Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	Cambridge Commodities Ltd	Site Code	6960330
Site name			
Scope of audit	The repackaging of dry, ambient stable nutritional food ingredients packed into bags for further manufacturing. The trading of a range of nutritional food ingredients including herbals, vitamins, minerals, amino acids, enzymes, probiotics, antioxidants, oils, gums, sweeteners and dietary supplements.		
Exclusions from scope	None.		
Justification for exclusion			
Audit Finish Date	2019-10-10		
Re-audit due date	2020-11-05		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
FSMA Preventative Controls and FSVP Preparedness	Passed	The repackaging of dry, ambient stable nutritional food ingredients packed into bags for further manufacturing.	None
Choose a module	Choose an item		

Head Office	Yes

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	AA	Previous audit date	2018-10-09		
Certificate issue date	2019-11-05	Certificate expiry date	2020-12-17		

	Fundamental	0

Number of non-conformities	Critical	0
	Major	0
	Minor	3

3.Company Details

Address	203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6 3NX		
Country	UK	Site Telephone Number	01353 667258
Commercial representative Name	Ian York	Email	Ian.york@c-c-i.com
Technical representative Name	Phil Barnhill	Email	Phil.barnhill@c-c-i.com

4.Company Profile

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

Shift Pattern	Days
Subcontracted processes	Yes
Other certificates held	FEMAS, Organic, Halal, Kosher, ISO 22000, Informed Sport, ISO14001, ISO9001 2015
Regions exported to	North America Europe Africa Choose a region Choose a region Choose a region
Company registration number	N/A
Major changes since last BRC audit	No major changes.

4.Company Profile

Company Description

Founded in the 1998, the company has grown rapidly in recent years, moving to the current, purpose built premises in May 2015. The company specialise in supplying ingredients for the sports nutrition, health and wellness, equine and pet sectors. The company sources and stocks a range comprising of around 1200 different product lines, which are either supplied in original packaging (traded) or repacked (powdered goods only) on site if smaller quantities are required. There is a wide range of product types, all of which are ambient stable, although a few products are stored at chilled temperatures to maintain product quality. All goods for repack are powdered and represent about 5% of total throughput, rest belongs to traded goods. The company employ 120 employees, of which 25 work in production, 18 in quality and rest in the office. Limited re-packing on site with total re-packing and storage area around 9000m square and the warehouse has 9000 pallet spaces. Production hours are 8.30 am to 5 pm with a dedicated cleaning team afterwards to clean walls and floor. The company also undertakes an on-site contract packing service for tabletted nutritional and health food supplements that do not come within the scope of the Global Food Standard. These are packed in a room that is completely separate to the in-scope products. The company has also commissioned a blending facility which is not currently operational.

5.Product Characteristics

Product categories	15 - Dried food and ingredients VM - FSMA Preventative Controls and FSVP Preparedness Category Category
Finished product safety rationale	Ambient, moisture typically 5% with a maximum of 15%.

High care	No	High risk	No	Ambient high care	No

Justification for area	All goods are ambient stable and risk assessment is based on BRC decision tree in issue 8, appendix 2).
Allergens handled on site	Cereals containing gluten Crustaceans Molluscs Egg Fish Soya Milk Celery Sulphur dioxide and Sulphites 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	Organic, Halal, Kosher, gluten free.

5.Product Characteristics	
Product recalls in last 12 Months	Yes
Products in production at the time of the audit	The repacking of powdered products.

6. Audit Duration Details			
On-site duration	18 man hours	Duration of production facility inspection	5 man hours
Reasons for deviation from typical or expected audit duration	The BRC audit was shorter than the expected duration because it was a simple operation with well laid out QMS. The duration of the production facility inspection was less than 50% of the duration of the BRC audit due to simple repacking operation.		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-10-08	09.00	17.50
2	2019-10-09	07.55	16.25

	Auditor (s) number	Name	Role
Auditor Number	135059	Simon Brookes	Auditor
Second Auditor Number	N/A		Please select

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Tom Stevens/Operations Director	X			X
Phil Barnhill/Quality Manager	X	X	X	X
Hannah Pritchard/Quality Manager	X	X	X	X

Non-Conformity Summary Sheet

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

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

Major							
No.	**Requirement ref.**	**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.	**Requirement ref.**	**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	4.9.6.1	The procedure for deboxing/debagging at raw material intake is not clearly documented.	The procedure will be amended to include the deboxing/debagging step described in the repacking procedure.	Be sure to review procedures involving the modular cleanroom when amending the repacking procedure as they are very similar processes.	QM07.SOP05 Goods in Product Inspection and Cleaning Procedure Issue 9 dated 11/10/19.	2019-10-31	S.Brookes

2	4.11.1	Warehouse cleaning equipment is not stored hygienically.	The warehouse cleaning equipment has now been stored in a hygienic manner in a designated area.	A toolbox talk will be given to the warehouse to explain the importance of storing the warehouse cleaning equipment hygienically. This will be monitored monthly through during our internal GMP audits.	Operator signed training record for QM08.SOP16 dated 15/10/19. Photos of cleaning equipment storage areas.	2019-10-31	S.Brookes
3	4.16.4	Cleaning procedures for FLTs are not clearly documented.	The warehouse cleaning procedure will be amended to include the cleaning of the FLT's.	This has now been added to the warehouse cleaning procedure and been trained out.	QM08.SOP16 – Warehouse cleaning procedure Issue 3 approved 16/10/19.	2019-10-31	S.Brookes

Comments on non-conformities

Additional Modules / Head Office Non-Conformity Summary Sheet

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

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Root cause analysis and proposed action plan**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Root cause analysis and proposed action plan**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	13.4.1	Cleaning procedures for FLTs are not clearly documented.	The warehouse cleaning procedure will be amended to include the cleaning of the FLT's.	This has now been added to the warehouse cleaning procedure and been trained out.	QM08.SOP 16 – Warehouse cleaning procedure Issue 3 approved 16/10/19.	2019-10-31	S.Brookes

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There is a documented food safety policy signed by Quality Manager and Operations Director and dated 30/05/19 which is in the shared folder on the system with all staff having read access. It is also included in the induction information given to all new employees.

The company demonstrated their commitment to the Standard based on the level of on-site managerial resource, staff training and financial investment sufficient to produce safe, legal, authentic and quality food.

A plan for the development and continuing improvement of a food safety and quality culture is in place, (doc ref QM02.FOR05 v1 dated 03/10/19 and Quality culture policy QM02.POL02 rev 1 dated 03/10/19).

The following activities are included in this plan: Annual staff performance reviews expressing the importance of quality and food safety (every 6 months), Conduct annual employee surveys (annually November) and plan to make improvements based on feedback, hold monthly staff meetings to include quality updates. Develop board reports and KPIs, organise an annual world food safety day and carry out related poster campaigns.

The effectiveness of these activities is reviewed annually in November.

The Operations Manager T.S was interviewed for this process as part of Senior Management review.

Clear objectives/targets are established by the company which are specific, measurable and achievable and these are:

Reduce the complaints raised due to CCL by 5%. 2018 1.13% YTD 0.69%
Increase supplier audits to 20 per year. Slightly behind due to resourcing.
Develop quality team through internal auditor training. 10 members changed. 100% Achieved.
Source and purchase a X ray detector – Trialled and still reviewing.
HACCP level 2 and external allergen training for all. – 2 employees started on apprentice scheme.
Prepare for BRC 8

These are monitored and reported monthly to senior management and reviewed at the Management Review meetings held monthly. Minutes reviewed for latest Quality monthly meeting dated12/09/19 and latest board meeting 17/09/19 which included the Quality Board report dated Aug 2019

Management Review meeting agendas include all elements of 1.1.4.

In addition, Quality meetings are held monthly in order to bring food safety, legality, integrity and quality issues to the attention of senior management.

Other meetings held include monthly Sales and Operations meetings, Monthly complaint review meetings and start of shift production and warehouse meetings covering last 24hrs.

Employees are aware that evidence of unsafe or out of specification raw materials or products must be reported to first line manager so that anything requiring immediate attention can be dealt with. Evidenced during facility inspection.

There is a confidential reporting system in place doc ref HRP22 rev 4. which enables staff to report concerns relating to product safety, integrity, quality and legality.

The method of reporting concerns is communicated to staff by email and people portal.

Senior management assess any concerns raised via the online portal or reporting box This assessment, and any actions taken, are documented on the online portal. No food safety or legality issues raised.

The site is kept informed of the points listed in 1.1.8 by members of Campden BRI, FSA alert, European Pharmacopeia sources of information and legal foods. These are reviewed by the quality team on ongoing basis and before approval of any new product. Last update received 07/10/19 and 08/09/19.

The 2 non-conformities raised at last year's audit have been resolved and there was evidence that root cause has been identified and actions instigated to prevent recurrence.

The site uses the BRC Global Standards logo and/or refers to its certification status on marketing materials, website, but not on products or packaging.

1.2 Organisational structure, responsibilities and management authority

There is an established and experienced team of managers based on site with the Managing Director and Commercial Director being in overall charge. The day to day operations of the site are shared between the Department Managers. An organogram is in place. Deputies for key staff are defined in job descriptions and organisational chart.

Job descriptions and work instructions are documented for all personnel and processes to communicate duties and responsibilities.

The following work instructions were challenged during the audit and found to be operational and relevant.

Goods in procedure – QM07/SOP05 issue 8 dated 30/09/19 (Includes magnet checks) – 24/04/19 - changed format. 30/09/19 added integrity check of magnet and taking samples of packing materials
FTIR testing – QM08/SOP12 issue 5 dated 30/10/17
Repacking – QM07/SOP01 issue 19 dated 13/09/19 – updated to define cleaning responsibilities
Vehicle inspection procedure - QM07/SOP22 issue 2 dated 10/11/16

Job descriptions were challenged for the following roles: Quality Assistant Manager and Cleanroom Supervisor.

2 The Food Safety Plan – HACCP

The company's food safety plan is based on Codex Alimentarius HACCP principles. There is one HACCP study, currently at issue 10 and dated 28/08/19.

The HACCP team is led by the Quality Manager (H.P) who is trained in Level 3 (Train4Acadamy), 15/02/17 and experienced within the industry.

The HACCP team includes representatives from production, warehouse, technical, quality and despatch and are experienced in the industry. All HACCP team are either qualified to a minimum of level 2 or are in the process of doing online HACCP Level 2 or Level 3 course e.g. Quality Manager (P.B) - Level 2 (Highfield, July 2011). The team members are; HP, PB (QA Managers), AB (Warehouse Manager), T.S (MD) and D.B (Cleanroom Manager).

The scope of the study includes material approval, positive release, processing, storage, despatch and covers all the products produced at the site. It is systematic, comprehensive and fully implemented and maintained.

A comprehensive pre-requisite programme is in place covering: personal hygiene, transport, allergens, pest control, foreign body controls, site/waste management, supplier approval/monitoring, hygiene and housekeeping.

Pre-requisites used to manage specific hazards e.g. wide range of potential raw material contaminants have been validated by reference to specific regulatory criteria and by testing, based on risk covering microbiological and chemical testing e.g. pesticides, PAH, mycotoxins, and are routinely verified by supplier COAs and analysis, with records kept.

General pre-requisites, such as pest control are validated by industry best practice and monitored by external approved supplier and site.

Product descriptions are defined as dry powders/food supplements mainly in 25kg quantities which require ambient storage (unless otherwise specified) with protection from moisture and light. Packed typically in a double layer of polyethylene bags and within a cardboard drum. They may also be packed in plastic lined paper bags or woven sacks. Pallet stacking formats are determined by the material supplier prior to receipt of goods and pallet stacking procedures for despatch of goods is at the discretion of warehouse operators since mixed pallets are common.

References to legislation have been made within the study including: food hygiene regulations, Contaminants in food EU 1881/2006, novel foods, and food additives EU 1333/2008 and EU231/2012.

Intended use is documented as for further processing or re-packing with no product sold direct to consumers. Products are not intended for any particular group and the end use is the responsibility of the customer. No alternate uses are known.

There is one flow process diagram QM02/GEN04, currently at version 10 and last verified by the team on 07//08/19. Meeting minutes reviewed.

The process flow diagram covers the process steps, which are: product approval, receipt, sampling and checks, positive release, repack if needed, finished goods storage and despatch.

Physical, chemical, microbiological fraud, malicious contamination and allergen hazards have been considered within the study (e.g. glass, metal, stones, wood, pests, salmonella, E. coli, Y&M, Entros, cleaning chemicals, pesticide residues, mycotoxins, aflatoxins, GMO, heavy metals, PAH). Allergen hazards (including supply chain risks, handled on site and via visitors/workers raw materials) are included within the HACCP study. Radiological statement dated 04/10/19.

Hazard analysis and CCP identification has been based on a likelihood x severity basis and the use of a 4 question decision tree.

No CCPs have been identified as limited handling of products on site. The key controls are product approval before starting supply; products are release based on intakes QA testing including rare earth magnet checks and Fourier Transformed Infra-Red check (FTIR) against a previously accepted delivery. A corrective action procedure is in place. Responsibilities for monitoring the critical limits and for corrective action are defined.
Verification is carried out during internal audits and the daily verification checks performed. Verification reviews are carried out annually and are based on a review of the system documentation, records, internal audits, deviations and corrective actions, complaints and incidents. The HACCP plan and pre-requisite programmes are reviewed at least annually (last reviewed on 07//08/19), when relevant changes or if a recall occurs. As a result of the last review, the following changes were made to the company's product safety policy and food safety objectives: Moved to single blue bags, changed supplier changed approval process and added new allergen questionnaire regarding raw materials sourcing from farms and potential cross contamination.

3. Food safety and quality management system

3.1 Food safety and quality manual

The Quality Manual has been written to meet the requirements of the Standard and contains policies, procedures, work instructions and forms. It is controlled electronically by the Quality Managers via Adobe EchoSign / docs vault.

Department specific work instructions are available at key locations and all documents are in English (with pictorial guides). Examples reviewed included the following;

Goods in procedure – QM07/SOP05 issue 8 dated 30/09/19 (Includes magnet checks) – 24/04/19 - changed format. 30/09/19 added integrity check of magnet and taking samples of packing materials
FTIR testing – QM08/SOP12 issue 5 dated 30/10/17
Repacking – QM07/SOP01 issue 19 dated 13/09/19 – updated to define cleaning responsibilities
Vehicle inspection procedure - QM07/SOP22 issue 2 dated 10/11/16.

3.2 Document Control

Controlled documents are listed on the S-drive (read only) and the doc register. Control is managed by the document control procedure QM04/SOP03 issue 2 dated 24/10/16, with the relevant Department Head responsible for authorisation, changes/amendments and replacement of existing documents. Change history is documented on each procedure.

The following forms and policy revisions were reviewed and found to be correctly controlled;

Vehicle inspection – QM07.FOR06 issue 1
Repack record – QM07.FOR07 issue 8 – updated re bag batches (previous versions archived)
Foreign body control QM04.POL06 issue 6 dated 11/09/19 – medical alert jewellery.

Electronic documents are stored securely, with access controlled by authorised access, password protection) and are backed up on off site server.

3.3 Record completion and maintenance

Records are completed manually and electronically and are stored electronically (manual records are scanned) and backed up daily to three servers.

Records reviewed during the audit (e.g. trace challenge/site tour) were seen to be legible and genuine and were easily retrieved.

Records are scanned into the system and retained indefinitely. (Typical shelf life of product is 2 to 3 years dependant on supplier information.)

3.4 Internal audits

There are 10 trained internal auditors based on site who are responsible for the site internal audits. Some members of the team are lead auditors and rest are trained internally by lead auditors.

SM, HLP, JO and J.B (Quality) JO – Internal auditor ALCUMUS 23/24/07/18, JSP (Operations), J.B (Technical Manager) Internal lead auditor ALCUMUS 23/24/07/18, PB – Lead auditor ISOQAR 27th to 31st Oct 14. CW – internal auditor ALCUMUS 7th and 8th Dec 2016.

The auditors on site cross audit departments to ensure independence from direct responsibility.

The internal audit schedule is documented QM04/FOR03 and covers all the documentation and processing systems on site. Each area is audited at least annually. Internal audits are carried out throughout the year on at least 4 different dates, spread across the year with the frequency determined by risk assessment.

Internal audit records reviewed included the following and were comprehensive recording both conformity and non-conformity and objective evidence for the findings.

Training – 30/09/19 – J.B – 3 observations and 1 N/C (training matrix not up to date). Due for closure date end of Oct 2019.

Supplier and product approval – 30/04/19 – JO and JB – 5 observations raised, all signed off 07/05/19

Pest Management – 25/09/19 – J.W and M.S – No N/Cs raised.

Food defence and food fraud – Planned for November

Non-Conformance system – 07/05/19 – SM and CA – 4 observations raised, all signed off 10/07/19.

Glass and hard plastics (biannual) – 29/04/19 – HP and HS – 4 actions raised for warehouse, all signed off by 30/04/19.

Corrective actions and their timescales had been agreed and completion had been verified by the Auditor, Quality Manager and relevant Department Manager.

In addition, monthly hygiene/fabrication and GMP inspections are carried out (QM08.FOR22), based on risk assessment. Reports reviewed included those for; July 29/30/07/19 – 2 minor NC raised - NCR-A01 and NCR-A02 dated 31/07/19 – full clean down procedure not performed, vehicle check sheet not completed for 23/07/19 – both signed off 06/09/19, August - 3 observations all signed off by 02/09/19.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

A risk assessment of raw materials and primary packaging has been carried out, which is reviewed annually for each supplier, with products assessed for allergen, foreign body, chemical, microbiological and substitution/fraud risks. The assessment is also based on nature of material (e.g. herbs), volume, type of certification and historical issues with risk-based testing regimes in place. With the controls in place all suppliers are assessed as low risk.

The risk assessment includes the following risks associated with raw materials which are subject to legislative control e.g. pesticide/aflatoxin/ochratoxins/PAH and HM.

There are no variety/species cross contamination risks.

Suppliers of products are approved and monitored by the Quality Manager (PB) using supplier and product approval procedure (QM07.SOP08 issue 8 dated 06/08/19) and assessment of suppliers is based on risk, quality and historical compliance.

The risk assessment is used to grade suppliers as low, medium or high risk.

All suppliers have been assessed as low risk.

Suppliers are requested to submit third party certification. They are also requested to complete a supplier approval questionnaire doc ref QM07.FOR02 (Not required for GFSI approved site), a supplier raw material questionnaire – QM07.FOR09 and provide a specification, manufacturing flow diagram, HACCP, picture of material, a sample and traceability details before material can be purchased. The company also have product specific forms e.g. PA risk assessment doc ref QM07.FOR29 and allergen risk assessment QM07.FOR36. Also based on this information a decision is made whether an audit by the Quality Manager is necessary. A performance rating is given and if issues are identified during the audit, a decision is made whether it is appropriate to try and improve the supplier or to not use them. Once this process has been completed a supplier approval form QM07.FOR04 issue 17 is completed and supply can commence.

Examples of supplier approvals reviewed included;

Citrus bioflavenoides 60% PO3329 supplier NNG - Audited 01/04/16 by Quality Manager, 4 minors raised and closed within 30 days. ISO 22000 HACCP expires 09/08/20. QM07.FOR04 dated 10/05/17
Maltodextrin DE 18-20 – from supplier BAO - Audited 14/04/16 by Quality Manager, no n/Cs raised. FSSC 22000 expires 17/11/20. IP program expires 22/10/19. QM07.FOR04 dated 01/06/16 – Reapproved QM07.FOR012 - 11/05/18
Coconut Milk powder supplier NOB, QM07.FOR04 dated 20/09/16 – FSSC 22000 expires 16/12/21. No longer supply Coconut Milk powder following recall. All batches of coconut milk powder are now tested for presence of casein as detailed in PS system.
Turmeric supplier – S – BRC I8 site code ****267 expires 24/06/20.

Packaging
LPDE bag supplier DeePack plastics – BRC Packaging site code ****811 expires 18/08/20

Supplier questionnaires are issued every three years and suppliers are required to notify the site of any significant changes in the meantime by updating questionnaire. There is an annual supplier re-approval form QM07.FOR12 issue 14 covering specifications, certification checks, changes to material or process and a re-check RASFF/google for any evidence of contamination risk for the material and allergens/animal by-products. CoAs are received with each batch and each batch is FTIR tested.

BRC certificate for LDPE bags from site code ****811 and Turmeric from site code ****267 were checked during the audit via the BRC database and found to be genuine and valid.

There is a documented, risk-based process for the on-going review of supplier performance (doc ref QM07.SOP08 issue 8), with the following performance criteria defined: complaint history site accreditation and volumes purchased and on site audit requirements if supplier not GFSI certified or high risk.

An approved supplier list is in place which is an IT live list. This lists supplier, manufacturer, date of approval, approved by, basis of approval or non-approval and due date. Relevant information from the list is made available to purchasing and intake staff via IT system.

Agents, brokers and wholesalers are used. The site knows the identity of the last manufacturer, packer or consolidation place. Examples below.

Information to enable approval is obtained from the agent or the manufacturer or the agent/broker has BRC Agents and Brokers certification.

Examples reviewed for;

Turmeric supplier – S – BRC I8 with traded goods, site code ****267 expires 24/06/20.

Suppliers' traceability procedures have been assessed by GFSI certification, or if required supplier audit. Supplier audits are carried out by the Quality Manager (PB) who is lead auditor trained and experienced in the industry. Supported by Chinese speaking Quality specialist. These are based on the outcome of supplier questionnaire review, quantity supplied, potential adulteration/contamination risk, historical issues and reputation of the company. The supplier audit report is based on BRC criteria (HACCP, quality management, product & process control, analysis, personal and environmental hygiene).

Audit reported reviewed for supplier of herbal powders and extracts (NG) Audit 01/04/16 – PB and CW – 4 minors all signed off 28/04/16.

No suppliers are approved via a questionnaire only.

Exceptions are covered under supplier and product approval procedure (QM07/SOP08). Products prescribed by customers or where information for effective supplier approval is not available and instead product testing is used to verify product quality and safety.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Raw materials and primary packaging are checked on intake for compliance with purchase orders and certificates of analysis/compliance are received.

Every product is sampled on delivery for visual/organoleptic assessment against CoA and put through magnet testing (Powders). A magnet is put through the sample bag to check any metallic contamination. If metal is found, a report is sent to Quality Manager and supplier informed. Product is put on quarantine. After magnet inspection product is sent for FTIR testing to ensure a close match to previous delivered lots.

An example of a material intake issue was seen for PO2252, batches GG2017002 and GG2018002 Pack ID 1720008 (4kg) Quarantine log - returned damaged from customer dated 19/07/19 and 1717070 (5kg) quarantined 08/10/19.

The PS system ensures that any approved changes to raw materials or primary packaging are communicated to intake staff.

3.5.3 Management of suppliers of services

Service suppliers are approved and monitored by Quality Department using supplier approval and monitoring procedure doc ref QM06/GDE01 issue 3 dated 02/10/19 and have appropriate contracts.

These were reviewed for suppliers of laundry (SL) (visitor lab coats/towels in kitchen only) signed 28/1/14 and haulier (Schenker) signed 01/10/19.

3.5.4 Management of Out sourced processing

The following processes are outsourced: Blending/packaging of powders.

The brand owner has been made aware of the outsourcing and has given approval via online hub for certain customers or statement/specification. Example reviewed for customer HB dated 29/11/17.

The following companies are used and have been approved by GFSI certification. The Company could also approve via supplier audit by a demonstrably competent product safety auditor as per clause 3.5.1.2.

NVR – BRC I8 site code ****101 expires 17/06/20 – POs stipulate processing requirement and terms and conditions. Example reviewed for Product P29949, PO 274738NVRP - Technical agreement signed 30/09/19.
HEZ - BRC I7 site code ****318 expires 03/01/20
WPB – BRC I8 site code ****080 expires 04/03/20

Contracts are in place between the two sites via technical agreements. Example above.

Traceability is maintained by checking batch records for every batch supplied back.

On receipt back to site the products are checked by FTIR testing to ensure it is similar to last batch made. Example of records seen for P29949 batch 17190 FTIR tested 19/09/19, External Lab micro test results within specification – Concept Life Sciences UKAS 1549 dated 30/09/19.

3.6 Specifications

Raw material and primary packaging specifications are sufficiently detailed and are held on site.

Reviewed for:

Raw material
Maltodextrin DE 18-20 – from supplier BAO – dated 11/04/18
Citrus bioflavenoides 60% PO3329 – from supplier NNG – dated 20/06/17

Packaging
Blue bag supplier DeePack plastics DQD High slip first grade LDPE – dated 09/09/19 – Migration report Smithers PIRA report dated 27/11/18. DOC ref 1935/2004, EU10/2011 dated 21/05/19.

Finished product specifications are generated by the company and are based on the raw material specifications and are supplied to customers on company format. No changes to materials are made as products are simply re-packed.

Specifications are agreed with customers by email example reviewed for customer (RMX) for P13014 dated 08/02/18, customer SAQ dated 08/02/18.

The following finished products specifications were reviewed and found to be sufficiently detailed and compliant.

Finished product
P13014 - Maltodextrin– dated 13/03/18
P03329 - Citrus bioflavenoides 60% – dated 14/05/18

Specifications are reviewed on receipt of each CoA or where changes occur. Finished product specifications are reviewed every 3 years as a minimum.

3.7 Corrective and preventive actions

Corrective action forms part of the internal auditing procedure (doc ref QM04.SOP02 issue 2 dated 27/10/17) is in place. Non-conformities that result in a risk to product safety, legality or quality are investigated and recorded in line with clause requirements. This includes the assessment of the consequences of the non-conformity by the quality team and verification of corrective action by the Quality Manager.

Root cause analysis and the implementation of further corrective action to address the root cause, are carried out, where this is necessary.

A root cause procedure is in place as part of the Complaints Procedure doc ref QM08.SOP09 issue 6 dated 08/10/18.

Examples seen for Internal audits and complaints;

Customer complaint – Product P0055, 1 box ref raised 22/08/19, NCR 19/57 dated 27/09/19 for FB – closed 27/09/19. Supplier complaint raised ref S383/19 dated 22/08/19, awaiting credit note.

Corrective actions taken are recorded and discussed during the monthly quality meetings.

3.8 Control of non-conforming product

Non-conforming products are identified by hold stickers with reason of non-conformance and quarantined on the PS system. The Quality department is informed and are responsible for the holding and release of products. All incidents of customer non-conforming product are recorded on QM08.FOR04 version 7 as detailed in procedure QM08/SOP01 issue 2 dated 24/10/16. Supplier non-conforming products are recorded on QM08.FOR03. All incoming raw material issues are recorded on Quarantine record sheet QM08.FOR33 version 1. A concessions procedure is also in place QM08/SOP04 issue 4 dated 27/10/17.

Examples reviewed for 2 items held in location 1 of the goods in area;

Product PO2252, batches GG2017002 and GG2018002 Pack IDs 1720008 (4kg) and 1717070 (5kg) NCR 115 - returned to supplier due to FB contamination.

Records are in place to demonstrate the investigation, analysis and cause of any non-conforming product. Defined responsibility and actions/timescales are documented. There have been no major trends in last 12 months.

3.9 Traceability

A documented traceability procedure is in place (doc ref QM08.SOP17 issue 1 dated 27/09/19).

A recording system is in place with all raw materials, in process materials, primary packaging and finished product coded to allow for full traceability through the system.

The traceability system is computerised and operates on a batch system with a unique batch code assigned against a purchase order; batch code is Julian date code for the material. The batch code is recorded on finished goods labelling. On intake, products are entered into the system against purchase order, a label with barcode information is printed which is scanned into location. When product is needed for re-packing or sale, a pick note is generated and products are picked as per requirement.

The traceability procedure includes a summary of the documents that should be referenced during the test, and clearly shows the links between them.

Traceability systems of suppliers approved via questionnaire only, without GFSI certification or a supplier audit, are verified by Quality Manager (PB) via QM07.FOR02.

No rework.

The company carry out an annual traceability challenge including mass balance, and this was undertaken forwards and backwards on Coconut Milk powder P31188 batches N17197 on 31/05/19. Mass Balance 100% (50kg). Other batches were also checked as this was part of the recall e.g. batches N18388, N19056 and N19129.

A traceability challenge and mass balance was undertaken during the audit on product P03329 (Citrus bioflavenoides 60%), batch 201906067, BB 21/06/21. The exercise was completed in <4 hours. Mass balance for batch – 1000kgs from supplier NNG – 500kg dispatched including 200kg to customer TAA on 28/08/19, 500kg are pending.

3.10 Complaint-handling

A system of complaint handling is implemented via complaint procedure GM08/SOP09 issue 6 dated 08/10/18 which also covers corrective actions. All complaints are logged and investigated by the customer care team with full details kept of all actions taken.

Complaint target is set at - reduce the complaints raised due to CCL by 5%, 2017 1.26%, 2018 1.13% YTD 0.69%

Complaints are trended by product/type and discussed at the weekly customer care and monthly operations meetings.

The top 3 customer complaints are packaging (damaged/dirty) short or incorrect delivery and wrong goods despatched (sales documentation issues).

Analysis of complaints viewed for the past 12 months indicate that the level of complaints is running at below target.

2019 to end of Aug – Customer complaints – 420 - 112 quality related mainly organoleptic/visual and raised 382 supplier complaints.

Examples reviewed for;

Customer complaint – Product P0055, 1 box ref raised 22/08/19, NCR 19/57 dated 27/09/19 for FB – closed 27/09/19.

Supplier complaint raised ref S383/19 dated 22/08/19, awaiting credit note.

3.11 Management of incidents, product withdrawal and product recall

The site has comprehensive procedures (doc ref QM08/SOP02 issue 11 dated 02/05/19) and an out of hours contact list for all key members of staff, customers and organisations including the Certification Body. The requirement to notify the Certification Body within three days of a significant food safety incident, including a recall or regulatory non-conformity, is included. There is a business continuity plan QM02/GDE01 issue 2 dated 26/10/17.

An actual recall was initiated by the company – 31/05/19, product Coconut Milk powder P31188 batches N17197, N18388, N19056 and N19129. The CB and relevant contacts/authorities were notified on 04/06/19. The procedure was used to conduct the recall and did not require any changes.

4. Site standards

4.1 External standards

The site occupies approximately 9200 m² and production and storage buildings occupy 7400 m².

The site was constructed in 2015 as a purpose built.

The buildings are in good repair and well maintained. The external areas are suitably constructed for traffic routes and are maintained in a clean and tidy condition.

Local activities include various industrial units but no impact on the site activities.

4.2 Site security and food defence

A documented risk/threat assessment is in place which forms part of the plan and considers both internal and external threats and risks from deliberate contamination or damage.

As a result of this, a threat assessment plan (doc ref QM02/FOR02 issue 4) has been generated. This is reviewed annually and whenever a new risk/threat emerges or there is a product security/defence incident. Last review 13/08/19.

No raw materials or products have been identified as being at particular risk:

No areas of the site are considered to be at significant risk. There are no external tanks, silos or intake points.

The site security is managed by 24 hr CCTV. Site security is managed as part of industrial estate with limited access out of hours. Security visits are carried out by estate security.

Entry doors to production are fitted with key fob systems. Internal CCTV are monitored by IT Manager.

There is reporting system for all visitors and contractors.

Staff training is in place on site security and food defence.

The site is registered with Cambridgeshire County Council AOO21 EC and feed hygiene registration GB026E216.

4.3 Layout, product flow and segregation

There is a site map, doc ref QM06/FOR08 issue 6 which includes all the points referred to in clause 4.3.1.

The site is classified as low risk/enclosed. The area is divided into two separate risk areas- white for clean room where products are packed and are open and amber for warehouse and lab.

The plan shows delineation, segregation, access routes for personnel, staff facilities, production process flow and waste removal.

Entrance to the clean area has barrier entry point controls, changing facilities and dedicated PPE.

Contractors and visitors are supervised on site and have signing in procedures which include references to relevant procedures and requirements for the areas visited and prevention of hazards and product contamination.

There were no temporary structures noted.

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

Internal fabrication is well maintained with wall/ceiling cladding to all production areas.

Floors are coated and impervious. No water pooling was noted.

There are no suspended ceilings or roof voids.

There are no elevated walkways next to or over production lines.

There are no windows or roof glazing which are designed to be opened for ventilation within the production and storage areas.

There are extraction systems in place at each repacking work station and no evidence of excessive dust was noted.

Positive air pressure is maintained in clean area using filtered air (HEPA filtration) and double airlock doors at raw material intake room and finished goods despatch room. This is done to maintain purity of the product rather than for microbial safety.

All doors were noted to be in good condition.

External doors are close fitting, adequately proofed where necessary and either keypad secured or alarmed (fire exits).

4.5 Utilities – water, ice, air and other gases

Water is the only utility used on site is potable and mains supplied from Anglian Water. Annual microbiological analysis is obtained from the supplier and additional surveillance testing is carried out by an external laboratory on a quarterly basis.

Report seen for Concept Life Sciences (UKAS 1549) – sample date 13/09/19.

Changing room water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, TVC@22°C 56 cfu/ml, TVC@37°C 162 cfu/ml).

Lab main water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, TVC@22°C 630 cfu/ml, TVC@37°C 680 cfu/ml)

Wet room water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, TVC@22°C 92 cfu/ml, TVC@37°C 1380 cfu/ml)

There is a plan of the water distribution system doc ref QM06/FOR08 issue 6 which identifies sampling points.

Ice/steam/gas and compressed air are not used.

4.6 Equipment

The on-site equipment is very limited. It consists of stainless steel work tables, stainless steel scoops, sieves, spoons and weighing scales. There is a dust extraction at each work station and clean room is maintained at positive air pressure using filtered air. Utensils in the clean room are counted at a minimum of three times a day and condition checked. The scoop used for raw material sampling is single use only.

A new equipment risk assessment and validation system is in place with engineering, technical and hygiene assessment prior to purchase.

The following certificates/evidence was seen to confirm suitability for food use: disposable powder scoop conforms to FDA 21 CFR 177.1520, 178.2010, EU 10/2011 and EU 1935/2004.

4.7 Maintenance

The site was purpose built in 2015 with all equipment purchased new. All maintenance such as dust extraction, chiller, ventilation, forklifts is contracted out. No onsite engineering workshop and no lubricants are used on site. If any work such as light change had to be done in clean room, it is done outside production hours. Limited use of equipment on site.

No temporary repairs were noted. Temporary repairs are subject to recording on maintenance request logs.

The safety and legality of products is protected during maintenance by carrying out maintenance outside production hours, removing equipment from the production area. A documented hygiene clearance procedure is referenced in the repack procedure (doc ref QM07.SOP01 issue 19 dated 13/09/19) which takes place after maintenance. Equipment and machinery are inspected and signed off by the cleanroom Manager and Ops Director before being released back into production.

4.8 Staff facilities

Staff changing facilities are sufficient and maintained in good and clean condition. Outer wear/personal items and workwear are stored in dedicated lockers.

The production area is accessed with hands free hand washing facilities and suitable toilet facilities are provided, both of which meet clause requirements.

There is a no catered canteen.

Staff are provided with microwave and refrigerators which were clean and temperature monitored and recorded on doc ref QM08.FOR29 (Daily fridge temperature record).

An external smoking shelter is provided and staff must remove their protective clothing prior to using. Entrance back into production is via the changing and handwashing facilities.

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

4.9.1 Chemical control

Non-food chemicals are risk assessed and managed. There is a limited usage of cleaning chemicals within the factory as most cleaning is by dry methods (brushing, spray cleaning and wiping with wipes). Chemicals are stored in a designated storage area with restricted access. The main chemicals used on site are; Caterclean spray supplied by Premiere Products meeting BS EN 1276 1997 BS EN 13697 2001 and alcohol wipes supplied by Medipal. There is also a dishwasher for utensils after every use which is located in the wet room. Chemical used Jantex dishwasher pro and rinse.

Strongly scented/taint-forming materials are not used.

4.9.2 Metal control

There is a documented foreign body control procedure doc ref QM04.POL06 issue 6 dated 11/09/19 – updated re medical alert jewellery) with a registration system for scissors and cutters. These are issued to operator and signed back on a daily basis.

Daily start up checks are performed and recorded on doc ref QM07.FOR26 version 2 records were viewed during the facility inspection.

Staples, pins etc are not used in open product areas or packaging.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Monthly glass and brittle plastic audits are carried out by the assistant Quality Manager doc ref QM08.FOR25 issue 3. An appropriate glass breakage procedure (QM08.SOP13 issue 4 dated 04/06/19 – updated regarding risk) is in place which includes isolation, cleaning and authorised clearance inspection procedures. Breakages are recorded on form QM08.FOR26.

4 breakage incidents in the warehouse have been recorded in last 12 months e.g. office filing trays which are recorded on the NCR report.

There are no external windows in production and storage areas. Internal windows are plastic and all lights are covered and protected.

4.9.4 Products packed into glass or other brittle containers

No products are packed into glass or other brittle containers

4.9.5 Wood

Wood is restricted to finished product pallets. Product is transferred to plastic pallet before it is moved to clean room.

4.9.6 Other physical contaminants

Procedures are in place to prevent physical contamination by raw material packaging e.g. visual checks of packaging and cleaning if necessary.

Staff follow a documented procedure which forms part of the repack procedure (doc ref QM07.SOP01) for removal of raw materials from their packaging, to avoid contamination. See minor N/C

Minor N/C 1, clause 4.9.6.1. The procedure for deboxing/debagging at raw material intake is not clearly documented.

Pens used in open product areas are controlled e.g. metal detectable, no small parts.

4.10 Foreign-body detection and removal equipment

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

Following a documented assessment as part of the HACCP study, it has been concluded that foreign object detection/removal equipment is not necessary. This is because all raw materials are supplied as sieved and metal detected by supplier and is documented on product approval documents. Re-packing process is minimal with the use of scoops and spoons and a check in place for sharps. Sieves used occasionally for weight control purposes.

Foreign body control policy QM04.POL06 issue 6.

4.10.2 Filters and sieves

Portable domestic type metal sieves are used occasionally for weight control purposes only. These are stored in the repack area and are subject to area cleaning regimes. Integrity checks are carried out and recorded on the equipment log QM07.FOR26

The mesh size is not specified as these are used for weight control purposes only.

4.10.3 Metal detectors and X-ray equipment

A risk assessment for metal contamination has been carried out as part of the HACCP study and it has been concluded that metal detection would not improve the protection of final products from metal contamination because all products are sieved and metal detected by suppliers. No risk of metal contamination on site as simple re-packing operation by scoop and spoons which are checked after use. Majority of raw material are supplied in drums with metal seal, so it will not be possible to test them with metal detector. This justification is documented in HACCP process step 80.

4.10.4 Magnets

A rare earth magnet is used for raw material sampling only to check material received and is not as foreign body control or removal equipment. Magnet certificated by Greenwood magnetics dated 10/07/19 – gauss 9263 (design strength 9000 gauss).

4.10.5 Optical sorting equipment

No optical sorting equipment is used.

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

No rigid packaging.

4.11 Housekeeping and hygiene

The site and the majority of equipment were seen to be maintained in a clean and hygienic condition. See minor N/C

Minor N/C 2, clause 4.11.1. Warehouse cleaning equipment is not stored hygienically.

Full and detailed cleaning procedures are in place for all areas and equipment. Cleaning is carried out between different products with scales and tables cleaned using spray and wipes. Cleaning procedures are documented within the repackaging procedure, with expected standard as visually clean. Utensils such as scoops, spoons and sieves (if used) are cleaned in a dishwasher after each use.

Repack procedure details that all used utensils and waste from previous product handling activities are removed from the area and this is verified by buddy check documented on Repack record – QM07.FOR07 version 7. Example reviewed for trace challenge 10/09/19 P03329 and during facility inspection.

Cleaning is verified by documented second checks listed as buddy check for each product changeover.

Limits of acceptable and unacceptable cleaning are defined by visual clean.

The corrective action to be taken when results are outside the acceptable limits is defined in the relevant cleaning procedure e.g. Cleaning procedure within doc ref QM07.SOP01 issue 19.

Validation records are available to show that cleaning regimes are effective. These are documented in cleanroom cleaning validation study conducted 03/11/15 on the cleaning process. The validation on three different products (based on risk) and tested for TVC, Y&M and allergens. External lab used ATL UKAS 2262. Following the study the one stage process was changed to a 2 stage process (Caterclean spray – followed by alcohol wipes). Surface swabbing is conducted quarterly and settle plates annually.

Concept Life sciences reports reviewed;
Air quality settle plates – 22/03/19 — 5 plates for TVC@30DegC, Moulds and Yeasts all results <1cfu/ml

Swabbing quarterly 27/03/19 and 25/06/19 and 10/09/19. A number of areas including scoops, bag box lids, workstation surfaces, scales and extraction fans. All results within limits.

Limits = Y&M – Max 100cfu/g, Entro <100 cfu/g, E.Coli <10 cfu/g, Salmonella ND, Listeria ND

Start-up hygiene checks are documented for all key processes and equipment and are documented on repack record QM07.FOR07 within the repacking area.

Colour coded and dedicated cleaning utensils based on usage e.g. Glass - Red

4.11.7 Cleaning in place (CIP)

CIP systems are not used.

4.11.8 Environmental monitoring

A documented environmental monitoring programme is in place, based on a risk assessment. Doc ref Environmental Microbiological assessment excel spread sheet 2019.

The programme includes: Air quality via settle plates, water quality and swabbing repack room, packing room, sampling tent, lab, equipment and worksurfaces, employee hands.

Appropriate control limits are in place, for example: Repack room - Limits = Y&M – Max 100cfu/g, Entro <100 cfu/g, E.Coli <10 cfu/g, Salmonella ND, Listeria ND. Limits have been set for pre clean, during and post.

Limits are based Health Protection agency Ready to eat guidelines and European pharmacopeia 7.0

There are no legal or customer limits.

The programme is reviewed minimum annually, and if there were changes in processing/equipment, where the programme has failed to pick up a serious issue, when out of spec levels are found in products and when the sites gets consistently negative results, indicating that the programme is not effective.

4.12 Waste

Waste is collected from site by licensed contractors; BIFFA CBDU104360 expires 23/05/2022. All food waste is sent for anaerobic digestion.

All waste is cleared regularly from the processing areas and stored in suitable and identified containers. External waste containers are covered.

There are collections for recycled waste, cardboard and plastics and for general waste.

Unsafe products/trademarked waste would be disposed of by specialist contractor and a disposal/condemnation note and evidence obtained.

4.13 Management of surplus food and products for animal feed

There are no customer branded products or surplus food products and there are no products on site which are intended for direct consumption. No staff shop and no charitable donations
.
A range of products are purchased as food grade but may also be used for feed materials; The site has FEMAS certification with KIWA expiry 31/03/20. Site is registered with Cambridgeshire County Council, approval number GB026E216.

4.14 Pest management

External contract with Prokill (BPCA M15/737 expires 29/02/20) consists of 12 routine visits and 4 inspections. Full records of pest control are maintained including site plan dated 03/11/16 (Verified for external BS 3, Internal 32 and EFK 13), bait data sheets, operative training records e.g. Technician GP - RSPH level 2 04/01/11, records of inspections and treatments. The last visit to site was carried out on 08/10/18 with no recommendation although increased external activity has been noted and the technician has visited site on a number of occasions, 30/09/19, 11/09/19, 02/09/19 call out and 05/08/19. There is currently building activity on one aspect.

In-depth pest control surveys are undertaken at a frequency based on risk and the last one was 11/09/19 – 5 minor housekeeping issues noted, all but one completed and signed off 04/10/19. The risk assessment is reviewed when there are changes to buildings or processes which could impact the pest management programme or any significant pest issues. Latest dated May 2018.

All toxic baits are secured, external and office area only.
All recommendations are completed by the company in a timely manner.
No evidence of infestation was found or has been identified during visits.
Inspection results are analysed for trends at least annually or when there is an infestation.
No issues highlighted through trending reports.
EFKs are situated throughout the site and catch tray analysis is performed quarterly.

The site has identified that there is no risk from birds roosting and/or entering the building.

Employees have been trained to understand the signs of pest activity and to report any evidence of pest activity to first line manager.

4.15 Storage facilities

All goods are stored in supplier packaging or if part used are double bagged and sealed and placed in boxes and are stored at ambient temperature on pallet racking. There is a small chiller for some specialist ingredients to maintain quality rather than safety with automatic monitoring and alarm is linked to Quality Department PC.

Products are long shelf life and are stored on site.

FIFO systems are used throughout the site to ensure the products are used/despatched in the correct order.

The following systems are in place to prevent cross-contamination during storage: All products are fully wrapped and in original packaging.

There is no controlled atmosphere or outside storage.

Packaging is stored away from raw materials and finished goods. Part used packaging is stored in clean, covered plastic crates within the clean room.

4.16 Dispatch and transport

The company do not own vehicles.

Product safety and quality are maintained during loading and transportation by securing loads on pallets to prevent movement and stretch wrapping. Vehicle checks are recorded for unloading of vehicles.

Vehicle checks are recorded for loading and unloading of vehicles. Doc ref QM07.FOR06. Example reviewed for repack trace challenge 28/08/19 for customer arranged haulier Malco.

Minor N/C 3, clause 4.16.4. Cleaning procedures for FLTs are not clearly documented.

Transport procedures are in place, covering clause requirements.

Approved third party hauliers are used and detailed contracts in are place which include security of load, cleaning, breakdown and maintenance and meet the requirements of this section.

Example of contract seen for Schenker signed 01/10/19.

5. Product control

5.1 Product design/development

Limited product development due to single ingredient products and site only buy in and re-pack products.

All new product approval is based on the raw material risk assessment and supplier approval with new product introductory process flow chart. This includes supplier and raw material approval, testing of sample on recipe and is signed off by HACCP team. Shelf life is based on supplier specification.

A table of 'Recommended Shelf Life, NPD, doc ref QM08.SPO03 version 4, dated 30/10/17 is in place, this is validated through EOL microbiological and organoleptic testing.

5.2 Product labelling

No products are retail packed and all are for further processing. Labelling information includes product name and batch number, with the rest of the information documented on the product specifications.

No specific nutritional/suitability consumer claims are made as products are not intended for direct consumption.

No customer branded products produced on site.

5.3 Management of allergens

The following allergens are handled on site: gluten, crustaceans, molluscs, eggs, fish, soya, milk, celery and sulphites. All products are supplied in sealed packaging with the majority traded.

An allergen policy doc ref QMO4/POL01 issue 3 dated 28/06/18, procedure and allergen matrix is in place. All raw materials, products and the process have been risk assessed. Supplier declarations are obtained for raw materials.

All allergens are identified on the raw material specifications (PS system). Allergens are stored together with non-allergenic products however this practise has been carefully risk assessed via the HACCP plan and both warehouse practises and product packaging (double bagged) such that the risk of cross contamination is adequately controlled.

There is a Spillage Control Procedure HSMO5.01.22 issue 3 dated 28/08/19 in place.

Visitor questionnaires include questions relating to allergens.

Production is not scheduled as all repack products are fully segregated with full cleaning between products.

All products are single ingredient, there is no rework.

Allergen cleaning methods have been validated by testing for caffeine (test is very sensitive (NOPS) and if it removes caffeine, all other materials are removed as well), gluten and milk - ALS lab reports signed off 24/08/16 (All results were reported as below level of detection) and are routinely verified by buddy checks re area and utensil clearance and cleaning procedures.

The following "free from" claims are made – Gluten Free.

They are validated by extensive external lab testing across various batches e.g. ALS UKAS 1282 P23020 batch 20150428, dated 28/10/15, Alta bioscience UKAS 245 ref 5838 batch 20160318 dated 30/06/16 and ref 9453 batch 20160718 dated 30/05/17 and Concept Life Science UKAS 1549 batch 20170505 dated 14/07/17 all results <5ppm. Supplier testing of each batch as documented on CoA, seen for batch 201711208 CoA <5ppm gluten.

Tested using R-Biopharm Gliadin kit employing Mendez extraction and the R5 Antibody.

5.4 Product authenticity, claims and chain of custody

The site obtains information on threats to the supply chain which could lead to adulteration/substitution of raw materials by reviewing each raw material and supplier. As part of annual material review, each material is checked via RASFF for reports of contamination incidents. A google search is also done on material and supplier for any potential incidents of adulteration.

A documented vulnerability assessment is carried out as part of raw material and supplier approval process. Each supplier and product has a vulnerability assessment. The assessments are kept under review to take into account changes in potential risks and are formally reviewed annually.

Example of recent approval Supplier YAB – P12734 (pea starch) - signed off 04/10/19 – testing HM, Micro, PAHs, soya, milk, SO2, Pas. Testing set up on P.S system.

Example of recent reapproval – supplier CVR – PO19347 (Organic coconut sugar) signed 29/08/19 – testing Pesticides, glyphosates and micro – testing complete next batch HM as per due diligence.

Testing results reviewed for;

Glyphosate – Phytocontrol Agrifood – accredited by FAVV-AFSCA and approved by INAO, BII – 18/07/19

Pesticides – Eurofins - 08/03/19

Micro – Concept life sciences - 06/03/19 – salmonella – N.D

Although all products are considered as low risk, the following assurance are in place: all ingredients are subject to physical and chemical analysis to verify their authenticity and CoAs are obtained.

The following claims are made: Halal, Kosher and Organic with valid certificates in place.

Halal cert ref CCL/FI/B/008715 expires 01/05/21
Kosher cert ref 42175 expires 09/12/19
Organic (Soil Association) licence number DA18397 (GB-ORG-05) expires 31/03/20.

Single ingredient products with full segregation.

A policy, work instructions and a process flow are in place, to ensure the integrity of all claims in this section.

5.5 Product packaging

Dry products are packed into LPDE bags and pouches which can range from 5g to 25kg. 25kg is typical supplier pack size so a whole bag will be sent without repacking and is covered under traded goods module.

Food contact information and suitability for the intended product has been provided by suppliers of all food contact packaging. Reviewed for polybag doc ref V2005/1.

All dry products are double bagged and sealed with black cable ties. Bags are typically 62.5 to 100micron gauge LDPE blue.

Traceability for all packaging used is recorded and maintained. No obsolete packaging as generic.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Sampling plan and testing requirements are detailed via PS system per WO.

Microbiological product analysis is mainly sub contracted to Concept Life Science which is carried out as surveillance only with a schedule covering all product ranges annually or more frequently if customer required. Sampling requirements are reviewed during supplier reapproval process.

The following laboratory tests are also carried out: pesticides, aflatoxins, heavy metals, PAH, identification and nutritional by Eurofins.

Examples reviewed for;

Product P13014 – Micro – ATL (UKAS 2262) 24/10/16 – TVC@30DegC<100cfu/g, Entros <10cfu/g, Salmonella not detected and Y&M

Product P13014 – Aflatoxin – ATL (UKAS 2262) 25/07/16, HM – Eurofins -12/09/18

Product PO3329 – Micro – Concept Life Science 22/08/19 – Tested for Aerobes <10cfu/g, Coliforms <10cfu/g, Salmonella not detected/25g, E. coli <10cfu/g, mould 60 cfu/g and yeast <20 cfu/g.

Trend analysis and reviews of all test results are carried out by the AD team (Analytical Department) and any out of specification results are risk assessed and the customer consulted if appropriate.

The following tests are carried out on site; FTIR for every batch.

Example seen for trace challenges during the facility inspection for P03329 batch 210906067 dated 23/08/19 >99% match (Herbals >95%, Chemicals >98%). A visual check against photo and CoA verses specification check are also conducted.

EOL testing is carried out to verify shelf life. This is based on (depending on material) bioassay (vitamin/nutritional supplement), microbiological (herbs), peroxide value (oil-based products) and organoleptic assessment. A shelf life extension guidance doc ref QM08.SPO03 issue 4 dated 30/10/17 is also in place which details risks and testing required.

5.6.2 Laboratory testing

Pathogen testing is subcontracted mainly to Concept Life Science (UKAS 1549) and Eurofins.

The following tests are critical to product safety or legality: pesticides, aflatoxins, heavy metals, PAH.

These are carried out using accredited methods by Concept Life Science (UKAS 1549) Eurofins China/Germany and ALS (UKAS 1282)

The following tests, which are not critical to product safety or quality, are also carried out: FTIR testing.

There is a FTIR room only. Reliability of results is ensured by comparison to COA, testing of previous batches, training and using calibrated equipment.

Laboratory results are reviewed by: AD Team

Actions taken on out of spec results include hold product and re-test, inform customer or inform supplier.

5.7 Product release

Approval is via raw material sampling and testing. This is based on visual, FTIR test and CoA. Goods automatically go on hold on PS system on arrival and QC release for use and sales after satisfactory results.

5.8 Pet Food

Not applicable – no pet food is manufactured.

6. Process control

6.1 Control of operations

Documented process specifications and work instructions/procedures are in place which reflect agreed finished product specifications e.g. Repack procedure Doc ref QM07.SOP01)

There are no equipment settings which are critical to the safety or legality of the product.

The following process monitoring checks are carried out and recorded for every batch: FTIR checks, visual checks against photograph within the specification, CoAs against specification, weight checks and labelling.

There is no in-line monitoring

There are no processing conditions critical to product safety or quality. Audible alarms and dataloggers are fitted to small storage chiller which is used for specialist ingredients. This is more for product quality rather than food safety. Datalogger is linked to the alarm system which is linked to Quality specialist via PC.

Procedure FTIR testing doc ref QM08.SOP12 issue 5 dated 30/10/17 is in place in the case of equipment failure or deviation of the process from specification. The company also have concessions procedure doc ref QM08.SOP04 issue 4 dated 27/10/17.

6.2 Labelling and pack control

There is no printed packaging. Labels are allocated to packing line for each production run by team leader. Raw material labels are scanned and based on order typically three labels are printed, one for pack, one for outer box and third for return to warehouse if needed, Products are only re-packed and label information includes PS code, product name, batch number, order number, GF as applicable and weight.

Documented start up and changeover checks are undertaken to ensure that lines have been suitably cleared, with all products and packaging from previous production removed.

Repack procedure doc ref QM07.SOP01 is in place, covering clause requirements, to ensure that products are packed into the correct packaging and correctly labelled and coded. All re-packing includes an operator check and a buddy check to ensure weight is correct.

6.3 Quantity, weight, volume and number control

All products are weighed to order and packed by minimum weight. Products are manually packed on scale which is checked by operator and countersigned by second operator as buddy check.

6.4 Calibration and control of measuring and monitoring devices

The site maintains a calibration matrix which identifies the item, location, calibration method, result, responsibility and frequency.

Scales are calibrated annually and checked internally daily against test weights calibrated annually by Blake and Boughton. Check weights 20kg, 5kg, 200gr and 1g calibrated 27/11/18.

Calibration certificate seen for:

Ohaus scale, serial number: 30921652 calibrated 22/11/18
Adam AZ extra - serial number: AE5532835 calibrated 23/11/18
Ohaus PA2202 - serial number: B750124836 calibrated 16/05/19

FTIR service visit Agilent Technologies 8/10/18. FTIR calibrated internally on a weekly basis against known reference standard.

No CCPs.

The calibration procedure doc ref QM08/SOP11 issue 5 dated 30/09/19 details the corrective action procedure.

7. Personnel

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

The company has a comprehensive training programme for staff on induction and production roles. Induction training includes personal hygiene, PPE, hand washing, jewellery, smoking, eating and drinking, allergen awareness and handling procedures, medicines, GMP, QMS and H & S.

Agency staff are not used.

Detailed individual training records, which meet clause requirements, and a list of approved trainers are kept. There are no CCPs.

Other staff training records reviewed included:

AT - AD Technician – Refresher training 02/10/18 which included personnel hygiene, security, pest awareness food safety and defence, commination control, allergens, concessions procedure, HACCP and FTIR testing. Goods inspection process 02/10/19.

S.B - AD Technician – Refresher training 01/10/18 which included personnel hygiene, security, pest awareness food safety and defence, commination control, allergens, concessions procedure and HACCP. FTIR testing – 21/09/16 (7.5hrs)

J.B – Cleanroom Assistant - Repacking procedure 10/06/19, Foreign body control 07/10/19, Glass and brittle plastics 08/07/19, Allergens 03/06/19, spillage procedure 07/10/19.

S.B – Warehouse operator – vehicle inspection 14/11/16, Spillage 16/07/18, Allergens 08/10/18.

Staff interviewed during the audit were competent in their roles e.g. Clean room team leader K.L, clean room operator J.B, Customer care T/L M.L, Assistant Quality Manager S. M and Warehouse Manager A.B

Competency of staff is reviewed twice per year via 121/PDP. Internal audits also include aspects of on the job monitoring. A programme of refresher training on updated procedures is in place e.g. briefings via line manager.

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

Personal hygiene standards, which meet clause requirements, are documented and covered during induction training and basic food hygiene training (carried out in house). Site hygiene is detailed in QM06/SOP02 issue 2 dated 26/10/17 and the foreign body control policy doc ref QM04.POL06 issue 6 dated 11/09/19

The correct method of hand washing is clearly displayed at all hand wash sinks and in toilet areas.

Blue plasters are controlled via issue log and sign back at end of the day to ensure it is intact. Last entry 07/10/19.

The use and storage of personal medicines is controlled by reporting to the Manager on arrival as detailed in Restrictions for handling open product procedure doc ref QM06.POL13, issue 2 dated 24/10/16.

There were no issues regarding compliance to the documented hygiene policies.

7.3 Medical screening

Employees are made aware of the symptoms of infection, disease or conditions which would prevent them from working with open food during induction training.

Restrictions for handling open product procedure doc ref QM06/POL13 is in place to enable staff, including temporary staff, to notify the site of any relevant symptoms, infection, disease or condition which they may have been in contact with or be suffering from.

A visitor health questionnaire is in place with a verification check by the company host.

A visitor health questionnaire (electronic) is in place with a verification check by the company host. Sign in process is documented in QMS03/SOP01 issue 2 dated 21/10/16.

Return to work interviews are carried out following absence/illness and this is detailed in the company handbook/rules issued to all staff members.

7.4 Protective clothing: employees or visitors to production areas

Documented procedures are in place for the wearing of protective clothing, which includes: Disposable, single use overalls (repack area), hair nets, beard snoods and area dedicated shoes.

Company visitor coats and kitchen towels are externally laundered. The external laundry, Swiss Laundry, operates procedures which meet clause requirements. Approved via SAQ and contract dated 28/01/14.

Protective clothing is changed a minimum of daily, based on risk.

Disposable blue nitrile gloves are worn which are changed after every batch or as needed.

Employees are issued with shoes which are dedicated to the area. Visitors are required to use shoe covers before entering to clean room.

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones

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

N/A

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

8.3 Maintenance in high-risk and high-care zones

8.4 Staff facilities for high-risk and high-care zones

8.5 Housekeeping and hygiene in the high-risk high-care zones

8.6 Waste/Waste disposal in high risk, high care zones

8.7 Protective clothing in the high-risk high-care zones

Details of non-applicable clauses with justification

Clause/section reference	Justification
2.9	No CCPs
2.10	No CCPs
3.5.2.3	No live animals
3.9.4	No rework
4.2.3	No external storage tanks or intake pipes
4.3.9	There are no temporary structures.
4.4.3	No drainage
4.4.5	No suspended ceilings in production areas.
4.4.6	No elevated walkways
4.4.7	No glazing designed to be opened for ventilation.
4.5.4	Ice, steam and gas are not used. Compressed air is used for machinery operation only.
4.7.5	Lubricants and greases are not used.
4.7.6	No engineers workshop
4.7.7	No engineers workshop
4.8.8	No catering facilities provided.

4.9.1.2	No strongly scented or taint forming materials are used.
4.9.2.2	No staples etc.
4.9.3.4	No glass windows which pose a risk to product.
4.9.4	No product packed into glass or brittle containers
4.10.1.2	No foreign body detection or removal equipment used
4.10.1.3	No foreign body detection or removal equipment used
4.10.1.4	No foreign body detection or removal equipment used
4.10.3.2	No metal detection or x-ray on site
4.10.3.3.	No metal detection or x-ray on site
4.10.3.4	No metal detection or x-ray on site
4.10.5	No optical sorting equipment used
4.10.6	There are no jars, cans and other pre-formed rigid containers.
4.11.7	No CIP
4.12.3	No unsafe or trademark waste
4.13.1 & 2	No surplus customer branded products.
4.14.3	Pest control is contracted externally.
4.15.4	No controlled atmosphere storage areas required.

4.15.5	No outside storage required for product.
4.16.3	No temperature-controlled transport required.
5.2.3	No nutritional/suitability or consumer claims are made.
5.2.5	No cooking instructions provided
5.3.5	No rework of allergen containing material.
5.3.6	No warning labelling is used
5.4.3	No ingredients are of particular risk of adulteration or substitution.
5.4.4	There are no specific claims (provenance, breed, IP etc.)
5.6.2.2	No onsite lab.
5.6.2.4	No onsite lab.
5.8	No pet food products
6.1.2	There are no equipment settings which are critical to the safety or legality of the product.
6.1.4	There are no inline monitoring devices which control process parameters or product quality.
6.1.5	No variation in processing conditions in equipment critical to product safety & quality.
6.2.4	No on-line vision equipment is used
6.3.2	All product quantities are covered by legislation

6.4.1	No CCPs.
7.1.2	No CCPs
7.2.4	No metal detection on site
7.4.7	All items either suitable for laundering or disposable
8.0	No high risk, high care, ambient high care zones

9 - Traded Products

9.1 Approval and performance monitoring of manufacturers/packers of traded food products

The supplier approval procedure (doc ref QM07.SOP08) covers the process for initial and ongoing approval of suppliers and manufacturers of all products traded. This is the same procedure as for raw materials and primary packaging.

A risk assessment is in place which covers clause requirements and takes into account safety, quality and legality and the ability of the supplier to meet the specifications of the products supplied. The assessment is also based on nature of material (e.g. herbs), volume, type of certification and historical issues with risk-based testing regimes in place. With the controls in place all suppliers are assessed as low risk.

Nearly all of the throughput is traded. Approx. 5% is repacked based on customer order. Exactly the same processes/procedures are in place whether products are traded or re-packed.

Suppliers are requested to submit third party certification. They are also requested to complete a supplier approval questionnaire doc ref QM07.FOR02 (Not required for GFSI approved site), a supplier raw material questionnaire – QM07.FOR09 and provide a specification, manufacturing flow diagram, HACCP, picture of material, a sample and traceability details before material can be purchased. Also based on this information a decision is made whether an audit by the Quality Manager is necessary. A performance rating is given and if issues are identified during the audit, a decision is made whether it is appropriate to try and improve the supplier or to not use them. Once this process has been completed a supplier approval form QM07.FOR04 issue 14 is completed and supply can commence.

Supplier questionnaires are issued every three years and suppliers are required to notify the site of any significant changes in the meantime by updating questionnaire. There is an annual supplier re-approval form QM07.FOR12 covering specifications, certification checks, changes to material or process and a re-check RASFF/google for any evidence of contamination risk for the material. CoAs are received with each batch and each batch is FTIR tested.

Records of approval and the evidence used for approval, such as verified BRC certificates, are kept.

The following BRC certificates were checked during the audit via the BRC database and found to be genuine and valid.

Turmeric powder from supplier S, BRC site code ****267 expires 24/06/20.

The following supplier audit reports were checked and found to be comprehensive:

Maltodextrin DE 18-20 – from supplier BAO - Audited 14/04/16 by Quality Manager, no n/Cs raised. FSSC 22000 expires 17/11/20. IP program expires 22/10/19. QM07.FOR04 dated 01/06/16 – Reapproved QM07.FOR012 - 11/05/18

Suppliers of traded products are monitored based on risk and according to the following performance criteria: quality of products supplied, complaints, customer feedback, results of product tests.

9.2 Specifications

Specifications for traded products are agreed by signing by both parties. Where formal approval from customers is not forthcoming, proof of specification issue and request for acknowledgement is retained. Orders are based on acceptance of specification. Change control – if specifications are changed the customer is emailed stating that if the company do not hear back within 2 weeks. Example reviewed for P2602 to all customers who purchased in last 2 years. Email date 09/10/19.

There are no customer specified requirements for traded products.

Specifications reviewed included;

Maltodextrin DE 18-20 – from supplier BAO – dated 11/04/18
CC Spec P13014 - Maltodextrin– dated 13/03/18

Specifications for traded products are reviewed on each purchase of raw materials.

9.3 Product inspection and laboratory testing

There is a documented schedule of risk-based product sampling/assurance tests carried out on traded products (doc ref PS system).

Traded goods are checked on intake for compliance with purchase orders and certificates of analysis/compliance are received. This involves sampling of every product/delivery, visual/organoleptic assessment against CoA/Specification and magnet testing. This involves shaking a rare earth magnet through the bagged sample to assess the level of metal contamination.

Pictorial standards existing within Goods In Product Inspection Process Procedure doc ref QM07.SOP05. Grading is: absent, small, medium, large. If any metal is found, this is reported to the Quality Manager. Product with 'large' metal contamination is rejected. The sample is then sent forward for FTIR testing. The FTIR test logs every result by material type and each new batch is assessed against the mean result of all previous batches which can show drift in quality or purity.

Example seen for trace challenges during the facility inspection for P03329 batch 210906067 dated 23/08/19 >99% match (Herbals >95%, Chemicals >98%). A visual check against photo and CoA verses specification check are also conducted.

Other tests may be carried out in order to investigate complaints, assess whether shelf-life can be extended or to verify CoA information. These include (depending on nature of material): moisture, bulk and tapped density bioassay (vitamin/nutritional supplement), microbiological (herbs), peroxide value (oil-based products) and organoleptic assessment. Specialist tests are carried out to verify CoA information such as heavy metal analysis, pesticides, mycotoxins, industrial and process contaminants (dioxins/PAHs).

Example of test reports reviewed

Product P13014 – Micro – ATL (UKAS 2262) 24/10/16 – TVC@30DegC<100cfu/g, Entros <10cfu/g, Salmonella not detected and Y&M

Product P13014 – Aflatoxin – ATL (UKAS 2262) 25/07/16, HM – Eurofins -12/09/18

Product PO3329 – Micro – Concept Life Science 22/08/19 – Tested for Aerobes <10cfu/g, Coliforms <10cfu/g, Salmonella not detected/25g, E.Coli <10cfu/g, mould 60 cfu/g and yeast <20 cfu/g.

Example of resent reapproval – supplier CVR – PO19347 (Organic coconut sugar) signed 29/08/19 – testing Pesticides, glyphosates and micro – testing complete next batch HM as per due diligence.

Testing results reviewed for;

Glyphosate – Phytocontrol Agrifood – accredited by FAVV-AFSCA and approved by INAO, BII – 18/07/19

Pesticides – Eurofins - 08/03/19

Micro – Concept life sciences - 06/03/19 – salmonella – N.D

The results of checks and tests on traded products are recorded and reviewed for each batch by AD Team with actions taken where appropriate.

9.4 Product legality

The site verifies the legality of traded products by the approval process.

Product legality is assessed prior to purchase and with consultation with Trading Standards or by obtaining import authorisations. All traded products are B2B.

9.5 Traceability

The site has a system which enables “one up one-down” traceability of traded products, by identifying the last manufacturer/packer and the recipient for every batch or lot. Products are identified by labelling and bar codes which is shown on the unit of sale as supplied to the customer.

Where relevant, suitable segregation/identification is in place to maintain the integrity of claims made for traded products. E.g. clear labelling of organic products.

Traceability tests, including mass balance, are carried out at least annually both forwards, from the site to the recipient, and backwards, from the site to the last manufacturer.

The last tests were on product P12072 on the 27/09/19 from customer ANL and to supplier JIH, with full traceability and mass balance achieved within 4 hours.

A traceability challenge and mass balance was undertaken during the audit on Maltodextrin P13014, batch 19031731. Purchased 25000kg 14/03/19, Traded 24475 kg 100kg sent to outsourced company for blending and 31kg for samples. 394 kg remains in stock. An example of delivery to customer VTC on 09/07/19 for 50kg. 0.132kg gain.

Module 11: Meat supply chain assurance	
Scope	
11.1 Traceability	
11.2 Approval of meat supply chain	
11.3 Raw material receipt and inspection	
11.4 Management of cross-contamination between species	
11.5 Product testing	
11.6 Training	

Module 12: AOECS Gluten-free Foods

Scope	
12.1 Senior management	
12.2 Management of suppliers of raw materials and packaging	
12.3 Outsourced production	
12.4 Specifications	

12.5 Management of gluten cross-contamination

12.6 Management of incidents, product withdrawal and product recall

12.7 Labelling

12.8 Product inspection and laboratory testing

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018				
Item no.	**Clause**	**Module item**	**Conforms (Y/N) or Not Applicable (NA)**	**Comments**
1	13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.	Y	Lighting is suitable and sufficient to permit effective cleaning of hands and maintenance of personal hygiene and facilitates the changing of personal protective clothing. Lux level report dated October 2018 Lighting at work HSE guidelines held on file
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	Y	Water is not used in the process. Domestic piping is as UK building regulations. No backflow or cross-connection from waste water and sewage pipework. The site water distribution schematic has been reviewed by the Facilities Office with no backflow or cross-connection from waste water and sewage pipework issues identified. Water testing in place.

3	13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.	Y	All food contact surfaces of plant equipment (tables) / utensils (scopes, sieves) are made of corrosion resistant materials, such as 300-series stainless steel or food grade plastics. Seams on food surfaces observed as part of the facility tour were seen to appropriate to standard requirements. The site has extensive cleaning procedures which include inspection and verification. Micro and allergen cross contact results indicate that there are no installation issues.
4	13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.	N/A	No ice is used for the process
5	13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.	Y	The site inspects incoming raw materials and have established DALs which are lower than the FDA Defect level limits. The site has implemented quality control operations to reduce defects to the lowest level possible. The site does not mix (dilute) product with defect levels at or exceeding the maximum limit with product containing minimum defects. All raw materials that exceed site DALs are returned with N/C raised.
6	13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards	Y	Economic adulterants, radiological hazards and unintentional adulterants have been considered as part of the site's food safety hazard analysis and TACCP risk assessment. These include; Historic Incidents, Foreign Bodies, Solvent Residues, Heavy Metals, Process Impurities, Pesticide Residues, Adulteration Risk – Producer, Adulteration Risk – Supply Chain, Substitution Risk – Producer, Substitution Risk – Supply Chain, Illegal Dyes, Microbiology, Mycotoxins, Allergens, Nuts / Nut Products, Skin Allergens, Irradiation, GMO, Animal Derivative, Antibiotic Residues, CMR, Bio

		• Unintentional adulterants which affect food safety		Security and Security, as detailed in the product technical dossier doc ref: QM07/FOR09 version 25
7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).	Y	Significant hazards have been considered as part of the site's supplier approval procedure and as part of the food safety hazard analysis and TACCP assessment.
8	13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.	Y	Preventative controls have been established for each of the identified hazards. Established positive release procedures are in place with the QA manager (PCQI) and nominated deputies approving product release.
9	13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product	Y	The site withdrawal / recall procedure doc ref QM08/SOP02 issue 11 includes notifying consignees of how to return or dispose of recalled product, how to conduct effectiveness checks to verify recall is carried out and appropriate disposal of recalled product procedures Observations following the annual mock recall are used as part of the recall procedure review and discussed at the post recall meeting. An actual recall was initiated by the company – 31/05/19, product Coconut Milk powder P31188 batches N17197, N18388, N19056 and N19129. The CB and relevant contacts/authorities were notified on 04/06/19. The procedure was used to conduct the recall and did not require any changes.
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.	Y	Monitoring activities are in place for each of the preventative controls in place e.g. Goods In procedure – QM07/SOP05 issue 8 dated 30/09/19 (Includes magnet checks). The preventive controls qualified individual (PCQI) and authorised deputies are

				responsible for conducting or overseeing the review of monitoring records within 7 days from the date of creation. They are members of the site Food safety team, understand FSMA requirements, aware of FDA preventative standards and have extensive technical industry experience.
11	13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).	Y	Corrective action procedures are detailed for each of the preventative controls, for example those detailed as part of the internal audits carried out, in line with the internal auditing procedure (doc ref QM04.SOP02) is in place. The site also has a complaints Procedure doc ref QM08/SOP09 issue 6 dated 08/10/18 and a concessions procedure is also in place QM08/SOP04 issue 4 dated 27/10/17.
12	13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.	Y	All established process controls including allergen, sanitation and supply chain controls are validated by the PCQI / QA Manager / food safety team prior to the implementation of the food safety plan, and / or changes requiring revalidation.
13	13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.	Y	Monitoring and corrective action records are maintained and reviewed by the PCQI (or their authorized designee) within 7 days.
14	13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically	Y	The site carries out testing according to a sampling plan and testing requirements are detailed via PS system per WO. A product testing procedure FTIR testing – QM08/SOP12 issue 5 dated 30/10/17 is in

		valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		place which identifies: the method, frequency and number of samples to be tested, the analytical method,
15	13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected	N/A	
16	13.1.16	Devices used to verify preventive controls must be calibrated.	Y	The site has a documented list of measuring devices which is updated as necessary. On site Product testing – All measuring devises utilized in the associated analytical method are calibrated at appropriate frequencies, with calibration activities recorded. Due to the nature of FTIR analysis results are verified against standards prior to being reported. FTIR service visit Agilent Technologies 8/10/18. FTIR calibrated internally on a weekly basis against known reference standard. A rare earth magnet is used for raw material sampling only to check material received and is not as foreign body control or removal

				equipment. Magnet certificated by Greenwood Magnetics dated 10/07/19 – gauss 9263 (design strength 9000 gauss).
17	13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.	Y	The company have identified a number of PQCIs including PB Quality Manager at CCL, who has 20 + years' experience in total within various food industries with 8 years of this spent with CCL. He regularly audits suppliers and has experience auditing sites over in China. Courses completed include lead auditor training and HACCP level 2. He has successfully implemented and managed food safety plans and BRC. HP Quality manager at CCL who has 5 years' experience in the food supplement industry and previously completed a doctorate in bio-inorganic chemistry. Courses completed include lead auditor training and HACCP level 3. HP has successfully implemented and managed food safety plans and BRC.
18	13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable	Y	Records reviewed were appropriate and readily available. The sites traceability system identifies the required records. For example - QM07.FOR15 - Clean & check record MCR Issue 10 dated 09/10/19 as seen during facility inspection
19	13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.	Y	A documented food safety plan is in place, with annual review.
20	13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the	Y	Records are retained indefinably and are retrievable within 24 hours.

		food safety plan, which must remain onsite.		
21	13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.	Y	Extensive supply chain procedures have been established which cover supplier approval and verification controls. Verification can be through review of supplier provided verification documentation e.g. third-party audit results, or second party on site audit. All materials received require certificate of conformance/ analysis and are subject to onsite testing and positive release. Verification is carried out during internal audits and the daily verification checks performed. Verification reviews are carried out annually as part of the HACCP review and are based on a review of the system documentation, records, internal audits, deviations and corrective actions, complaints and incidents.
22	13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.	Y	Supplier approval is documented before receiving and using raw materials and ingredients. Raw materials are subject to testing and positive release prior to use.
23	13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.	Y	Appropriate supplier controls are in place.
24	13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual	N/A	

		name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
25	13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.	Y	The company have identified a number of QIs including PB Quality Manager at CCL, who has 20 + years' experience in total within various food industries with 8 years of this spent with CCL The QIs are responsible for developing the site's food defence plan, conducting a vulnerability assessment identifying mitigation strategies, and conducting a reanalysis of the plan. The QIS responsible for developing the food defence plan are identified on the site's organizational chart. The QI's are responsible for implementing mitigation strategies at actionable process steps.
26	13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps	Y	The site have a written food defence plan, which includes; A vulnerability assessment identifying significant vulnerabilities and actionable process steps, Mitigation strategies appropriate to reduce the vulnerability and procedures for food defence monitoring, corrective action and verification

		• Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
27	13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum): • Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.	Y	A written vulnerability assessment has been prepared for each food type packed, or held, which evaluates the following key criteria (at a minimum): Scale and severity of threat if a contaminant is added to product FDA alerts including AHPA for known adulterants, BRC Guidance on authenticity of herbs and spices. Degree of physical access to the product Ability of an attacker to successfully contaminate product—including consideration of an inside attacker The vulnerability assessment is documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.
28	13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.	Y	Written mitigation strategies are established and implemented for each actionable process step identified in the vulnerability assessment. Justification is documented within the food defence plan explaining how the strategy significantly minimizes or prevents the vulnerability.
29	13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies.	Y	Written monitoring procedures are in place and implemented to include the activity and frequency for monitoring food defence mitigation strategies.

		Procedures shall include recordkeeping requirements for all monitoring activities.		E.g. Magnet and FTIR testing Procedures include recordkeeping requirements for all monitoring activities.
30	13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions	Y	Written corrective action procedures have been established and implemented when mitigation strategies are not properly implemented. The procedure includes; Methods for identifying and correcting a lack of implementation, Methods for reducing the likelihood of recurrence and recordkeeping.
31	13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities	Y	Written verification procedures have been established and implemented in order to ensure that food defence monitoring and corrective action are performed according to procedures. Verification procedures describe activities to verify implementation of mitigation strategies. Verification procedures include: A review of monitoring and corrective action records within 7 days, Internal audits, Methods for verifying that reanalysis of the food defence plan was conducted, Frequencies for verification activities and record keeping requirements.

32	13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence	Y	Reanalysis of the food defence plan is documented and performed annually or whenever there is a change in facility operations which creates a new significant vulnerability, new threats applicable to the food or facility becomes known, mitigation strategies are not implemented as intended and if the FDA requires reanalysis.
33	13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable	Y	Records reviewed were appropriate and readily available. The sites traceability system identifies the required records.
34	13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.	Y	The Operations Director has signed the written food defence plan.
35	13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.	Y	All records relating to the food defence plan are retained at the facility for 7 years after the record is created. All records are stored on site. Electronic records are held indefinably. Record retention policy is defined with doc control procedure do ref QM04.SOP03, issue 2 dated 24/10/16
36	13.4.1	Vehicles and transportation equipment must be maintained and	N	Vehicles and transportation equipment are maintained and stored in a sanitary condition

		stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they are not used. Cleaning procedures for FLTs are not clearly documented.
37	13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.	N/A	All shipping is arranged via sister company - Cambridge Commodities Inc who are based in North California and deal directly with approved manufacturers.
38	13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the	Y	Approved third party hauliers are used and detailed contracts in are place which include security of load, cleaning, breakdown and maintenance and meet the requirements of this section. Example of contract seen for Schenker signed 01/10/19

		loader and carrier, which are appropriate for the type of food.		
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	N/A	Contracts with carriers are held by sister Company.
40	13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.	N/A	
41	13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper	N/A	Contracts with carriers are held by sister Company.
42	13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems	N/A	Contracts with carriers are held by sister Company.

		• Responsibilities of the carrier		
43	13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.	N/A	Records are held by sister Company.
44	13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.	Y	Records are either retained on site or by sister company which are available within 24hrs.
45	13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job	Y	Personnel (permanent and temporary) who handle produce or food contact surfaces receive principles of food hygiene and food safety.
46	13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment	N/A	
47	13.5.3	One or more supervisors or individuals responsible for the operation must have successfully	N/A	

		completed food safety training equivalent to standardized curriculum recognized by the FDA.		
48	13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.	N/A	
49	13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.	N/A	
50	13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.	N/A	
51	13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.	N/A	
52	13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.	Y	Report seen for Concept Life Sciences (UKAS 1549) – sample date 13/09/19 Changing room water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, (Limits of detection) TVC@22°C 56 cfu/ml, TVC@37°C 162 cfu/ml).

				Lab main water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, TVC@22°C 630 cfu/ml, TVC@37°C 680 cfu/ml) Wet room water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, TVC@22°C 92 cfu/ml, TVC@37°C 1380 cfu/ml)
53	13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.	N/A	
54	13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), ‘‘Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007),’’ December, 2009 or equivalent method.	N/A	
55	13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to	N/A	

		include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
56	13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.	N/A	
57	13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.	N/A	
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	Y	The site water distribution schematic has been reviewed by the Facilities Office with no backflow or cross-connection from waste water and sewage pipework issues identified.
59	13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.	Y	All produce safety related records are reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.
60	13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at	Y	All produce safety documents and records are retained at the site for 2 years after the record is created.

		the site for at least 2 years after their use is discontinued.		
61	13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: • Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's ‘‘Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples,’’ Version 1, October 2015 (or equivalent).	N/A	
62	13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive surfaces and the surrounding area to	N/A	

		determine the extent of contamination • Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate • Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		