at VCO line, drying and packing machine in DC line, CIP system, evaporation and blending tank in CWC line, water treatment system, air compressor, boiler and others. 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 ET-2A (NSF registration no. 070012). The ingredient of Lubricant is synthetic white oil and no allergen source was used.

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. Adequate segregation of street cloth and protective clothing was evident in the change rooms. 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-DP-06 (28/04/2014) 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.

1 minor CAR was raised – see CAR attachment

4.9.2 Metal control

Metal control procedure QA-SP-01A (28/04/2014) 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, brittle, hard plastic, ceramics and similar material control was defined in QA-SP-01A (28/04/2014). Glass usage was used to be primary packaging such as glass jar. Lay-out or mapping for glass and hard plastic control was established covering all section in production plant and warehouse such as light bulb, side glass, electric fly killer lamp, part of machine. It was defined covering list of item, location, number, condition. Weekly monitoring record during Feb. – Apr. 2017 at production, storage area and warehouse were maintained in PCPI-BC-03 and verified on-site. In case of glass and other brittle material was damaged and breakage, action taken was conducted to clean up, inspect before production start including changing workwear as defined instruction and record was maintained.

4.9.4 Products packed into glass or other brittle containers

Glass control instruction was established covering action to be taken in case of breakage of glass which include glass jars used in virgin coconut oil line i.e. inspection of glass condition monitoring during cleaning and production, glass breakage area control, handling of glass/brittle materials breakage (removal and disposal of products, cleaning of the line or equipment which may be contaminated by fragments of the container, use of dedicated cleaning equipment for removal of container breakages and authorisation is given to Production and QC supervisor for restart production) and control of nonconformity products or affected products to ensure the product safety. Records of glass containers condition monitoring and breakage by QC were maintained on PCPI-VCORP-GJP and clearly conducted as work instruction.

4.9.5 Wood

Wood Policy has established, implemented and maintained as defined in QA-SP-01A. 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, non-ferrous and stainless steel were used for challenge test. Details of validation parameters for metal detector detection were considered and defined in service report from supplier's metal detector 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 every 6 months. Verified monitoring records on Feb. – Apr. 2017 and magnet intensity reports which carried out on 23/01/2017.

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

Glass jar for virgin coconut oil was washed by hot water before filling with products. They were then 100% visual inspected by trained QC staff. Record of glass bottle inspection was maintained. Pressure water was used for clean empty can and water pressure were monitoring. Clearly records were verified.

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. 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. – Apr. 2017 were verified. Swabbing for cleaning effectiveness verification was carried out that covering equipment and machines as weekly. Verified swabbing records on Jan. 2017 – present.

4.11.7 Cleaning in place (CIP)

CIP instruction has been implemented for cleaning in storage tank and piping system of coconut milk powder and coconut water concentrate line including 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 Feb. – Apr. 2017, they were compliance with plan and specification. CIP validation was seen for CWC on 24/04/2017 and CMP on 20/04/2017.

4.12 Waste / waste disposal

Procedure of waste management was established and implemented as defined in EM-SP-06.1C (28/04/2014) covering general waste, recycle waste and hazardous waste. All waste types were

segregated and disposed by authorized service provider, e.g. solid waste and recycle waste by Mr. Lilim Cabrera, etc. 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 QA-DP-08. 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. Paring and rotten coconut were used intended for animal feed which they were segregated from the other waste and appropriately protect from contamination.

4.14 Pest Control

Pest control procedure was established, implemented and maintained as QP-SP-21 (12/05/2016). Pest control service was performed by Chemsol Industries INC., contract no. 88 (service period 10/04/2017-09/04/2018) 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 defined in PCPI-PL-PLM (29/03/2017). Service reports in 2017 were verified with service details. Training records of service providers were maintained such as Mr. Wenibaldo C. Yebra. Using of pesticide complied with local regulation and MSDS was provided, such as Max Force; Fipronil (registration no. HSR-5107, valid until 28/10/2018), Crack Down; Deltamethrin (registration no. HSR-5245, valid until 15/05/2018), Fendona; Cypermethrin (registration no. HSR-5600 (26/01/2018). 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 on March, 2017 by Mr. Alvin E. Gomez. Recommendation from expert was consider to correct problem and improve pest control program. All staff were trained on GMP on 1.5.17 where they were informed about pest sighting and 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. – Apr. 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 every 30 minutes. 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 QA-SP-27 (10/10/2016). Transportation was carried out by company own vehicles. 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. 517, loading on 15/03/2017, product Organic coconut flour Lot 170300, container no. SEGU 220240-0, seal no. YMLL 414714
- Contract no. V74, loading on 09/02/2017, product Organic virgin coconut oil Lot 163300, container no. YMMU 40781-0, seal no. YMLL 412011
- Contract no. 34945-2440, loading on 12/01/2017, product Coconut water concentrate Lot 143240, 143270, 143290, container no. TEMU 937333, seal no. TSB1505447
- Contract no. M7923, loading on 10/02/2017, product coconut milk powder Lot 170253, container no. TEMU 882782-9, seal no. MOL B009188
- Contract no. P110752, loading on 24/02/2017, product Desiccated coconut Lot 170450-2, container no. EMCU 524341-7, seal no. EMC EWC 8496

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
4.3.9	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
4.8.10	No catering facilities provided. No vending machines in place.
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
4.12.1	Licensing for the removal of waste isn't required by law
4.14.3	The site doesn't undertake its own pest control
4.15.4	No controlled atmosphere is required
4.15.5	No Outside storage

5. Product control

5.1 Product design/development

New product development procedure QA-SP-39 (16/01/2017) has been established as guideline for restrictions to scope of new product. Hazard analysis and related regulations review were conducted and considered by QA. Shelf life study of new product will be studied that covering safety such as microbiological, quality and sensory evaluation.

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 QA-SP-31. 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 sodium casinate and sodium metal bisulphite (sulphur dioxide). Training of allergen knowledge was provided to all concerned staff. Coconut is a tree nut and is categorized in other category.

5.4 Product authenticity, claims and chain of custody

Documented of vulnerability assessment has been in place and carried for all materials. 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 is maintained and valid certificate is seen. Certificate validity was till 31.3.18.

5.5 Product packaging

Product packaging and contracted sheets were inspected before receiving. Testing reports are available for plastic bags and aseptic bags which primary packaging. Verified testing reports as Test report no. MNLH 16030207 for chemical migration of plastic bag and test report no. FDD 01G008729001 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.

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

- Microbiological of desiccated coconut as test report no. PH17-00737-01 on 08/03/2017
- Heavy metal of desiccated coconut as test report no. PH17-00737-10.010 on 08/03/2017
- Mycotoxin of desiccated coconut as test report no. PH17-02258-09.010 on 19/05/2017
- Pesticide of desiccated coconut as test report no. 17CB-0312 on 09/02/2017
- Nutrition testing of desiccated coconut as test report no. CQ1701-0576 on 19/01/2017

- Microbiological, heavy metal of virgin coconut oil as test report no. PH17-00737 on 08/03/2017
- Mycotoxin of virgin coconut oil as test report no. PH17-02258-12.013 on 19/05/2017
- Microbiological of low fat desiccated coconut, coconut milk powder and coconut flour as test report no. PH17-00737-03 on 08/03/2017
- Heavy metal of low fat desiccated coconut, coconut milk powder, coconut juice concentrate and coconut flour as test report no. PF17-00737 on 08/03/2017
- Mycotoxin of low fat desiccated coconut as test report no. PH17-022858-11.012 on 19/05/2017
- Mycotoxin of coconut milk powder as test report no. PH17-02258-10.011 on 19/05/2017
- Mycotoxin of coconut flour as test report no. PH17-02258-13.014 on 19/05/2017
- Microbiological of coconut juice concentrate as test report no. PH17-00737-06 on 08/03/2017
- Mycotoxin of coconut juice concentrate as test report no. PH17-02258-14.015 on 19/05/2017

All results of testing complied with their specifications.
Ongoing shelf life was implemented according to procedure: QA-SP-03. 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. Good laboratory practice has been applied for internal laboratory. Procedure of hygiene control, access movement, waste management of internal laboratory is in place for implementing. 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 27/02/2017 for Salmonella (program no. MA140), 06/02/2017 for E. coli (program no. MA 139) and 06/02/2017 for Yeast & Mold (program no. MA 139). Accredited 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.

5.7 Product release

Product release procedure: QP-SP-06.3A 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 such as

- Product Organic coconut flour Lot 170300
- Product Organic virgin coconut oil Lot 163300
- Product Coconut water concentrate Lot 143240, 143270, 143290
- Product Coconut milk powder Lot 170253
- Product Desiccated coconut Lot 170450-2

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
5.2.3	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, SO_2 dosing 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. Alarm testing was carried out for blanching machines and pasteurization unit once a week. Records of testing were maintained.

6.2 Labelling and pack control

Documented procedure for labelling and pack control was in place. 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. During audit change over from coconut butter paste to creamed coconut was verified. Thorough cleaning of the line was done and visual checks for allergen residue was carried out prior to starting of the new process.

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. The weighting inspection records were maintained.

6.4 Calibration and control of measuring and monitoring devices

Calibration plan and procedure 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, virgin coconut oil and coconut milk powder
- Thermometer no. FSCMR-D3-01, TC-C-01, TI-C-01, TC-BS-01, IR-VCO-01
- Stop watch no. SW-D3-01, ST-LAB-02
- Gauss meter no. IDR-329

- Flow meter no. KFW-CMP-01, KFM-CMP-01
- Digital balance no. DWS-CMP-01
- pH meter no. PHM-LAB-01
- Analytical balance no. OAB-CMP-01
- Incubator no. MCI-LAB-01
- Auto clave no. HAS-LAB-LW04

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 3/2/2017, allergen awareness on 2/5/2017, GMP and HACCP on 1/5/2017, 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 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 PL0018 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 QA-DP-01 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.