FSSC Food Safety & Quality Management System Audit Report

NAME OF Client:	Chicago Processed Fruit Group (a unit of Greenwood Associates Inc)		
Address:	6280 West Howard St, Niles, IL 60714		
Audit Type	☐ Initial Certification - ☐ Stage 1 ☐ Stage 2 ☒ Annual Surveillance ☐ Re-certification		
Business Sector	Food manufacturing	**Food Categories**	Fruit Juice, concentrates, purees, essences and essential oils
No Employees:	**35**	**No Shifts:**	1 shift, 5 days per week
Lead Auditor	Vikash Lutchmiah	**Additional Team Member(s)**	
Audit Commencement Date	5 Oct 2016	**Audit Conclusion Date**	6 Oct 2016
Date of last audit	7 Oct 2015	**Previous CB**	Not Applicable
Description of last audit	Re-certification		
Current certificate issue date	19 Nov 2015	**Current certificate expiry date**	19 Nov 2018
Any Other Certificates Held	Kosher, Organic		
Scope of Audit:			
Processing (Blending and/or pasteurization) of fruit products (juices, purees and concentrates) and fruit by-products (essential oils, essences). Receiving, storage and shipping of processed fruit products.			
Any scope exclusions are appropriate and justified:			☐ Yes ☐ No ☒ NA
Facility Summary (including overview of relevant changes to documentation, requirements, processes, and products since last audit)			
Chicago Processed Fruit Group (a unit of Greenwood Associates) is a small private company, established in 2009. The company is involved in processing of fruit products (juices, purees and concentrates), fruit by-products (essential oils, essences), as well as importation and distribution of the stated products. The company is located in a 59,000 square foot facility that was constructed in Oct 2011. The facility employs approximately 35 full time employees, working 1 production shift over 5 days per week. Fruit and fruit by-products are either blended, and pasteurized (single strength juices), and packaged for ambient, refrigerated or frozen distribution. There is also a limited amount of product receipt to direct distribution that is conducted. The facility uses third party companies for distribution, or products are picked up by customers.			
List Recalls in past 12 months as well as any complaints or reports that have been registered with the government.			
None			

List of Key Personnel present at audit (name and title)	
Jim Berman	General Manager/ Owner
Craig Scharoff	Director of Sales/ Owner
Michael Hansche	Director of Plant Operations
André Molina	Quality Lab Manager
Caroline Kuehn	Production Process Engineer
Nicholas Tarleton	Regulatory Specialist
Suraya Gabel	Director of Quality & Food Safety

Audit Objectives:

- *To confirm that the food safety management system conforms with all the requirements of FSSC 22000*
- *To confirm that the Food Safety & Quality Management system has been effectively implemented*
- *To confirm that the facility is capable of meeting the Food Safety & Quality Management system requirements*
- *To provide feedback to the organization to facilitate continual improvement*

Audit Recommendation

The audit team concludes that the organization:

1. ☒ Has established a Food Safety & Quality Management system in accordance with FSSC 22000
2. ☒ Has implemented and/or maintained its Food Safety & Quality Management system in accordance with FSSC 22000
3. ☒ Has demonstrated the ability of the food safety & quality system to systematically achieve agreed requirements for products or services within the scope and the organization policy objectives.

Based on the results of this audit and the client's Food Safety & Quality Management system demonstrated state of development and maturity, it is recommended that certification be

Should proceed to Stage 2 of Initial Certification to FSSC 22000	
Granted	☐
Granted following satisfactory resolution of Non Conformances	☐
Maintained	☐
Re-certified	☒
Suspended	☐

Future Audit Scheduling	
Your next scheduled audit activity is a	Surveillance
At the present time this activity is tentatively scheduled for	Oct 2017

Thank you for your ongoing support of Merieux NutriSciences Certification as your Certification Service Provider.

Should you have any queries, comments or questions pertaining to the content of this report including the classification of any non conformity raised at this audit, feel free to contact our certification office at certification@mxns.com

Lead Auditor Name	Vikash Lutchmiah	**Signature**	

Date	7 Oct 2016

Explanation of Audit Report contents:

Addendum 1	Summary of Findings – ISO 22000 Requirements
Addendum 2	Summary of Findings - FSSC 22000 Requirements
Addendum 3	Non-Conformity Schedule (Corrective Action Requests)
Addendum 4	Observations for Continuous Improvement
Addendum 5	Verification of Closure of Identified Non Conformities (by Assessor)
Addendum 6	Certification Status Summary: NB- This report will be updated and presented after each audit activity to assist in reviewing the overall “health” of the FSSC Certification

Addendum 1

Summary of findings for ISO 22000 requirements

	Conforms			
Clause		**Yes**	**No**	**Remarks**
4	***Food Safety Management System***			
4.1	*General requirements*	x		
4.2	*Documentation requirements*	x		
	Summary Clause 4: The scope defined in the Quality Policy Manual included the requirements of the standard. The scope was: Blending and pasteurisation of fruit juices; Blending of fruit products (purees and concentrates) and fruit by-products (essential oils, essences). Receiving, storage and shipping of processed fruit products. The document control procedure (DOC-1004, 8 Nov 2013) described the management of documents and approval of changes. Any changes would be recorded in the "Change control" section of each document. The procedure was properly implemented. The record control procedure (Doc-1009, 1 Jul 2014) described the management of records and retention. Records were retained for a period of shelf life plus 2 years, or 5 years for production, maintenance & training. Processing and production records randomly reviewed for the period of 7-9 Dec 2015, 7-9 Mar, Jun & Sep 2016. These were legible, properly completed, and readily available.			
5	***Management responsibility***			
5				
5.1	*Management commitment*	x		
5.2	*Food safety policy*	x		
5.3	*Food safety management system planning*	x		
5.4	*Responsibility and authority*		x	The organization did not include personnel recently recruited (Process Engineer & Regulatory Specialist).
5.5	*Food safety team leader*	x		
5.6	*Communication (including registered complaints and reports to concerning government)*	x		
5.7	*Emergency preparedness response*	x		

5.8	*Management review*	x		

Summary Clause 5:

Various processes were established for continual improvement (such as monthly meetings, quarterly management review, daily operational meetings, HACCP meetings). Sufficient resources were provided, which include additional of personnel to the QA, Purchasing & Sales departments so as to improve the programs. KPIs are established as food safety objectives, which included customer complaints (less than 8/month), testing results (0 retested), Sanitation swabs (<10% failure rate for 3 consecutive months), Specification variance (Less than 2%), environmental monitoring (0 Listeria, Coliforms & ATP).

The food safety policy was part of the Quality Policy manual, and communicated through training and posted at the entrance to the plant. Measurable objectives had been established and reviewed during the monthly food safety meetings. The manual was reviewed on 8 Sep 2016. KPIs (Objectives) have been established for various departments to monitor performance of various pre-requisites and processes.

The organization chart dated 31 Mar 2016 outlining the various team members with food safety responsibility. Employees were aware of their responsibility to report deviation. Job descriptions had been developed, and signed by the employees (Reviewed for the Process Engineer, date 6 Jun 2016). Minor: The organization did not include personnel recently recruited (Process Engineer & Regulatory Specialist).

External communication included suppliers, customers, and regulatory authorities. Material specifications were communicated to the suppliers at the time of purchase, and verified for conformity at receipt. The Director of Sales and Director of Food safety and Quality were responsible for communicating any changes in specifications to customers. The General Manager and Director of Operations were responsible for contacting customers with regards to complaints, which would then be communicated internally during the food safety meetings and annual management review. Any changes of specifications would be sent with the sales confirmation to the customer. Internal communication channels included postings, email, One Point lessons, training and meetings. The Director of Food safety and Quality is responsible for keeping the company updated of changes to legislations, changes impacting food safety and customer specs. Food safety meetings were held on a monthly basis, and an agenda was prepared that includes all of the requirements of the standard. Minutes were reviewed for Jan-Jun 2016, and conforming. HACCP meetings were also held to reassess the programs and changes required to the food safety plans. Changes to the process were reviewed with the team before initiated in the plant.

The management review was conducted on 3 Mar 2016, and met the requirements of the standard. Improvements had been identified, including resource requirements.

Clause		Conforms Yes	No	Remarks
6	***Resource management***			
6.1	*Provisionofresources*	x		
6.2	*Human resources*		x	• Training records reviewed for “One point lessons” (8 Oct 2015) & GMP orientation (9 Feb 2016) did not included evaluation of implementation and effectiveness. Instead employees were required to sign or initial that they "read and understood". • The training matrix had not been updated to include the employees recently recruited (Process Engineer & Regulatory Specialist)
6.3	*Infrastructure*	x		
6.4	*Work environment*	x		
	Summary Clause 6: Competencies for each position had been identified in a training matrix and job descriptions. The matrix was being used to tracking training provided. Various types of training records were maintained, and reviewed for personnel interviewed and observed.			
7	***Planning and realization of safe products***			
7.1	*General*	x		
7.2	*Prerequisite programs (PRPs)*	x		
7.3	*Preliminarystepstoenablehazard analysis*	x		
7.4	*Hazard analysis (including description of the assessment of the identification of food safety hazards).*	x		
7.5	*EstablishingtheoperationalPRPs*	x		
7.6	*EstablishingtheHACCPplan*	x		
7.7	*Updating of preliminary information and documents specifying the PRPs andtheHACCPPlan*	x		

7.8	*Verification planning*	x		
7.9	*Traceability system*	x		
7.10	*Control of nonconformity*		x	Existing stock of raspberry flavor (lot#31045) with expiry date of 1 Aug 2015 had not been held.

Summary Clause 7:

Pre-requisite programs have been established to meet FDA, customer as well as requirements of the standard. The PRPs were properly implemented at the time of the audit.

There were 13 HACCP plans developed, to include the scope of products and processes under certification. A software was used to conduct the hazard analysis, and had been updated in 28 Sep 2016. The analysis was based likelihood and severity of hazards, and included reasonably likely hazards such as E.coli, Listeria, Salmonella, patulin, allergens, and foreign materials. There were no OPRPs established

The Director of Food Safety & Quality was the Food safety Team leader, and had been trained in HACCP on 24 Oct 2012. A multidisciplinary HACCP team was established, which meets monthly to discuss improvements required.

Specifications were developed for each raw material and finished product. Specifications were reviewed for Raspberry flavour (8 Jan 2016), pails (Rev 0), and Raspberry juice (8 Dec 2015), and were conforming. Specifications were reviewed on an annual basis, and included all the requirements of the standard. Specifications for finished products were online, and emailed to customers upon request. Specifications were also reviewed for Raspberry juice RACWF 6502 & 6503 (8 Dec 2015), and were conforming.

A product description was developed for each HACCP Plan (28 Sep 2016), and included the intended uses as well as potential misuse. A flow diagram had been developed for each of the HACCP plans, reviewed on 28 Sep 2016, and verified onsite on the same date. Control measures had been identified for each step, and properly implemented. A software was used to conduct the hazard analysis. The HACCP plans and analyses had been reviewed on 28 Sep 2016 by the FST. Customer and regulatory requirements were also included as part of the hazard analyses. The hazard analyses were based likelihood and severity of hazards, and included reasonably likely hazards such as E.coli, Listeria, Salmonella, patulin, allergens, and foreign materials. Control measures have been established for each hazard, which included pre-requisites, CCPs and process controls. A matrix and decision tree had been used for determining CCPs. The CCPs had been reviewed by the team on 28 Sep 2016. CCP monitoring records were reviewed for the period of 7-9 Dec 2015, 7-9 Mar, Jun & Sep 2016, and were conforming.

Critical limits had been established through review of scientific literature, testing, challenge studies, and regulatory requirements. Validation of CCP and critical limits were carried out through scientific literature and regulatory requirements. The critical limits for pasteurization had been reviewed and revalidated by the Process authority (letter dated 14 Jan 2015). The validation of the PRPs had been carried out during the HACCP meeting and management review (2 Mar 2016), and confirmed that the programs were effective. New processes are validated through challenge studies, and approval by a Process authority. Reviewed for the new process of batch pasteurization (9 Sep 2016), and conforming. Corrective actions are established for deviations, and effective to control the likely hazards.

The CAPA program (CAPA-1002, 7 Jul 2014) described the management of non-conforming materials, equipment and products. These would be held, identified, segregated, and evaluated before release. All products were shipped with a COA, as part of the positive release process. A software was used for the management of corrections and preventive actions. Various records randomly reviewed for the period of 7-9 Dec 2015, 7-9 Mar, Jun & Sep 2016 indicated that the process was properly managed. CAPAs were summarised, and reviewed during the monthly food meetings and annual management review. All held products were released after products were tested, and pre-shipment review conducted.

	Summary Clause 7 (Continued): All incoming materials are assigned an internal lot number, which is linked to the product name and purchase order. The label includes a bar code which is scanned when used in production. A new Purchase order is generated for each blend, which is traceable to the finished product label and shipping records. The lot number of the finished product was a combination of product code, blends number, and manufactured date. The code was also printed directed on pails. Drums contain 2 labels (top and side). The Crisis Control policy-005 (15 Aug 2016) included the management of various scenarios, as well as recall management. The Recall procedure described the management of traceability and recall. An electronic client contact list was reviewed, and included the customers, regulatory authorities. The Recall procedure included communication to the Certification body. A mock recall test had been performed on 30 Aug 2016 for 88 pails of Prune Juice concentrate (PUC31062). 100% of the materials used had been traced to the finished product and the first external customers within 13 minutes. A mock trace exercise was also conducted during the audit for 25 lbs of raspberry flavour (lot#RBF31045), received on 24 Jan 2016, and used in the production of 410 pails of Raspberry Juice (Lot#31058) on 11 Feb 2016. 100 % of the materials and finished products were traced to the first external customers in 20 minutes.			
8	***Validation, Verification and improvement of the FSMS***			
8.1	*General*	x		
8.2	*Validation of control measure combinations*	x		
8.3	*Control of monitoring and measuring*	x		
8.4	*Food safety management System verification*	x		
8.5	*Improvement*	x		

	Summary Clause 8: Verification procedures were established for PRPs and CCPs. A positive release was also established- Products (except oils) are tested to confirm that absence of indicator pathogens, after which products are released for shipping. Results of the verification activities were documented electronically, and communicated to the food safety team during the monthly meetings. Please refer to Section 7 above for details on validation of the CCPs and critical limits. An electronic calibration schedule was established as part of the PM Master schedule. The schedule included calibration of equipment impacting food safety (such as HTST, magnets, CIP, laboratory equipment). Calibration was being conducted internally (such as magnet, pH meter & scale) or by external contractors (such as HTST & CIP). Calibration records were reviewed for HTST & CIP (15 Jan 2016), and scales (9 May 2016), and were conforming. Equipment were protected against damages, and properly stored. Corrective actions have been developed, and effective in controlling food safety. Softwares used for HTST and CIP were verified through records review and annual validation. CAPAs were issued for deviations identified during verification activities. These CAPAs were then reviewed during the monthly meetings, analysed by the Director of Food Safety, and then reviewed during the management review. Electronic records of verification review indicated that the process was properly managed. The 2015 CAPA review included analysis of verification activities. The review included improvements required.
	The internal audit program (DOC 9002) consisted of an independent evaluation of the quality management system, pre-requisites, facility inspections and customer requirements. A schedule had been prepared to assess the programs from Feb to Jun 2016. An external contractor, independent of the programs conducted the internal audit; Reviewed results for management system (4 May 2016), verification activities (28 Apr 2016), HACCP (4 May 2016), Purchasing (25 Feb 2016). The contractor had been trained in internal auditing on 9 Feb 2016. Monthly building inspections were also performed to assess GMPs, sanitation & condition. Results of internal audits were reviewed by the management during the monthly food safety team meetings, and during the annual management review. All of the CAPAs had been closed, and verified for effectiveness. Monthly food safety meetings were conducted to review objectives, deviations, CAPAs, results of verification activities, and customer complaints. Monthly CAPA meetings were also held to review trends in deviations and follow up on the CAPAs. Annual HACCP and management meetings were also held. Minutes reviewed for 2016, and conforming. Improvements were communicated to employees.

Addendum 2

Summary of Findings - FSSC 22000 Requirements

	Conforms		
Clause	**Yes**	**No**	**Remarks**
4. Construction and layout of buildings			
4.1 General requirements	x		
4.2 Environment	x		
4.3 Locations of establishments	x		
Summary Construction and layout of buildings: The building was constructed in 2011 and well maintained. The building was physically separated into different areas based on activities and associated food safety risks. There was no risk of contamination from external environment.			
5. Layout of premises workspace			
5.1General requirements	x		
5.2 Internal design, layout and traffic patterns	x		
5.3 Internal structures and fittings	x		
5.4 Location of equipment	x		
5.5 Laboratory facilities	x		
5.6 Temporary/mobile premises and vending machines	x		
5.7 Storage of food, packaging materials, ingredients and non food chemicals	x		
Summary Layout of premises workspace: The building was properly designed and maintained. A regulated flow of materials, employees, products and waste was observed, and there was no risk of cross contamination observed. Internal structures and fittings were properly designed and maintained. Equipment were properly designed, maintained and located. Laboratory practices met the requirements of the standard, and the laboratory was maintained locked. There were no vending machines onsite.			
6. Utilities – air, water, energy			
6.1 General requirements	x		
6.2 Water supply	x		
6.3 Boiler chemicals	x		
6.4 Air quality and ventilation	x		
6.5 Compressed air and other gases	x		
6.6 Lighting	x		
Summary Utilities – air, water, energy: *Potable water from by the City of Chicago was being used for cleaning and production.*			

Summary Utilities – air, water, energy:

The water used in production was filtered, and the filter monitored on a daily basis. Water was tested on a quarterly basis for residual chlorine and microbiological indicators of potability (E.coli, Coliforms and SPC). Results reviewed for 27 Jun 2016 & 6 Sep 2016 were conforming. Compressed air was used for cleaning of processing lines, and filtered (Specification dated Apr 2000 indicated 0.01 micron). Compressed air has been tested internally for APC, Yeast and Mould. Results for compressed air testing dated 26 Apr & 19 Sep 2016. Food grade oil was used, and verified throug the SDS (Pristine FG). Steam generated by the boiler was not used in contact with food. The boiler chemicals had been approved for use in a food environment. Positive air pressure was provided in the blending and filling rooms.

		Conforms		
Clause		**Yes**	**No**	**Remarks**
7. Waste disposal				
7.1 General requirements		x		
7.2 Containers for waste and inedible or hazardous substances		x		
7.3 Waste management and removal		x		
7.4 Drains and drainage		x		
Summary Waste disposal: *Waste was properly disposed in color-coded or identified containers. Waste was properly stored until removal by an approved contactor. There was no waste accumulation observed at the time of the audit. There was no hazardous waste generated. Drains were conforming, clean and well maintained.*				
8. Equipment suitability, cleaning and maintenance				
8.1 General requirements		x		
8.2 Hygienic design		x		
8.3 Product contact surfaces		x		
8.4 Temperature control and monitoring equipment		x		
8.5 Cleaning plant, utensils and equipment		x		
8.6 Preventive and corrective maintenance		x		

Summary Equipment suitability, Cleaning & Maitenance:

There was minimal processing involved at this facility: Products are pumped into tanks, blended if required, and then pumped to filler nozzles. A pasteuriser was used for single strength purees and juices, and operated around once a month. The pasteurizer is calibrated annually by an approved contractor. A program was established for commissioning of new equipment based on AMI Sanitary design checklist. A schedule was established for identifying various preventive maintenance tasks, and their frequency based on manufacturer's recommendation and usage. Most preventive tasks were based on usage and history. Preventive maintenance records were reviewed for the pail filler, agitator for 201 tank and compressed air filters, and were conforming. The premises were clean and well maintained. Processing and packaging equipment were hygienically designed and well maintained. Maintenance personnel had been trained, and understood the requirements of the standard. A form was used for reconciliation of tools.

9. Management of purchased materials			
9.1 General requirements	*x*		
9.2 Selection and management of suppliers		*x*	*There was no documented program established for monitoring the performance of existing suppliers.*
.3 Incoming material requirements (raw/ingredients/packaging)	*x*		

Summary Management of purchased materials:

The procedure DOC-9001 described the approval of suppliers. Potential suppliers are approved based on a Basic Facility information forms, GFSI based audits, applicable certification (such as Kosher, non-GMO), allergen statement & HACCP plan. Annual audit reports and HACCP plans were required. Performance was monitored by review of COAs at receipt, and CAPAs are generated for deviations. Supplier approval records were reviewed for suppliers of raspberry flavor & packging (pails). A risk level was carried for each material, which is based on the usage of the ingredients and pH. Documents required from suppliers include letter of guarantee, allergen declaration, kosher or organic certification (where applicable), and third party food safety audits (high risk materials). Receiving records were reviewed indicated that materials were received from approved suppliers. COAs were required for critical materials, and verified upon receipt. Bulk ports were secured in a "bulk pump house". Deviations arising from supplier origin were being investigated, and discussed during the CAPA meeting.

	Conforms			
Clause		**Yes**	**No**	**Remarks**
10. Measures for prevention of cross contamination				
10.1 General requirements		*x*		
10.2 Microbiological cross contamination			*x*	*Positive air pressure was supplied in the filling and blending rooms (based on design). However, the records dated 13 May & 30 Aug 2016 indicated a negative air pressure at some entrances to the filling room (from the cooler).*
10.3 Allergen management		*x*		
10.4 Physical contamination		*x*		
Summary Measures for prevention of cross contamination: *The facility was physically segregated into different areas, based on risk to food safety, to prevent cross contamination. Regulated flows were established, and conforming, with no risk of cross contamination.* *Positive air pressure was supplied in the filling and blending rooms. However, the records dated 13 May & 30 Aug 2016 indicated a negative air pressure at some entrances to the filling room (from the cooler).* *Hygiene practices were conforming, and including use of gloves, protective clothing, sanitising of food contact & non-food contact surfaces.* *There were no allergens handled: Only sulfites were present in the red grape juice concentrate, which is stored in a designated area of the cooler. Any production of allergen containing ingredients A full cleaningMagnets and screens were used.*				
11. Cleaning and sanitizing				
11.1 General requirements			*x*	*Flooring was not being sanitized.*
11.2 Cleaning and sanitizing agents and tools		*x*		
11.3 cleaning and sanitizing programmes		*x*		
11.4 Cleaning in place (CIP) systems		*x*		
11.5 Monitoring sanitation effectiveness			*x*	*(1) The daily sanitation records were being verified at the end of the day, but did not provide evidence that each of the cleaning tasks had been monitored for effectiveness. (2) The concentration of sanitizer was being recorded as 130 ppm on the Form 11 (pages 2*
Summary Cleaning and sanitizing: *A master cleaning & sanitation schedule was developed, which included daily and non-daily tasks. Sanitation records were being completed by sanitation employees at the end of cleaning to acknowledge the tasks completed, and verified by the supervisor at a later time. Minor: The daily sanitation records were being verified at the end of the day, but did not provide evidence that each of the cleaning tasks had been monitored for effectiveness. Please refer to the non-conformance report for improvements required.*				

12. Pest control			
12.1 General requirements	*x*		
12.2 Pest control programs	*x*		
12.3 Preventing access	*x*		
12.4 Harbourage and infestations	*x*		
12.5 Monitoring and detection	*x*		
12.6 Eradication	*x*		
Summary Pest control: *A new contractor was appointed for management of the integrated pest management program (Business license with expiry date of 31 Dec 2016; Agreement dated 31 Aug 2016; Liability insurance with expiry date 1 Jan 2017; License of the contractor had an expiry date of 31 Dec 2016; List of approved chemicals dated 28 Sep 2016); EPA registration was maintained on file; The map of devices was dated 14 Sep 2016; The trend reports indicated that there were no signs of infestation; The building and practices were conforming, with no cracks or gaps, and no signs of infestation observed during the audit.*			
13. Personnel hygiene and employee facilities			
13.1 General requirements	*x*		
13.2 Personnel hygiene facilities and toilets	*x*		
13.3 Staff canteens and designated eating areas	*x*		
13.4 Workwear and protective clothing	*x*		
13.5 Health status	*x*		
13.6 Illness and injuries	*x*		
13.7 Personal cleanliness	*x*		
13.8 Personal behavior	*x*		
Summary Personnel hygiene and employee facilities: *Personal hygiene practices were conforming at the time of the audit. Work wear were laundered by an external company, except for freezer coats, which were laundered in-house. Uniforms are bagged (individually wrapped), and inspected at receipt to monitor the condition and cleanliness of the uniforms. Records (Form 1022) reviewed for Jul-Sep 2016 were conforming. GMP signs were posted at entrances, and included personal clothing and practices. Gloves were properly used and changed when contamination. Health requirements and disease reporting were included in the GMP training. In addition, employees complete a health questionnaire during the GMP training. Records reviewed for temporary employees were conforming.*			
14. Rework			
14.1 General requirements	*NA*		
14.2 Storage. identification and traceability	*NA*		
14.3 Rework usage	*NA*		

Summary Rework: *There was no rework carried out.*			
15. Product recall procedures			
15.1 General requirements	*x*		
15.2 Product recall requirements	*x*		
Summary Product recall procedures: *The Recall procedure described the management of traceability and recall. An electronic client contact list was reviewed, and included the customers, regulatory authorities. The Recall procedure included communication to the Certification body. A mock recall test had been performed on 30 Aug 2016 for 88 pails of Prune Juice concentrate (PUC31062). 100% of the materials used had been traced to the finished product and the first external customers within 13 minutes. A mock trace exercise was also conducted during the audit for 25 lbs of raspberry flavour (lot#RBF31045), received on 24 Jan 2016, and used in the production of 410 pails of Raspberry Juice (Lot#31058) on 11 Feb 2016. 100 % of the materials and finished products were traced to the first external customers in 20 minutes.*			
16. Warehousing			
16.1 General requirements	*x*		
16.2 Warehousing requirements	*x*		
16.3 Vehicles, conveyances and containers		*x*	*The shipping records did not provide evidence that LTL loads were secured; The same records did not demonstrate that transport*
Summary Warehousing: *Storage areas (Cooler, freezer and dry warehouse) were clean and well maintained during the audit. Transport vehicles were battery operated, and restricted to non-production areas. Manual pallet jacks were used in the filling rooms. Materials are conveyed from the cooler to the production area. Waste and chemicals were segregated from food products. The chemical storage areas were secured, and accessed only by trained employees. The temperature of the cooler, freezer and filling rooms were monitored continuously, and a text message would be sent in the event of failure. The temperature of the storage areas was being verified thrice daily. The temperature of the filling room was verified during pre-operational inspections, and monitored during the day.*			
17. Product information/consumer awareness			
Summary Product information/consumer awareness: *There were no retail product manufactured-All products were shipped for further processing.*			
18. Food defence, biovigilance and bioterrorism			
18.1 General requirements			
18.2 Access controls			
Summary Food defence, biovigilance and bioterrorism: *The food defense plan and mitigation measures were reassessed on 27 Sep 2016, and indicated that the measures were effective. All external doors were secured, and access restricted through key cards from the exterior and within the facility (sensitive areas). Cameras were also installed in critical locations (blending, filling, shipping/receiving). Employees are reminded to inform management of any suspicious activities.*			

Additional FSSC Requirements			
Specifications for services	*x*		
Supervision of personnel in application of food safety principles	*x*		
Specific regulatory requirements	*x*		
Announced, but unscheduled audits of certified organisations	*x*		
Management of Inputs	*x*		
Other items required by applicable legislation, recognized sector codes and customer requirements.	*x*		
Facility is aware of requirements for proper usage of FSSC Logo. (refer to FSSC document No 20451001 "How to use the FSSC Logo")	*x*		

Summary of Additional FSSC Requirements:

Specifications had been developed for all contracted services, and included food safety expectations. Reviewed the contract for the laundry company (4 Aug 2016), and met the requirements of the standard. Monitoring was performed at the time of service delivery.

The employees were supervised during production, and monitored on the record "Form 1040". Practices were conforming during the audit.

The company ensured compliance to local regulations, and countries where products were exported. The management review and regulatory list included specific regulatory requirements.

Programs were established for announced audits, and the facility had a culture of being audit-ready.

Customer requirements were communicated through Sales and customer service personnel, and discussed during the monthly meetings. Specific requirements were being met, such as testing of products for customers.

The logo was being used only in emails, and had been approved by the Certification Body on 24 May 2016.

Addendum 3

Major Non-Conformities (Corrective Action Requests) - Resolution with supporting evidence must be submitted to the auditor within **14 working days** of **after completion of the audit.**

Minor Non-Conformities (Corrective Action Requests) - Resolution with supporting evidence must be submitted to the auditor within **30 working days after completion of the audit.**

CAR No.	Major	Minor	Clause	Identified Issue	Resolution
1	☐	☒	5.4	The organization did not include personnel recently recruited (Process Engineer & Regulatory Specialist).	CAPA 16 – 227 (full details) Corrective Action Summary: The organization charts for Greenwood and CPFG will be updated as follows: 1) Add Production Process Engineer 2) Add Regulatory Specialist 3) Director - Global Operations will be removed - Replaced by Director Procurement and Supplier Relations 4) Individual names will be replaced with positions only Policy 023 - new employee orientation will be assessed and updated to make more user friendly and compliant with FSSC guidelines. This will likely include addition of a checklist containing key elements in addition to existing HR guidelines.
2	☐	☒	6.2.2	Training records reviewed for One point lessons (8 Oct 2015) & GMP orientation (9 Feb 2016) did not included evaluation of implementation and effectiveness. Instead employees were required to sign or initial that they "read and understood". The training matrix had not been updated to include the employees recently recruited (Process Engineer & Regulatory Specialist).	CAPA 16 – 228 (full details) Corrective Action Summary: One Point Lessons as all know them will be archived. Training Form, form 100, will be updated to include a column for competency assessment initial and dating by the trainer of record. Personnel will also be informed that OPL and other training approaches may continue to be used, but must have the newly formatted Form 100 attached. Training matrix will be re-assessed by Food Safety Team and additions will be made as necessary. Consideration during "new hire" checklist will also be given. New Hire Procedure revision, integrated with checklist, which will include position appropriate training based on training matrix
3	☐	☒	7.10.3	Existing stock of raspberry flavor (lot#31045) with expiry date of 1 Aug 2015 had not been held.	CAPA 16 – 229 (full details) Corrective Action Summary: IT will make sure this is addressed by E21 before Go Live. We will work to go live as soon as possible.
4	☐	☒	9.2	There was no documented program established for monitoring the performance of existing suppliers.	CAPA 16 – 230 (full details) Corrective Action Summary: A Supplier Evaluation Program will be established to maintain the performance of manufacturers (suppliers). The Supplier

					Evaluation Program will specifically maintain any problems (product quality, food safety, documentation, pricing, packaging, labeling) and positive feedback (documentation, customer service, and communication) on a continuous basis to be shared with team members at monthly Food Safety Team Meetings. A procedure is currently being drafted that provides guidelines to how suppliers (manufacturers) will be rated on a scale.
5	☐	☒	10.2	Positive air pressure was supplied in the filling and blending rooms (based on design). However, the records dated 13 May & 30 Aug 2016 indicated a negative air pressure at some entrances to the filling room (from the cooler)	CAPA 16 – 231 (full details) Corrective Action Summary: Recommend using outside contractor to annually check for over pressure, and determine base line. Will continue to do in house monitoring with cheap velometer monthly. Also adjusted motor sheave on RTU5 to increase RPM on unit. Fill room readings taken on 10.14.16 are as follows. PacMat man door-(+290) PacMat overhead door-(+220) Fill Room Cooler man door-(+160) Fill Room Cooler Conveyor Door-(+150) Fill To Blend room Man Door - (+150) Cooler To Blend Man Door - (-180) Blend Room Drum Cooler Door- (0) Blend to Maintenance Hallway-(+120) Will adjust motor sheave on RTU6 and retake. Outside Contractor scheduled to be out on 11.4.16.
6	☐	☒	11.1 & 11.5	(1) Flooring was not being sanitized. (2) The daily sanitation records were being verified at the end of the day, but did not provide evidence that each of the cleaning tasks had been monitored for effectiveness. (3) The concentration of sanitizer was being recorded as 130 ppm on the Form 11 (pages 2 & 7), but was not being measured. Also, the paper strip test kit used for measuring the concentration of the PAA sanitizer (aimed at 90-130 ppm) does not clearly indicate the color at 130 ppm, but at 160 ppm. (4) The filter screens are	CAPA 16 – 232 (full details) Corrective Action Summary: Meeting held with John Sada of ChemStation for the purpose of developing a plan for post-production sanitizing of flooring. ChemStation will supply, at no charge a Flood Sanitizing system that will dispense a proportioned amount of PAA. ChemStation will additionally supply an SSOP template for development of our own SSOP process. CAPA 16 – 233 (full details) Corrective Action Summary: daily task MSS forms require updating to include "monitoring" of each task by a competent individual. Forms: 017 - Suraya 1036 - Suraya 1050 - André 1052 - Eric Trainings forms will be attached once

				installed after CIP and pre-operational inspections have been conducted, and would be sanitized before being installed. The environmental monitoring program did not include swabbing of these screens.	competency assessments have been completed, which cannot occur until a few days after implementation (11/01/16). A review period of completed records will be necessary to assess effectiveness of form updates, which should be completed by December 2016. CAPA 16 – 234 (full details) Corrective Action Summary: form 011 will be amended to remove all columns where the concentration was being recorded without live checking and include a table for recording all relevant daily used chemicals will be checked for concentrations strength at the point of use proportioner by the most suitable method. Test kits from ChemStation training on form update Training on titration/ other test kits for chemical concentration checks. CAPA 16-235 (full details) Corrective Action Summary: After sanitizing, operators will now be required to swab the screens before use. This will be recorded on the manual cleaning table in form 011. Operators will be informed of this change at the next production meeting. SSOP to outline proper screen sanitation will be assigned as SSOP 1009 - (formerly) sanitation of jumper connections -- the scope will be broadened to include screens, magnets and other food contact surface equipment that is cleaned in the same/ similar manner.
7	☐	☒	16.3	The shipping records did not provide evidence that LTL loads were secured; The same records did not demonstrate that transport vehicles were being checked for condition and cleanliness; Shipping records (Bill of lading) would include the temperature for maintaining products during distribution. However, the completed records reviewed (such as BL#88974) indicated the	CAPA 16 – 236 (full details) Corrective Action Summary 1) Securing of LTL loads – SOP 1015 will be amended to include instructions regarding the securing of LTL loads. a. All outbound shipments will require that a padlock be applied t load.. B. The GAI Straight Bill of Lading – Short Form will be revised to include a check box for verification that the trailer was locked properly. (WO 1113) In the event that a driver does not have a padlock, a zip – tie will be applied by shipping personnel and noted as such on the BOL. 2) Cleanliness of outbound trailers – SOP 1015 will be amended to include more

				set temperature was not achieved (0 F for frozen), since pre-cooling was not being performed.	detailed instructions regarding the inspection of outbound trailers. A. The GAI Straight Bill of Lading – Short Form will be revised to include a more detailed assessment of trailer condition, similar to that of the GAI Arrival Notice. (WO1113) i. Trailer clean? Ii. Trailer intact? Iii. Trailer free of pests? Iv. Trailer has no foul odors? 3) Outbound temperature set point of trailers – SOP 1015 will be amended to include instructions regarding the temperature set point of trailers. Pre-cooling will be required for all outbound shipments. A. Trailer temperature set points will be established for products as follows: i. Frozen ≤ 32F ii. Refrigerated ≥32F ≤ 45F iii. Ambient ≥45F ≤120F b. Trailer temperature will be assessed by recording the reefer setting and current temperature indicated on the unit. C. Trailer temperature will be further assessed by recording the interior temperature using IR thermometers. D. The GAI Straight Bill of Lading – Short Form will be revised to include fields for recording the aforementioned points. (WO 1113) 4) Training will be conducted, and compliance verified on all amendments to SOP 1015.

The above non-conformities were presented to the client Representative and discussed at the closing meeting

Lead Auditor Name	VikashLutchmiah	**Signature**	
		Date	6 Oct 2016

Verification of receipt of Non-Conformity Schedule (to be completed by the client representative)

Name		**Signature**	
		Date	6 Oct 2016

Addendum 4

Observations for Improvement
Under the requirements of ISO 17021, Merieux NutriSciences Certification is not permitted to offer solutions or recommendations to clients, since this will establish a Conflict of interest. The following observations are offered to assist in the continual improvement of the Food Safety and Quality systems. As necessary, they could include minor anomalies in the current system, where raising a Corrective Action Request was not considered warranted or where further investigations may be warranted for continual improvement.
The form used for recording preventive maintenance tasks for tank 201 indicated tank 101.
Coats worn in the filling and production areas were not removed when leaving these areas (such as maintenance & shipping areas). Also, maintenance coats were stored in a cabinet along with footwear.
Food grade grease guns in the maintenance area were not labelled;

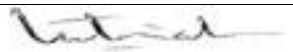
Appendix 5

Verification of closure of Identified Non Conformities (to be completed by the Auditor)

I verify that the evidence submitted by the client has been reviewed and the action taken is sufficient to warrant closure of the identified non conformities.

Evidence Sighted and Auditor Comments	
CAR No.	**Evidence & Comments**
1	Updated Organisational charts were conforming.
2	The updated training form was conforming.
3	New software and restrictions for held items are conforming.
4	CAPA 16-231 and corrective actions for updated supplier program were conforming
5	CAPA 16-231 and corrective actions for use of contractors were conforming.
6	CAPA 232, 233, 234 & 235 and corrective actions provided (Training, updated SSOP to be implemented, & Swabbing program) were conforming
7	CAPA 236 and corrective action plan were conforming.

Additional Comments

Lead Auditor Name	Vikash Lutchmiah	**Signature**	
		Date	8 Nov 2016

Mérieux NutriSciences Certification LLC

Addendum 6

Certification Status Report

	Stage 1	Stage 2	Stage 2	Stage 2
Audit Type	Initial Certification only	Initial Certification/Re-certification	Surveillance 1	Surveillance 2
Audit Date				
Facility				
Assessor				
Certificate No				

Audit Outcome

	Major NCRS	Minor NCRS	Major NCRS	Minor NCRS	Major NCRS	Minor NCRS	Major NCRS	Minor NCRS
Total No identified								
Applicable Clauses								