Audit Report

1.Audit Summary			
Company name	Cambridge Commodities Ltd	Site Code	6960330
Site name			
Scope of audit	The repacking of dry, ambient stable nutritional food ingredients packed into bags for further manufacturing. The outsourced blending of dry, ambient stable nutritional food ingredients. 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	Justification for exclusion		
Audit Start Date	2022-03-29	Audit Finish Date	2022-03-31
Re-audit due date	2023-05-04	Head Office	No

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		

2. Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit type	Unannounced
Previous audit grade	AA	Previous audit date	2021-05-04		
Certificate issue date	2022-05-10	Certificate expiry date	2023-06-15		
Number of non-conformities		Fundamental	0		
		Critical	0		
		Major	0		
		Minor	1		

3.Company Details

Address	203 Lancaster Way Business Park Ely Cambridge CB6 3NX		
Country	UK	Site Telephone Number	01353 667258
Commercial representative Name	Tom Stevens	Email	Tom.stevens@cambridgecommodities.com
Technical representative Name	Phil Barnhill	Email	Phil.barnhill@camebridgecommodities.com

4.Company Profile

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

Shift Pattern	9:00 – 17:30 (Office, Cleanroom, Warehouse); 15:30 – 00:30 (night shift Warehouse)
Subcontracted processes	Yes
Other certificates held	FEMAS, Organic, Halal, Kosher, Informed Sport, ISO 14001, ISO 22000 and GMP+
Regions exported to	Europe Africa Choose a region Choose a region Choose a region Choose a region
Company registration number	AO 021 and GB026/216.
Major changes since last BRCGS audit	There have been no major changes since the last audit

Company Description

The company is privately owned with a sister site in the US, but the sites run independently. Founded in the 1998, the company has grown rapidly in recent years, moving to the current, purpose-built premises in May 2015. The main customers are on-line based.
The company specialise in supplying ingredients for the sports nutrition, health and wellness, equine and pet sectors, sourcing and stocking a range comprising of around 1200 active different product lines, which are either supplied in original packaging (traded) or repacked (powdered goods only, 5% of total

4.Company Profile

throughput) on site if smaller quantities are required. The wide range of product types are all ambient stable. The company employ circa 150 employees (25 work in production, 20 in quality). There is 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 5:00 pm day shift with a night shift of 15:30 to 00:30 with a dedicated 3rd party 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 which falls outside the scope of the Global Food Standard. These is undertaken in a completely separate area to the in-scope products.
The company has also commissioned a blending facility which is not currently operational.
Outsourcing is limited to blending or the making of tablets which are classed as food supplements.
The site has continued to trade normally through Covid with controls in place. Certain staff are working from home and temperatures are taken prior to entry. A no visitor policy has been largely adopted, other than for critical services.

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				
Product claims made e.g. IP, organic	Organic, Halal, Kosher, Gluten Free				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	The repacking of powdered products e.g., P11597, PSID 366292.				

6. Audit Duration Details

On-site duration	20 man hours	Duration of production facility inspection	6 man hours
Reasons for deviation from typical or expected audit duration	The BRC audit was shorter than the expected as 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 with 95% of product sold as traded goods requiring storage only. No products are produced for America, so no production time was required for this AVM.		
Next audit type selected	Announced		

Audit Duration per day

Audit Day	Date	Start Time	Finish time
1	2022-03-29	09.00	17.30
2	2022-03-30	09.00	17.00
3	2022-03-31	09.00	11.30

	Auditor number	Name	Role
Auditor Number	20336	Simon Brookes	Lead 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
Rebecca Smith – Head of Quality			X(Part)	
Phil Barnhill – Quality Manager	X		X	
Hannah Pritchard - Quality Manager	X	X	X	
Justine Banas – Technical Complaince Manager			X(Part)	
Elisabath Sheppard – Senoir Quality specilist			X(Part)	
Shannon McKenna – Assistant Quality Manager	X		X	

GFSI Audit History

Date	Scheme/Standard	Announced/Unannounced
2021-05-04	BRCGS Food Safety issue 8	Announced

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No	Clause	Detail	Critical or Major	Ant. re-audit date

Critical			
No.	Clause	Detail	Ant. Re-audit date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	5.1.2	The NPD procedure doc ref QM07.SOP27, issue 1 dated 04/05/21 is not fully aligned to the requirements of the clause in that only products with restrictions need to be signed off by the HACCP team.	Updated the procedure which has been reviewed by senior Quality Management.	Going forward all procedures will be reviewed by senior Quality Management.	Oversight of the BRC standard when creating the procedure.	2022-04-11	S.Brookes

Comments on non-conformities
None

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit due date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There is a documented food safety, legality, quality and authenticity policy signed by the Quality Manager HP), signed 30/04/19 and the Operations Director (TS), 30/05/19 which is held electronically in the shared folders, where all staff have feed access. It is also included in the induction information given to all new employees. The policy covers the safety, legality and authenticity of materials from manufacturing to CCL customers. CCL is committed to supplying materials that always meet the specification requirements, with MSDS documents to preserve material integrity and prevent contamination.

The company demonstrated its 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.

Covid has had no impact on staff availability to date, as most goods dispatched are sold in the original packaging, requiring little manual input

The areas covered by this section were discussed with the Operations Director during the audit.

The Quality Culture Policy, doc ref: QM02.POL02, issue 1, dated 03/10/19 describes how quality culture is defined at CCL and the work in place to highlight the importance of having a working quality culture within the company.

A plan for the development and continuing improvement of a food safety and quality culture is in place, doc ref: QM02.FOR05, issue 2, dated 07/03/22.

The following activities are included in this plan:

- Conduct annual staff performance reviews expressing the importance of Quality and food safety. (Every six months). All reviews were last carried out in Dec 21.
- Conduct annual survey (all employees) and manager to review feedback. Survey completed Feb 2022, reviewed 14/03/22.
- Conduct staff meetings regarding quality updates (Monthly).
- Reports to the Board regarding quality and performance statistics including but not limited to the following – Food safety issues, complaints, testing out of spec vs passes, concessions and deviations, quality compliance (Monthly).
- Posters/information in various positions on site promoting the importance of quality and food safety.
- Hold monthly drop in sessions for the sales team re any issues relating to food safety, quality, legality.

The effectiveness is of these activities is reviewed at least annually, with the last review on 14/03/22. Seen for all employee survey completed Feb 2022 and staff meetings conducted 2022.

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

- Quality compliance based on the number of formal complaints from customers – Target >95%, 2021 99.62%. YTD 99.8%

- Increased supplier audits – Target increase to 20 in coming year. Not possible in 2021 re Covid. To be planned when restrictions are lifted, pencilled in for July.
- HACCP level 2 training – Target for all team members where required. 2022 training booked.

These are monitored and reported monthly to senior management via Board Reports and reviewed by the Board monthly with feedback to site via post Board reports (reviewed for Feb 2022), in order to bring food safety, legality, integrity and quality issues to the attention of senior management. Attendees included T.S and the directors.

Management Review meeting agendas include all elements of 1.1.4. Minutes were reviewed for the meeting held on 23/03/22. The output of the meeting included methods for meeting the objectives and targets through the coming year.

Meetings are now held remotely via Team's meetings.

In addition, HACCP, Food Defence meetings are held annually.

Other meetings held include daily meetings with Customer Care covering customer requirements and issues and a weekly Management meeting is held with department Heads to discuss Quality issues.

Employees are aware that evidence of unsafe or out of specification raw materials or products must be reported to their Line Managers, via Induction training, so that anything requiring immediate attention can be dealt with. An example of the induction topics was reviewed on the sites' electronic 'People HR' system

There is a confidential reporting system in place which is detailed in the Confidential Reporting Policy, doc ref: HRP22, issue 4, dated 07/10/19. This enables staff to report concerns relating to product safety, integrity, quality and legality.

The method of reporting concerns is communicated to staff via the Policy, which states the steps to be carried out:

1. Report issue to the appropriate Line Manager (unless the worker reasonably believes his/her Line Manager to be involved in wrongdoing, or there is another reason why the worker would not wish to approach the Line Manager).
2. An investigation will be carried out, either by the Line Manager or another appropriate individual.
3. The issue will be reported to the Board, who will undertake the necessary action and make a final report to HR, who will then carry out the necessary proceedings, such as carrying out disciplinary hearings etc.
4. The worker will be made aware of the outcome of the investigation, by the Board.
5. Where the worker declines to take the matter to the Line Manager, he should inform HR directly.
6. HR will keep records of each stage of the matter.
7. If the worker feels the matter has not been managed effectively, they will be made aware of reporting bodies, such as HM Revenue and Customs, the Financial Conduct Authority, the Competetive Markets Authority, HSE, the Environment Agency, Independent Police Complaints Commission or the Serious Fraud Office.

Senior management assess any concerns raised by the online portal or reporting box. This assessment, and any actions taken, are documented on the online portal. There have been no food safety or legality issues raised to date.

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.

The one non-conformity raised at last year's audit has 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 direct consumer product packaging.

1.2 Organisational structure, responsibilities and management authority

There is an established and experienced team of managers based on site, which includes: The Managing Director and Commercial Directors who are in overall charge of the site. 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:

- Repacking Product Procedure, doc ref: QM07/SOP01, issue 23, dated 12/01/22 – added additional H&S information.
- Foreign Body Control Procedure doc ref: QMO4.POL06, issue 6 dated 11/09/19.
- Complaints Procedure doc ref: QM08. SOP09, issue 6 dated Oct 2018.
- Goods in product inspection and cleaning procedure doc ref QM07/SOP05 issue 11 dated 21/12/21 – Section 5 and 9 added referance to QM07.SOP26 – Magnet probe handling and cleaning procedure
- Magnet probe handling and cleaning procedure doc ref QM07.SOP26 issue 1 dated 14/10/21
- FTIR testing doc ref QM08/SOP12 issue 5 dated 30/10/17
- Vehicle inspection procedure doc ref QM07/SOP22 issue 3 dated Nov 2021 – Addition of tamper evidence checks

Job descriptions were challenged for the following roles A.D Technician and the Clean Room supervisor.

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

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 11 and dated 05/05/21.

The HACCP team is led by the Quality Managers (PB and HP) who are competent in HACCP having Level 2 training PB and Level 3 HP, both have worked at the site in excess of 5 years.

Other team members are the Warehouse Manager (AB), planned for Level 2, the Operations Director (TS) and the Cleanroom Manager (DB), both have HACCP Level 2. All members are trained and have industry experience with food safety systems.

The scope of the study includes all raw materials purchased and sold by CCL The materials may be specifically sourced with a particular associated certification e.g., FEMAS assured materials for feed, but primarily the bulk of materials are sourced for the food supplement industry. The process steps assessed cover approval through to delivery to the customer, along with outsourced processing (blending) doc ref QM02.FOR06 issue 1 dated 21/05/21. 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, heavy metals, 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 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:

- The Contaminants in Food (England) Regulations 2013 and amendments.
- European Food Safety Authority (EFSA) — ensuring safe food and animal feed in the EU and amendments (2021).
- EC Novel Food Catalogue.
- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs and amendments eg Regulation (EU) 2020/2040 of 11 December 2020, which amends Regulation (EC) no. 1881/2006, establishes new maximum values for the presence of pyrrolizidine alkaloids in food products such as tea, chamomile, infusion herbs, food supplements with plant and pollen-based extracts.

Intended use and storage are documented within the study. Products are intended for further processing, so the use of the finished product is not known.

There is 1 main flow process diagram doc ref QM02/GEN04, currently at version 10, which was last verified by the team on 06/08/21. There is also a outsourced processor process flow doc ref QM02.GEN06 issue 1 last verified 21/05/21.
The main process flow diagram covers the process steps, which can be summarized as: product approval, receipt, sampling and checks, release procedure, repack (if required), finished goods storage and despatch.

Physical, chemical, radiological, microbiological, fraud, malicious contamination and allergen hazards have been considered within the study.

- Biological contaminants cover bacteria, fungi, viruses, parasites and algi
- Chemical contaminants cover cleaning chemicals from the food preparation area, pesticides fungicides, insecticides, herbicides and pedenticides, allegens, toxic metals, veterinary medicines, fertilisers, packaging chemical compounds, hazardous gases and aerosols.
- Physical hazards cover glass, metal, stones, twigs, leaves, wood, pests and jewellery
- Radiological hazards are covered at product approval in line with Regulation 737/90

Allergen hazards considered as a chemical contaminant and include raw material and supply chain risks, risks from allergens handled on site and risks from visitors/workers. Suppliers' complete allergen statements on doc ref: QM07 FOR09, issue 25.

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.

The following Quality Control points have also been established: 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.

Corrective action procedures are in place. Responsibilities for monitoring the control limits and for corrective action are defined.

The HACCP plan and pre-requisite programmes are reviewed at least annually (last reviewed 06/08/21), when relevant changes occur, such as processing changes or emergence of new risk, or if a recall occurs. As a result of recent reviews, no changes were made to the company's product safety policy and food safety objectives.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
2.9	No CCP's
2.10	No CCP's

3. Food safety and quality management system

3.1 Food safety and quality manual

The Quality Manual held electronically has been written to meet the requirements of the Standard and contains policies, procedures, work instructions and record forms. It is controlled electronically by the Quality Team, with restricted access. The contents are communicated to key staff by via the People HR software system.

Department specific work instructions are available at key locations and all documents are in English.

3.2 Document Control

Controlled documents are listed on a register within the Quality Manual index and on People HR, and control is managed by the Document Control procedure doc ref: QM04.SOP03, issue 3, dated Apr 2021 reference to ISO 9001 removed.

The Quality Team are responsible for authorisation, changes/amendments and replacement of existing documents.

Electronic documents are stored securely, with access controlled by password protected PCs with a virtual private network and are backed up daily to an off-site server.

3.3 Record completion and maintenance

Records are completed manually and/or electronically and are stored electronically. Every paper document is scanned in and backed up to the offsite server.

Records reviewed during the audit were seen to be legible and genuine and were easily retrieved, these included:

- Repack Equipment Log, doc ref: QM07.FOR26, issue 4, reviewed as part of site inspection.
- Clean & Check Record, doc ref: QM07.FOR15, issue 12, reviewed for 10/03/21 as part of pine bark resin trace and doc ref QM07.FOR15, issue 14 reviewed for 11/01/22 as part of tumeric powder trace .
- Vehicle Inspection Record, doc ref: QM07.FOR06, issue 1, reviewed for 18/01/22 and 07/02/22 as part of trace challenges.

Records are retained indefinitely. Longest shelf life of product is typically 5 years but some items such as salt have no shelf life.

3.4 Internal audits

There are 9 trained internal auditors who are responsible for the site internal audits. These include:

- The Quality Manager PB – Lead Auditor Training (Alchemist) 17/11/17;
- Assistant Quality Manager SM – Lead Auditor Training (Alchemist) 17/11/17;
- Sales and operations process manager JW – Lead Auditor Training (Alchemist) 17/11/17;
- Head of process JS – Lead Auditor Training (Alchemist) 17/11/17;
- Quality Manager HP – Lead Auditor Training (Alchemist) 17/11/17;
- Quality Specialist ED – Internal auditor training 23/07/18;
- A.D team leader A.T– Internal auditor training 26/04/19;
- A.D Technicain F.P – Internal auditor training 23/04/21.

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

The internal audit schedule is documented 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, carried out on at least 4 different dates, spread across the year with the frequency determined by risk assessment.

Internal audit records reviewed included:

- 18/03/22 - Repacking process (bi annually) – audited by ED and EK, No N/Cs raised.
- 28/02/22 - Quaratine area – audited by A.T and F.P. No N/Cs raised.

- 21/10/21 - Quaratine area – audited by A.T and L.S. One N/C raised, which was closed on 28/10/21. This audit was picked to observe systems for raising non-conformances and corrective actions, as it was the only audit where N/Cs were raised since that date.
- 26/11/21 - Food defence and site security – audited by P.B and S.M. No N/Cs raised.

Records were comprehensive recording both conformity and non-conformity and objective evidence for the findings.

Corrective actions and their timescales had been agreed and completion had been verified by the person carrying out the audits and a third person to verify the audit.

In addition, monthly hygiene/fabrication and GMP inspections are carried out, based on risk assessment. Reports reviewed included:

- 28/01/22 by E.D and E.K – 1 minor N/C raised re fridge temp record – email sent to staff.
- 16/02/22 by L.S and T.K – 7 minor N/C raised with actions completed.

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 is carried out, 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.

Known hazards associated with the raw materials used include allergens, pesticides, aflatoxins, heavy metals and other chemical hazards.

The risk assessment includes the following risks associated with raw materials which are subject to legislative control: such as allergens, pesticides and heavy metals and feed items on the ‘Undesirables list’ held.

Note: CCL is a peanut free site, peanuts are not permitted within any areas of the site. CCL Cleanroom and Warehouse are tree nut and sesame free areas. No products containing these ingredients or at risk of cross contamination can be approved for purchase unless stored off site. If at risk materials are approved for purchase, the need to store these materials off site must be communicated to all relevant personnel.

The risk assessment also includes various variety/species cross contamination risks, mainly either where the site handles animal bi-products, or in plant extracts.

The following documentation/information is required for all approvals, where relevant:

- Accreditation certificate and audit report;
- Material Safety Data Sheets and Certificate of Analysis;
- Product Flow Diagram and/or risk assessment;
- A picture of the Product (Powder) before it is packed;
- An example of nutritional information and a list of compound ingredients within the product and the percentages;
- Heavy Metals break down and the method of Assay;
- Original Assay test results that are carried out and Original Pesticide test results that are carried out with identification and method;

- IP (Identity Preserved) Certificate and Kosher & Halal Certificates;
- Completed Ethical SAQ doc ref: QM07.FOR35, Pyrrolizidine alkaloids questionnaires doc ref: QM07.FOR29 (now replaced by legislation), Allergen Risk Assessment Questionnaire, doc ref: QM07.FOR36, Raw Material Drying Questionnaire (PAH), doc ref: QM07.FOR16, Mineral oils Questionnaire, doc ref: QM07.FOR28 issue 3, Raw Material Specification Questionnaire, doc ref: QM07.FOR09 and a completed Supplier Evaluation Questionnaire doc ref QM07.FOR02, only if not GFSI certified. Once this process has been completed a supplier approval form QM07.FOR04 issue 18 is completed and supply can commence..

If the supplier does not have an GFSI accreditation they can be approved using the Supplier Evaluation Questionnaire doc ref QM07.FOR02, issue 4 and providing evidence of an effective traceability system. Supplier questionnaires are issued every three years and suppliers are required to notify the site of any significant changes in the meantime via T&Cs. All suppliers must be approved before purchases can be sold on to the customers and the ethical questionnaire doc ref QM07.FOR35, issue 2 must be sent to HR for approval once completed.

Where deemed necessary (according to the judgment of the Quality Manager following the consideration of complaint history, site accreditation and volumes purchased), additional information for a supplier assessment is obtained through a quality audit, performed by designated trained personnel from Quality Assurance, with a scope to meet clause requirements. Based on the evaluation results of the above assessment, the supplier is approved or rejected.

Suppliers of all raw materials and primary packaging are approved and monitored by the Quality Manager and the Senior Quality Specialist, using the Supplier Approval Procedure, doc ref QM07.SOP08, issue 10 dated 26/11/21 – updated re customer prescribed products and site requirements, and assessment of suppliers is based on risk, quality and historical compliance.

The risk assessment is used to grade suppliers as approved or not approved.

All suppliers have been assessed as low risk when approved. Any suppliers deemed as anything other than low risk would not be approved.

Examples of supplier approvals looked at as part of vertical audits, as below:

- Pine bark resin P1612 from supplier NNG, approved via FSSC 22000 certification, expiry 23/12/22, Product approval doc ref QM07.FOR12 last reviewed 26/02/22.
- Fruit powder supplier AAP, QM07.FOR02 and QM07.FOR04 signed 27/09/21.
- Magnisium citrate P13032 supplier LYD BRCGS Food, site code ****412, expiry 11/10/22.
- Inulin powder P15363 supplier CHED, BRCGS Food, site code ****379, expiry 25/02/23.
- Silicon dioxide P19139 supplier NHS, FSSC 22000 expires 26/04/23
- Blue bags from supplier DPL BRCGS Pack certification, site code ****811, expriy 18/08/22.

The above BRCGS certificates were checked during the audit via the BRCGS 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, with the following performance criteria defined: complaint history, site accreditation and volumes purchased. All products must be re-approved at least every three years using doc ref QM07.FOR12, issue 18 unless their accreditation expires within this time frame. If the accreditation certificate expires within the three years, the expiry date is used as the re-approval date. Form QM07.FOR12 covers checks on specifications, certification, any changes to material or process and a re-check RASFF/google for any evidence of contamination risk for the material.

An approved supplier list is in place, which is a live spreadsheet. Relevant information from the list is made available to purchasing and intake staff via an electronic system whereby approved suppliers are made available for purchasing by the Quality Manager.

Agents, brokers and wholesalers are used. The site knows the identity of the last manufacturer, packer or consolidation place. An example of a supplier who has BRCGS certification included: Turmeric Powder P20095, from supplier SQA, approved via BRCGS Food including traded goods, site code ****267, expiry 08/04/22. Doc ref QM07.FOR4 includes manufacturing site details.

Suppliers' traceability procedures have been assessed by GFSI certification, or if required supplier audit, by the Quality Manager and the Senior Quality Specialist. Supplier audits are carried out by the Quality Manager (PB) who is lead auditor trained and experienced in the industry. Supported by Chinese speaking Senior Quality specialist (C.W). 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 BRCGS criteria e.g., product safety, traceability, HACCP and GMP. No active suppliers are currently approved via site audit.

Where supplier approval is done via a questionnaire, traceability is verified by either a trace test, worked example, or a description of the supplier's traceability system. Example reviewed for fruit powder supplier AAP mock recall exercise dated June 2021 re batch 10038.

Exceptions are covered under supplier and product approval procedure doc ref 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), which is conducted in the modular clean room within the warehouse. 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. This is detailed in the goods in product inspection and cleaning Procedure doc ref: QM07.SOP05.

An example was reviewed for a delivery of Magnesium Citrate P13032 batch 12211216 delivered 29/03/22 during facility inspection. Visual/Magnetic inspection doc ref Clean and Check Record QM07.FOR15 tested on 29/03/22 re container CAIU6307341 seal YMAJS03995 – Supplier LYD, FTIR result 99.7%, passed. Supplier COA dated 16/12/21, CCL COA dated 30/03/22.

The electronic 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 Operations using the procedure doc ref QM06/GDE01 issue 3 dated 02/10/19 and have appropriate contracts. These were reviewed for suppliers of:

- Haulage to customers MF, Service Level Agreement signed 06/11/15;
- Haulage from dock to site (TFM), Service Level Agreement signed 03/11/15;
- Laundry supplier Swiss Landry – Service protectal dated Sept 2019, ISO 9001 expires March 2028.

Service suppliers have been permitted access to the site during Covid.

3.5.4 Management of Outsourced processing

The only process outsourced is blending. The customer is made aware of the outsourcing and has given approval, where applicable. Example seen as part of trace, email sent to Customer NBB dated 24/11/21 detailing the outsourced processor details,

The company used is outsourced Processor/blender NVR, approved by BRCGS Food certification, site code ****101, expiry 24/11/22.

Contracts are raised for each order detailing requirements. Technical agreement signed 30/09/19

Traceability is maintained as both parties hold third party certification.

On receipt back to site the products are checked via the FTIR database and intake documents held. FTIR stands for Fourier transform infrared and is the method of infrared spectroscopy. When IR radiation is passed through a sample, some radiation is absorbed by the sample and some passes through (is transmitted). The resulting signal at the detector is a spectrum representing a molecular 'fingerprint' of the sample. This is used to ensure that the same product is returned from the outsourced processor. Example reviewed as part of trace challenge.

3.6 Specifications

Raw material and primary packaging specifications are sufficiently detailed and are held electronically.

Reviewed for:

- Pine bark resin P1612 v7 dated 04/03/21;
- Tumeric powder P20095 v7 dated 20/11/21;
- Magnesium citrate P13032 v8 dated 17/06/21;
- Steviol Glycoside P12317 v3 dated 03/01/20;
- Inulin powder P15363 v1 dated 26/11/20;
- Silicon dioxide P19139 v4 dated 20/04/20.

Packaging

- Blue bag supplier DPL DQD High slip first grade LDPE – dated 22/02/22 – Migration report Smithers PIRA report dated 27/11/18. DoC ref 1935/2004, EU10/2011 last reviewed 30/09/20.

Finished product specifications are generated by the site and are supplied to customers on either site format or via customer portals. Customer can review all specifications on the website. COAs can also be viewed by customers with log in details.

No customer branded products

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

- Stevia (sweetener) blend P12512 v4 dated 03/03/20.

Specifications are reviewed on a 3-yearly basis, or where changes occur. These are managed electronically.

3.7 Corrective and preventive actions

Corrective action procedures e.g., internal auditing procedure doc ref QM04.SOP02 issue 3 dated March 2022 – updated to include NCR log, and Complaints Procedure doc ref: QM08.SOP09, issue 6 dated 08/10/18 are in place to address failures identified in the food safety and quality management system. Non-conformities that result in a risk to product safety, legality or quality are investigated and recorded in line with clause requirements.

Corrective actions are closed out by either the customer or the owner of the non-conformance. This includes the assessment of the consequences of the non-conformity via daily meetings with the Customer Support Team and verification of corrective action by Quality Team.

Root cause analysis, and further corrective action to address the root cause, are carried out, when there is a food safety, legality or quality issue.

Root cause analysis is carried out by the Customer Care Team working with any other department that may need to be involved. A Root cause procedure is in place as part of the Complaints Procedure doc ref QM08.SOP09.

An example of an RCA was reviewed for a FB complaint dated 14/06/21, Supplier N/C raised doc ref QM08.FOR03 ref NCR58-21 detailing RC and CA – Supplier NVR to make improvements to air separator flow in order to add FB removal. Completed 30/06/21. No further issues.

Corrective actions taken are recorded and reviewed during the Quality meetings held daily and within the Board meetings held monthly.

3.8 Control of non-conforming product

Non-conforming products are identified and held in an appropriate location but controlled electronically. The Quality or Customer Care Team is informed and are responsible for the holding and release of products. All incidents of non-conforming product are recorded either on the complaints log or a N/C record is completed.

Records are in place to demonstrate the investigation, analysis and cause of any non-conforming product. Defined responsibility and actions/timescales are documented. No particular trends.

Records are in place to demonstrate the investigation, analysis and cause of any non-conforming product. Defined responsibility and actions/timescales are documented. An example was reviewed for QUAR8 - PO3138 batch 49741 pallet ID 990112450 quantity 150kg for out of date product awaiting disposal.

3.9 Traceability

A documented traceability system is in place doc ref QM08.SOP17, issue 1.

All raw materials, in process materials, primary packaging and finished product are coded to allow for full traceability through the system.

The traceability system is mainly electronic and operates on a batch system with a unique batch code assigned. The batch code is recorded on finished goods labelling

There is no rework

The site carries out traceability and mass balance tests at least annually and these were undertaken as follows:
Forwards and backwards on 05/05/21 on raw material (P19220 Spinach powder batch 202006028). Full traceability was achieved in 1hr and 50min. Mass balance was achieved.

A traceability test and vertical audit were undertaken during the audit on Pine bark extract, PSID number 326027, product code P1612, batch number 202012038, product quantity 300kg, delivered 10/03/21 from supplier NNG. Of the 300kg, 74.9kg was repacked over 12 different dates into smaller units e.g., 50g and 1kg, and dispatched between 09/04/21 and 18/01/22. All the remaining product (225.1kg) was traded between 17/03/21 and 30/09/21, apart from 10g which was in held in location 35GS3A. Traceability was achieved in 70 minutes.

A traceability test and vertical audit were undertaken during the audit on traded Turmeric powder, PSID number 357250, product code P20095, batch number 1TU14HP015, product quantity 3000kg, delivered 11/01/22 from supplier SQA. Of the 3000kg, 25kg was repacked 01/02/22 and dispatched to customer 21/02/22. Of the remaining product (2975kg) 2725kg remains in stock (various locations e.g., 850kg in 03i3b with 250kg traded between 07/01/22 and 22/02/22. Traceability was achieved in 50 minutes.

A traceability challenge and mass balance were also undertaken during the audit on a blended product NBB Stevia (sweetener) blend P12512, batch numbers 17905-1 and 17905-2, BB 14/012/23. This consisted of 3 ingredients delivered to CCL between 14/05/21 and 02/12/21. Intake testing reviewed for Silicon dioxide P19139 – passed, dated 14/05/21 Silicon dioxide repacked 09/12/21. All products sent to outsourced processor NVR on 10/12/21, quantity 997.5kg. Blended product return from UIL – 16/12/21 – quantity 997.5kg. Goods intake checks completed 16/12/21, FTIR check 11/01/22 – passed. Sent to customer 14/01/22 (customer specified blend). The exercise was completed in 2 hours and 7 min.

A mass balance exercise was also carried out on both the Pine bark extract, PSID number 326027, product code P1612, batch number 202012038 and the Turmeric powder, PSID number 357250, product code P20095, batch number 1TU14HP015. Records were presented for all steps in the process, with mass balance 100%.

Documents and records reviewed during the vertical audit included those pertaining to intake, dispatch, CCPs, processing control and traceability, internal audits, cleaning, specifications, supplier approval and training. Details of these documents and records have been included in the relevant sections of this report.

3.10 Complaint-handling

A system of complaint handling is implemented via the Complaints Procedure doc ref: QM08.SOP09. All complaints are logged onto the Complaint Log and investigated by the Customer Care Team, (part of the Quality Department), with full details kept of all actions taken.

Complaint target is set as a monthly product compliance figure (as per the KPI), set a >95% compliant. Complaints are trended by product type, and sectors including contamination, delivery, documentation adverse reaction, packaging, production errors, shelf life etc., which combine towards the compliance figure.

Analysis of complaints viewed for the past 12 months indicate that the level of complaints is running at 99.54% compliance to date.

Serious complaints, or significant increases in complaints, are investigated using root cause analysis. The last serious complaint resulted in a recall in 2018. There have been no serious issues since that date

Complaints for 2022 reviewed e.g., 18/03/22 ref 22035C re OOS ETO P01233 – batch ending 034 – In progress and 04/03/22 ref 22027C re FB – closed 22/03/22, supplier NCR raised ref S030-22 and completed.

3.11 Management of incidents, product withdrawal and product recall

The site has a comprehensive incident procedure, doc ref: QM08.SOP02, issue 13 dated 09/09/21 – updated re GMP+, and an out of hours contact lists for all key members of staff, customers and organisations including the Certification Body. A Business Continuity Plan is also in place doc ref: QM02.GDE01, issue 3 dated March 2021

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.

No recalls in last 12 month.

An emergency response plan to Covid-19 is in place. Covid has not impacted on the sites' ability to carry out a recall challenge.

A recall challenge is undertaken by the company with the product traced to the customer. The last challenge was undertaken forwards and backwards on raw material Pine bark extract on 02/09/21, PSID code 330098, batch number 202101053. Full traceability and mass balance was achieved. All product dispatched to one customer on 15/02/21.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.2.3	No live animals
3.6.3	No customer branded products
3.9.4	No rework.

4. Site standards

4.1 External standards

The site occupies approximately 9290m2 and production and storage buildings occupy 7432m2.
The site was purpose built in 2015.

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.

The site is situated on an industrial estate and there are no neighbouring activities which would impact on product.

4.2 Site security and food defence

A documented risk/threat assessment is in place doc ref Food Defence and Site Security document, QM02.FOR02, issue 5, which considers both internal and external threats and risks from deliberate contamination or damage.

As a result of this, a threat assessment plan has been generated. This is reviewed at least annually and whenever a new risk/threat emerges or there is a product security/defence incident. Last reviewed 26/11/21

No raw materials or products have been identified as being at particular risk while on the site.

No areas of the site are considered to be at significant risk.

The site security is managed by 24-hour CCTV, a security team monitors the site through the night with registration numbers taken for cars on site post 18:00, all site members have area restricted key fobs.

Entry doors to production are fitted with key fob access systems.

There is reporting system for all visitors and contractors.

There is reporting system for all visitors and contractors, with additional temperature monitoring systems and one way flow system in place. No visitors are permitted on site (other than critical service suppliers).

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

There is a legal requirement for the site to be registered with East Cambridge District Council, approval number AO 021 for the rewrapping, storage and distribution of meat, fish, dairy, egg and gelatine products The site's hygiene approval number is GB026/216.

4.3 Layout, product flow and segregation

There is a site map, dated 21/03/22 which includes all the points referred to in clause 4.3.1.

There are no high risk/high care/ambient high care areas on site.

Most of the areas are dedicated to warehousing. There is a repacking area which is detailed on the plan and a small sampling area at Goods in and apart from these areas the product is enclosed at all times.

One-way systems have been implemented in areas where there is heavy traffic, however the site is very spacious and naturally allows for social distancing in most areas.

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 appeared to be well maintained with panelled walls throughout

Floors are sealed concrete or resin. There are no drains through the repacking area or Warehouse areas. 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 within the Clean Room and at each repacking station. No evidence of excessive dust or condensation was noted. A Class A certification is held for the Clean Room, repack room and small sampling area (10) by third party Clean Rooms, carried out 24/04/21, which details changes to air and air flow.

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 used on site is potable and mains supplied from Anglian Water. Annual microbiological and chemical analysis is obtained from the supplier for period Jan to Dec 2021 and additional surveillance testing is carried out by an external laboratory, SGS.

Water is not used for product. It is used for cleaning of staff areas and hand washing only.

Tests reviewed included:

- 18/03/21 – Wet room (dishwasher), tested for E. coli. TVC, Coliforms and Entro.
- 15/11/21 – Warehouse hot tap tested for E. coli. TVC, Coliforms and Entro.

All tests were within the required tolerances.

There is a plan of the water distribution system dated 21/03/22. Sample points have been identified using risk assessment based on usage.

Ice/steam is not used.
No gas is used
Compressed air is not used

4.6 Equipment

The on-site equipment is very limited. It consists of stainless-steel worktables, stainless steel scoops, sieves, spoons, weighing scales, industrial dishwasher and MHE. There is a dust extraction at each workstation 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. No new equipment in last 12 months.

Certificates/evidence was seen to confirm suitability for food use for the Stainless-steel scoops which are constructed of SS 316. Disposable powder scoop (goods in only) 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, forklifts, racking repairs or fabrication issues are contracted out. Racking is maintained by the sites insurers (Allianz). All areas were seen to be in good condition. 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 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. No examples in last 12 months.

No food contact chemicals/lubricants are used on site.

No engineering workshop.

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 personal 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 no catered canteen, staff are provided with fruit, coffee, tea and milk. No vending machines.

Covid controls include limited people in the canteen area to promote social distancing, staggered breaktimes, additional cleaning of amenity areas (third party Service Master), home working where possible.

Staff are allowed to bring their own food on site and are provided with a microwave and refrigerators which are cleaned daily, and the temperature monitored by the Quality Team. The site is nut free and staff are prohibited from bringing these items in which is implemented via induction training and monitored via GMP audits.

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 with 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. MSDS reviewed.

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 with a registration system for scissors, scoops, sieves, spoons, tools, funnels 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 4 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 Quality Team. Examples reviewed as part of vertical audit for clean room dated 28/09/21 and 12/10/21.

An appropriate Glass Brittle Plastic and Ceramic Procedure doc ref: QM08.SOP13, issue 4, dated 04/06/19 is in place which includes, training of staff, isolation, cleaning, safe disposal of contaminated product and authorised clearance inspection procedures. One cracked tray in freezer in canteen dated 08/04/21. No breakages in storage or clean room recorded for the last 12 months.

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, as per the Foreign Body Control Policy doc ref QMO4.POL06.

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 within the Goods-in and Inspection Procedure, doc ref: QM07.SOP05 for removal of raw materials from their packaging, to avoid contamination.

Pens used in open product areas are controlled. They are consolidated at the end of the shift and are metal detectable and one-piece.

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 as all products will be further processed. All raw materials are supplied as sieved, and metal detected by supplier as documented on product approval documents. Re-packing process is minimal with the use of scoops and spoons and a check in place for condition. Sieves used occasionally for weight control purposes. A Foreign body control policy QM04.POL06 is in place.

4.10.2 Filters and sieves

Filters are used in the extraction area and are cleaned annually by a third party, last cleaned 24/04/21 by CR.

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 as part of the HACCP study has been carried out and it has been concluded that metal detection would not improve the protection of final products from metal contamination because they will be further processed. Metal detection is not required by customers.

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 14/07/21 – ave gauss 10077 (design strength 10000 gauss. Certified to 10,000 +/- 500).

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 products are packed into glass jars, cans or other rigid containers

4.11 Housekeeping and hygiene

The site and equipment were seen to be maintained in a clean and hygienic condition.

Additional touch point cleaning is carried out re Covid.

Equipment and areas checked for cleanliness during this audit included the repacking room.

Full and detailed cleaning procedures are in place for all areas and equipment and include:

- Warehouse Cleaning Procedure, QM08.SOP16, issue 4 dated 14/12/21 – updated re outside yard and loading area.
- Repacking of product Procedure (which covers cleaning) QM07.SOP001.

Cleaning is carried out every day at the end of shift with full machine strip down and surface washing by operatives using a 2-stage clean involving an alcohol spray and wipes.

Cleaning is verified by documented visual checks for each product changeover, which includes a buddy check

Limits of acceptable and unacceptable cleaning for food contact surfaces and equipment are defined by visual inspection at start-up

The corrective action to be taken when results are outside the acceptable limits is defined in the relevant procedures.

Validation records are available to show that cleaning regimes are effective. These are covered by the environmental monitoring procedure and allergen cleaning validation. Surface swabbing and air plates (micro) are conducted quarterly.

SGS (UKAS 1549) micro reports reviewed.

- 20/01/22 – Wet room surface and floor – Salmonella ND and Listeria ND
- 25/03/22 – Repack room work surfaces and utensiles - ACC 10 cfu/g Y&M – <20cfu/g, Entro <10 cfu/g, E.Coli <10 cfu/g, Salmonella ND, Listeria ND
- 15/11/21 clean room small scale, no issues.
- Air quality settle plates last conducted – 17/03/22 — 4 plates for TVC@30DegC, Moulds and Yeasts all results <1cfu/ml

Start-up hygiene checks are documented for all key processes and equipment.

There are colour coded and dedicated cleaning utensils based on usage e.g., Glass breakage red and allergens is pink.

4.11.7 Cleaning in place (CIP)

No CIP systems are used

4.11.8 Environmental monitoring

A documented environmental monitoring programme is in place, doc ref Environmental Microbiological assessment excel spread sheet based on a risk assessment, dated 14/01/19.

The programme includes:

- Sampling protocol, for example ait plate, swab;
- Sample locations, for example extraction units, tables and food contact areas;
- Frequency of tests, for example annually, hand swabs 3 times annually;
- Target organism, for example TVC, Yeast, Mould, Entrobacteria, E.coli, Salmonella, Listeria;
- Test methods e.g. settle plates;
- Recording of results, examples were reviewed for air plate testing.

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 post cleaning.

There are no legal or customer limits for environmental limits (HPA guidance used).

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 site gets consistently negative results, indicating that the programme is not effective.

4.12 Waste

All waste is collected from site by licensed contractors Biffa, licence number CBDU104360, expiry 23/05/22 and the associated food waste transfer note. All food waste is sent for anaerobic digestion.

Animal by-products are stored and labelled for sale, these include whey proteins, which are sold as food supplements.

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.

There is no trademarked or unsafe waste.

4.13 Management of surplus food and products for animal feed

No products are disposed of for animal feed, however some of the items sold from the site can be used within the pet trade.

There are no staff shop/charity arrangements.

Vitamin products are intended for use in animal feed and sold under the FEMAS certification held, Scheme ID 38608 expiry 31/03/23. Approval Activity AA1 - The manufacture and/or placing on the market of nutritional additives, Registration Activity: R7 Manufacture and/or placing on the market of feed materials. Cambridge City Council, certificate of approval dated 26/10/21, licence number GB026/216.

4.14 Pest management

The external contract with Prokill (BPCA membership number M15/737 expires 28/02/23 covers rodents, flying insects, crawling insects and birds and consists of 12 routine visits and 4 in-depth inspections per year. Full records of pest control are maintained including site plan dated 04/12/20, verified for external BS 10, moth pot 16 and internal 25 bait data sheets, operative training records G.P RSPH level 2 dated 04/01/11, records of inspections and treatments.

The last visit to site was carried out on 03/03/22 some minor external rodent activity.

Other reports reviewed included:

- 28/01/22, no internal activity noted. Some external activity noted due to neighbouring farm land

In-depth pest control surveys are undertaken at a frequency based on risk and the last one was 09/09/21.

The risk assessment is reviewed when changes to buildings or processes which could impact the pest management programme and any significant pest issues. Latest signed 07/05/21

In-depth pest control surveys are undertaken at a frequency based on risk and the last one was 09/09/21. The report details minor proofing/housekeeping activities. All actions closed 26/10/21.

All toxic baits are secured, they are used externally only.
All recommendations are completed by the company in a timely manner.
No evidence of infestation was seen at the audit or has been identified during visits.
Inspection results are analysed for trends annually as a minimum, or when these has been a pest issue
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 a risk from birds roosting and/or entering the building. The following prevention measures are in place: spikes

Employees have been trained to understand the signs of pest activity and to report any evidence of pest activity to the senior quality specialist E.S.

4.15 Storage facilities

No temperature-controlled storage is required.

Products are long shelf life and are stored on site within the Warehouse areas.

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 inspected for suitability/cleanliness and covered. The bags/boxes are generic.

4.16 Dispatch and transport

The company has no owned vehicles

Product safety and quality are maintained during loading and transportation by securing loads on pallets to prevent movement, and full stretch wrap.

Forklift trucks, pallet trucks are cleaned and checked according to the warehouse cleaning procedure doc ref QM08.SOP016, with records checked.

Transport procedures are in place within the Vehicle inspection Procedure doc ref: QM07.SOP22, issue 3 dated Nov 2021 – addition of tamper evidence checks, covering clause requirements

Approved third party hauliers are used:

- Haulage to customers MF, Service Level Agreement signed 06/11/15
- Halage from dock to site (TFM) Service Level Agreement signed 03/11/15

The Hauliers are approved based on the Service Level Agreements held and an historical trading history.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.2.2	No products have been identified as being of particular risk
4.2.3	No areas of significant risk
4.3.5	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.
4.5.3	Gas is not used. Compressed air is used for machinery operation only.
4.7.6	No engineering workshop on site
4.8.8	No catering facilities provided.
4.9.1.2	No strongly scented or taint forming materials are used.
4.9.3.4	No risk to product from glass windows
4.9.4	No packing into glass or brittle containers.
4.10.3.2 -.4	No metal or X ray detection equipment used
4.10.5	Optical sorting equipment is not used.
4.10.6	There are no jars, cans and other pre-formed rigid containers.
4.11.7	No CIP.
4.12.3	There is no unsafe or trademarked/customer branded waste.
4.13.1	No surplus customer branded products.
4.13.2	No customer branded products passed through charities or other organisations
4.14.3	Pest control is contracted externally.
4.15.3	No temperature-controlled storage areas required.
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. Product control

5.1 Product design/development

New product variations would currently include repacked products of the similar type to those used sold on site.

Guidelines are in place which detail the following restriction to scope: no nuts, no sesame, no glass or brittle plastics or porous or fibrous packaging materials or anything outside of the sites' BRCGS scope

An NPD procedure is in place, doc ref: QM07.SOP27, issue 1 dated 04/05/21, with HACCP a key part of the development procedure.

Full development systems are being implemented based on a development checklist (stage gate process) which will be followed prior to launch and includes a HACCP sign off for sign off of restricted items only (see N/C), with production trials undertaken as required, and shelf testing where appropriate. No new products.

Minor N/C 1, clause 5.1.2. The NPD procedure doc ref QM07.SOP27, issue 1 dated 04/05/21 is not fully aligned to the requirements of the clause in that it states that only products with restrictions need to be signed off by the HACCP team.

Shelf life is determined and validated through EOL testing, based on the conditions expected throughout the life of the product, recorded on the Shelf-Life Record, which will include start of life, end of life with comparison analysis. An example reviewed for a product P15009 (Oat flour) (G.F) batch A717A – SGS micro report dated 04/02/22, no issues noted. FTIR report dated 18/02/22 – 99%. Original BB date 31/01/20, following testing shelf life extended to 22/03/23 – COA updated and supplied to customer. FTIR is used as a fingerprint and overlays the original batch to detect any difference in the composition through the life of the product and post life for potential shelf-life extension.

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.

The site details that certain products are suitable for vegetarians and vegans. This is verified via traceability challenges and supplier controls. An example was reviewed for finished product Maltodextrin P13014 v11 dated 13/04/21. No other specific nutritional/suitability consumer claims are made.

No customer branded products produced on site.

No cooking instructions are detailed.

5.3 Management of allergens

Allergens are handled on site include all of the declarable allergens with the exception of peanuts, tree nuts or sesame. All products are supplied in sealed packaging with the majority traded.

An allergen Policy/Procedure, doc ref: QM04/POL01, issue 4 dated 18/02/22 – updated to include site allergen status, is in place which details the allergens handled on site and where they will be opened for repacking. Allergen containing raw materials are managed via information from the supplier specifications

An allergen matrix is place as part of QM04/POL01, which details where the allergens are handled on site. All raw materials, products and the process have been risk assessed. Supplier declarations are obtained for raw materials.

The risk assessment has concluded that there are no allergen cross contamination risks due to barriers in between workstations and air extraction systems which are portable and placed directly in close contact with the raw material being packed.

No separate areas are required for allergen as each product has its own segregated bay during storage. Colour coded equipment is in place for spillages.

All allergens are identified electronically and are fully labelled.

There is a spillage control procedure HSMO5.01.22 issue 5 dated 18/02/22 – updated re pink boxes 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 warnings are not considered necessary because of the controls in place.

Allergen cleaning methods have been validated by accredited external lab testing of the next product after an allergen. This was last carried out 21/01/21 and no trace of milk powder was detected. Eurofins report dated 09/11/20 rpt number 706-2020-00220254 - beta lactoglobulin <0.031 mg/kg and casein <0.25 mg/kg, and positive report dated 12/01/21. No changes to processes. Allergen cleaning is routinely verified by visual inspection and buddy checks re area and utensil clearance and cleaning procedures.

The following “free from” claims are made – Gluten Free.

This is validated by extensive external lab testing across various batches and supplier CoAs e.g., Example reviewed for P15009 (Oat flour) (G.F) - Eurofins Dakks report dated 11/03/22 re batch 22046 <3.12 mg/kg ELISA sandwich, Eurofins Dakks report dated 25/08/21 re batch 21215 <3.12 mg/kg ELISA sandwich. Supplier testing of each batch as documented on CoA, seen for batch 22046 CoA <5ppm gluten dated 16/02/22 – ELISA R5 Mendez (Romer UKAS 4400).

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 RASSF, FEMAS, Nutraveris.

A documented vulnerability assessment has been carried out for each product produced with FTIR testing for all products, resulting in a vulnerability assessment plan, for example testing frequency. The plan is kept under review to take into account changes in potential risks, and is formally reviewed every 3 years, or on change or if there is an issue, for example Ethyl Oxide in Green Tea, all products purchased from China have been retested. Example reviewed dated 23/11/21.

No particular risks have been identified due to the controls in place. The supplier approval process identifies risks.

No raw material status claims are made

Method of production claims are made these include Organic. The site has certification by Soil Association, licence number DA18397, expiry 31/03/23.

Documented mass balance tests are carried out on a 6-monthly basis as a minimum. The last challenge was carried out 21/09/21 on product Organic coconut flour, P31749.

Halal and Kosher claims are made on traded goods as detailed in section 9, but not on repacked products

- Halal cert ref CCL/COM/CCL/009043X expires 01/05/22
- Kosher cert ref 51977 expires 09/12/22

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

Products are packed into blue bags and cardboard boxes, where repacked, or sold in the original packing where the product is traded (>95% of product)

Food contact information and suitability for the intended product has been provided by suppliers of all food contact packaging.

Product contact liners are not used, products are decanted into the finished product packaging. 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, example reviewed for pine extract trace P13605 batch 112340.

There is no obsolete packaging as all packaging is generic.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Microbiological product analysis is sub-contracted to SGS, UKAS 1549, which is carried out as surveillance only with a schedule covering all product ranges annually or more frequently if customer required.

Laboratory tests are also carried out according to the individual specification of the product, for example:

- Micro ACC, E.coli , Salmonella, Yeasts Moulds, Entero and Listeria as per the HPA guidelines.
- Chemical tests include Heavy Metals, pesticides, PAH (drying process), ID or assays for vitamins, PLC for plant identification, colourants etc.

Results reviewed as part of vertical audits were within the required tolerance levels and included:

- Pine Bark extract P1612 Eurofins Dakks PAs report dated 02/06/21;
- Pine bark extract P1612 Campden BRI Heavy metals report dated 04/05/21;

- Pine Bark extract P1612 Concept Life Sciences (SGS) – UKAS 1549. Micro reports dated 15/03/21;
- Turmeric powder P20095 batch 1TU14HP015 (SGS) – UKAS 1549. Micro report dated 21/01/22;
- Turmeric powder P20095 GCA Dakks mycotoxins and illegal dyes report dated 16/03/20;
- Stevia Blend P12512 SGS micro report dated 29/12/21, batch 17905-2;
- Silicon Dioxide P191139 batch 210223 Campden BRI Heavy metals report dated 27/04/21;
- Silicon Dioxide P191139 batch 2101112 Eurofins Dakks Heavy metals report dated 11/12/20.

There is no general testing schedule. The tests are detailed within the PS system for each individual product, which allocates the tests to be carried out each time a batch is produced. This information is generated from the supplier approval process.

The testing schedule is considered to be appropriate, based on the risks associated with the raw materials and products.

Trend analysis and reviews of all test results are carried out by the Quality team and any out of specification results are risk assessed and the customer consulted if appropriate.

The only tests are carried out on site are the visual assessment and the FTIR tests.

Examples seen for trace challenges >99% match (Herbals >95%, Chemicals >98%). A visual check against photo and CoA verses specification check are also conducted.

Shelf life is validated and routinely verified by the approval process, specification and testing. Suppliers are required to detail the stability details to show the life of the product. 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. An example reviewed for a product P15009 (Oat flour) (G.F) batch A717A – SGS micro report dated 04/02/22, no issues noted. FTIR report dated 18/02/22 – 99%. Original BB date 31/01/20, following testing shelf life extended to 22/03/23 – COA updated and supplied to customer.

5.6.2 Laboratory testing

In-depth pathogen/micro testing is carried out and subcontracted to SGS UKAS 1549. No pathogen testing is carried out on site.

Other tests are carried out by third parties including:

- Eurofins DAKKS (Germany and Neogen, UKAS1906 is used for allergen testing;
- Inform Sport Testing is used for prohibited sports substances (enhancement testing), UKAS 1187;
- Eurofins, UKAS DAKKS (Germany) is used for chemicals such as Heavy Metals etc;
- Campden BRI (UKAS 1079) is used or inorganic arsenic and other specialist tests;
- Achalimist is used for ID testing using HPLC (A2LA certificated).

The FTIR tests are carried out to assess the actual makeup of the raw material, this critical to product safety or legality, this looks at colour and makeup and is saved via the FTIR library. The equipment is calibrated annually by a third party, last calibrated externally and weekly internally.

A visual check is also made by the Analytical Department Technicians against a photographed library sample of the previous batches. Library sample photographs are sent by the suppliers.

All tests are critical to either product safety or quality, due to their nature, hence the regime of testing carried out.

Laboratory results are reviewed by the Analytical Department Technicians.
Actions taken on out of spec results include holding the product while an investigation is carried out with the supplier and the customer is contacted.

All products reviewed were within the required specification

5.7 Product release

Every product is positively released from the site based on all the tests undertaken. The Quality Team is responsible for release of product.

5.8 Pet Food

Not applicable – no pet food is manufactured.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.5	No cooking instructions are 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 raw material status claims (provenance, breed, IP etc.)
5.5.2	No ingredient or WIP bags used.
5.5.3	No obsolete packaging as all packaging is generic
5.8	No pet food

6. Process control

6.1 Control of operations

Documented process specifications and work instructions/procedures are in place which reflect agreed finished product specifications. This is controlled at intake. No processing is carried out.

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

Process monitoring tests carried out in-house include intake checks via product testing according to a schedule, and FTIR testing for consistency

Other checks include organoleptic checks, visual checks and COA tests any third-party testing is reviewed by the Quality Team and weight checks are counter signed via a Buddy system

There is no in-line monitoring.

There are no processing or storage conditions critical to product safety or quality.

Procedure FTIR testing doc ref QM08.SOP12 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

Packaging is allocated to packing lines electronically according to the repacking requirements daily.

Coding and printing are done off-line, with setting and amendments to the printer carried out by the Team Leaders. Buddy checks are carried out to ensure all products are packed and labelled correctly, in line with the Repack Procedure, doc ref: QM07.SOP01, which includes start-up checks for each product.

Specific start up and changeover checks are controlled as part of the repacking procedures. Only one product is packed at any one time, with 2 labels only printed for each repacked product – 1 for the product and the other for the raw material bag showing the weight adjustment undertaken to ensure that lines have been suitably cleared, with all products and packaging from previous production removed. A box label is printed, and buddy checked.

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.

Packaging checks, including coding and any other printing, are carried out at the start and end of packing runs, there are no changes to packaging types.

No on-line verification of product labels is required

6.3 Quantity, weight, volume and number control

Products are sold by weight, according to customer requirements.

Products are packed and weighed, and the finished product weight is monitored by the Buddy system, with 2 signatures held. Every finished pack is weighed

The system and records kept meet legislative requirements.

There are no bulk quantities sold.

6.4 Calibration and control of measuring and monitoring devices

No CCPs have been identified

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

The site maintains a calibration matrix which identifies the item, location, calibration method, result, responsibility and frequency, doc ref: QM08.FOR24, issue 3

No thermometers are required for the processes undertaken at the site.

Scales are verified daily using a set of known weights calibrated annually. Scales are also calibrated annually, or before if they fail the daily test.

Calibration certificates reviewed included:

- Scale SN AE553G3512 (15kg), last calibrated 08/11/21 by Blake & Boughton UKAS 0003;
- Scale SN B503485237 (60KG), last calibrated 08/11/21 by Blake & Boughton;
- FTIR SN MY2051CU13, last calibrated 01/03/22 by OEM Agilent Technologies;
- Weights various, last calibrated 08/11/21 by Blake & Boughton.

The calibration procedure doc ref: QM08.SOP11, issue 7 dated 11/03/22 – updated more information details the corrective action procedure, should measuring equipment be found to be inaccurate

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.1.2	Equipment settings are not critical to the safety or legality of the product
6.1.4	There are no inline monitoring devices
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
6.3.3	No online check weighers are used
6.4.1	No CCPs.

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, CCPs, medicines, GMP, QMS and H & S.

There have been no issues performing training due to Covid. Training requirements are limited as there are no CCPs, or processing and 95% of product is sold in the original packaging. A buddy system is used to ensure products are correctly repacked and labelled, where required

Agency staff are not used.

Detailed individual training records, which meet clause requirements, and a list of approved trainers are kept.

L.W Clean Room Operative:
Repacking Product QM07.SOP01 issue 22 dated 26/05/21 covers labelling and packing process – 27/05/21, issue 23 refresher training – 21/01/22

R.M Clean Room Operative (now left the business):
Repacking Product QM07.SOP01, issue 22 dated 26/05/21 3 covers labelling and packing process – 27/05/21.

Other staff training records reviewed included:

T.K AD Technician:
FTIR Procedure QM08.SOP12, issue 5 – 07/08/19;
Induction/Security -29/07/19;
Induction/Allergens – 29/07/19.

T.A (Warehouse operative):
Induction – 14/02/22.

Staff interviewed during the audit were competent in their roles e.g. A.B Warehouse Manager, J.C and T.A Warehouse operatives, J.E repack (clean room supervisor), L.W repack operative, T.K and L.M A.D Technicians.

Competency of staff is reviewed on an on-going basis. A programme of refresher training on updated procedures is in place on change or if an issue is highlighted.

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). The Guide to CCL Expectations of Staff Hygiene Procedure doc ref: QM06.SOP02, issue 2 documents the site rules and policies.

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

The site has installed hand sanitisers at all doorways.

Plasters are controlled, via individual issue, recorded on the Plaster Issue Log which includes disposal checks. They are blue in colour and metal detectable.

The use and storage of personal medicines is controlled. They are held in locked containers, controlled by HR, as per the Restrictions for Handling Open Products Procedure doc ref: QM06.POL13, issue 2.

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 via induction training.

Policy for staff members who fall ill or may have been exposed to Covid-19 comprises staff phoning from home. An HR help line is made available for staff to report all issues of illness, as detailed on the Absence Management Document, doc ref: HRP30.V3, available on each workers' People HR portals.

The Open Products Procedure, doc ref: QM06.POL13, issue 2 is in place to enable 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.

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

There are no changes to return-to-work procedures due to covid-19, as this is managed via the HR reporting line

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.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
7.1.2	No CCPs
7.2.4	No metal detection equipment is used
7.4.3	No laundering, all PPE used by staff in open product areas are disposable
7.4.7	All items are disposable or washed by Operatives

Template control	Food	**Version**	1.0

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
No High-Risk, High-Care and Ambient High-Care Production Risk Zones
8.2 Building fabric in high-risk and high-care zones
Not Applicable.
8.3 Maintenance in high-risk and high-care zones
Not Applicable
8.4 Staff facilities for high-risk and high-care zones
Not Applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not Applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not Applicable
8.7 Protective clothing in the high-risk high-care zones
Not Applicable

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
8	No high-risk, high-care or ambient high care Production risk 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.

The risk assessment is used to grade suppliers as approved or non-approved. Nearly all of the throughput is traded. Approx. 5% is repacked based on customer order. Where products are repacked, they are taken from traded goods stock. All suppliers are therefore controlled under the same principles, as set out in section 3.5.

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

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

- Turmeric Powder P20095, from supplier SQA, BRCGS site code ****267, expiry 08/04/22;
- Magnesium citrate P13032 supplier LYD BRCGS Food, site code ****412, expiry 11/10/22;
- Inulin powder P15363 supplier CHED, BRCGS Food, site code ****379, expiry 25/02/23;
- Silicon dioxide P19139 supplier NHS, FSSC 22000 expires 26/04/23.

The following SAQs were reviewed and found to cover all the requirements: Fruit powder from AAP, SAQ reviewed by Quality Manager on 27/09/21.

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

9.2 Specifications

Specifications for traded products are agreed by signing by both parties. All documentation must be in place prior to product supply, this includes a signed specification. Customer can also review all specifications on the CCL website. CoAs can also be viewed by customers with log in details.

The following specifications for Traded Products were reviewed and found to be acceptable:

- Pine bark resin P1612 v7 dated 04/03/21;
- Tumeric powder P20095 v7 dated 20/11/21;
- Magnesium citrate P13032 v8 dated 17/06/21;
- Inulin powder P15363 v1 dated 26/11/20;
- Silicon dioxide P19139 v4 dated 20/04/20.

There are no customer specified requirements for traded products.

Specifications for traded products are reviewed on a 3-yearly basis as a minimum, or on change. or where changes occur. A new specification is required on change. Specifications are managed electronically.

9.3 Product inspection and laboratory testing

There is a documented schedule of risk-based product sampling/assurance tests carried out on traded products to ensure the products meet legal and safety requirements. These tests are detailed in the electronic 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.

Examples seen for trace challenges and for a delivery during the facility inspection:

- Turmeric powder, PSID number 357250, product code P20095, batch number 1TU14HP015, delivered 11/01/22 from supplier SQA. Magnetic inspection doc ref Clean and Check Record QM07.FOR15 tested on 18/01/22, FTIR including visual check tested 18/01/22, passed. Supplier COA checked 17/01/22.
- Pine bark extract, PSID number 326027, product code P1612, batch number 202012038, delivered 10/03/21 from supplier NNG. Magnetic inspection doc ref Clean and Check Record QM07.FOR15 tested on 16/03/21, FTIR including visual check tested 16/03/21, passed. Supplier COA checked 16/03/21.
- Magnesium Citrate P13032 batch 12211216 delivered 29/03/22. Magnetic inspection doc ref Clean and Check Record QM07.FOR15 tested on 29/03/22 re container CAIU6307341 seal YMAJS03995 – Supplier LYD, FTIR result 99.7%, passed. Supplier COA dated 16/12/21, CCL COA dated 30/03/22.

Product safety risks associated with the traded product are the same as those used for repacking and include microbiological, chemical, allergenic and foreign body risks, as detailed in the HACCP system. Legal risks associated with the traded product include heavy metals, pesticides, mycotoxins, pathogens, industrial and process contaminants (dioxins/PAHs/ethyl oxide/illegal dyes).

Tests carried out by third party laboratories include:

- Micro ACC, E. col, Salmonella, Yeasts Moulds,, Entero and Listeria as per the HPA guidelines.
- Chemical tests include Heavy Metals, pesticides, PAH (drying process), ID or assays for vitamins, PLC for plant identification, colourants etc.

Example of test reports reviewed

- Pine Bark extract P1612 Eurofins Dakks PAs report dated 02/06/21
- Pine bark extract P1612 Campden BRI Heavy metals report dated 04/05/21
- Pine Bark extract P1612 Concept Life Sciences (SGS) – UKAS 1549. Micro reports dated 15/03/21
- Turmeric powder P20095 batch 1TU14HP015 (SGS) – UKAS 1549. Micro report dated 21/01/22
- Turmeric powder P20095 GCA Dakks mycotoxins and illegal dyes report dated 16/03/20
- Silicon Dioxide P191139 batch 210223 Campden BRI Heavy metals report dated 27/04/21
- Silicon Dioxide P191139 batch 2101112 Eurofins Dakks Heavy metals report dated 11/12/20

Certificates of conformity/analysis are provided by suppliers. These are supported by independent analysis, with a frequency determined by risk assessment at approval.

Claims are made about traded products, including Organic, Halal, Kosher and Gluten Free.

The claims are verified by certificates, traceability challenges, CoA, product testing, evidence from supplier.

- Soil Association, licence number D18397, expiry 31/03/23;
- Halal cert ref CCL/COM/CCL/009043X expires 01/05/22;
- Kosher cert ref 51977 expires 09/12/22.

Documented mass balance tests are carried out on a 6-monthly basis as a minimum. The last challenge was carried out 21/09/21 on product Organic coconut flour, P31749.

Gluten Free claims are validated by extensive external lab testing across various batches and supplier COAs e.g., Example reviewed for P15009 (Oat flour) (G.F) - Eurofins Dakks report dated 11/03/22 re batch 22046 <3.12 mg/kg ELISA sandwich, Eurofins Dakks report dated 25/08/21 re batch 21215 <3.12 mg/kg ELISA sandwich. Supplier testing of each batch as documented on CoA, seen for batch 22046 CoA <5ppm gluten dated 16/02/22 – ELISA R5 Mendez (Romer UKAS 4400).

The FTIR tests are carried out to assess the actual makeup of the raw material, this critical to product safety or legality, this looks at colour and makeup and is saved via the FTIR library. The equipment is calibrated annually by a third party, and weekly internally against a known standard.

A visual check is also made by the Analytical Department Technicians against a photographed library sample of the previous batches. Library sample photographs are sent by the suppliers.

All tests are critical to either product safety or quality, due to their nature, hence the regime of testing carried out.

Laboratory results are reviewed by the Analytical Department Technicians.

Actions taken on out of spec results include holding the product while an investigation is carried out with the supplier and the customer is contacted.

9.4 Product legality

The site verifies the legality of traded products via the product approval processes, with FTIR and third-party testing.

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. Finished product labelling is the responsibility of the customer and is included in the product specification and T&Cs.

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 are sold on the unit of sale supplied to the customer.

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

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

The last tests were as detailed in section 3.9, where some of the product was traded and some was repacked, with full traceability and mass balance achieved within 4 hours. The challenge was carried out on P19220 Spinach powder on 005/05/21 batch number 202006028.

A number of traceability tests were carried out during the audit with all information available in <4hrs.

A traceability test and vertical audit were undertaken during the audit on Pine bark extract, PSID number 326027, product code P1612, batch number 202012038, product quantity 300kg, delivered 10/03/21 from supplier NNG. Of the 300kg, 74.9kg was repacked over 12 different dates into smaller units e.g., 50g and 1kg, and dispatched between 09/04/21 and 18/01/22. All the remaining product (225.1kg) was traded between 17/03/21 and 30/09/21, apart from 10g which was in held in location 35GS3A. Traceability was achieved in 70 minutes.

A traceability test and vertical audit were undertaken during the audit on traded Turmeric powder, PSID number 357250, product code P20095, batch number 1TU14HP015, product quantity 3000kg, delivered 11/01/22 from supplier SQA. Of the 3000kg, 25kg was repacked 01/02/22 and dispatched to customer 21/02/22. Of the remaining product (2975kg) 2725kg remains in stock (various locations e.g., 850kg in 03i3b with 250kg traded between 07/01/22 and 22/02/22. Traceability was achieved in 50 minutes.

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018			
Clause	Module item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.	Y	Adequate lighting was observed in the handwashing and staff areas. As a benchmark a full site Lux level survey was conducted October 2018.
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	Y	Water systems have been installed to prevent backflow from, or cross-connection between, piping systems that discharge wastewater or sewage. There is a plan of the water distribution system dated 21/03/22. Sample points have been identified using risk assessment based on usage. Water testing in place.
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	Food surfaces of plant, equipment and utensils used in food areas were corrosion resistant and seems on food contact surfaces were suitably constructed and/or maintained to minimise accumulation of food particles, dirt, and organic matter, to minimise the risk of cross contamination from microorganisms and allergens.
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
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 where applicable, 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.

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 • Unintentional adulterants which affect food safety	Y	The hazard analysis covers economic adulterants, radiological hazards, or unintentional hazards which affect food safety. There are no RTE products, all products require further processing
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	All known or foreseeable hazards identified are evaluated to determine those requiring preventive controls. This is managed via the HACCP system, which is reviewed annually, or on change. The last review was 06/08/21. No CCPs have been identified
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	The site has systems in place for preventive controls. Root cause analysis investigations are carried out where necessary to establish the preventive action required
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	Y	The Recall and Withdrawal Procedure is updated on change and contains procedures to notify the consignee of how to return or dispose of the recalled product. Effectiveness checks are carried out following the meeting to ensure that any non-conformances are closed out and used to shape future practice. The procedure details the appropriate procedures for product disposal or rework, i.e. placed on quarantine until the recall team liaises with the supplier and a decision Is made

	• Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		The last challenge was undertaken forwards and backwards on raw material Pine bark extract on 02/09/21, PSID code 330098, batch number 202101053. Full traceability and mass balance was achieved. All product dispatched to one customer on 15/02/21.
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 and procedures are in place for each preventive control required. There are no CCPs, but controls are detailed for both OPRPs and PRPs, for example at step 130 – Goods Release a hazard is detailed as physical, chemical or biological contamination resulting in loss of product, complaint from customer or harm to end user. Prevent action controls established include the positive release of all items dispatched from the site, based on test results (different according to each product)
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 internal auditing procedure doc ref QM04.SOP02 and complaints procedure doc ref QM08/SOP09. Although no CCPs have been identified, there are QCPs procedures which detail corrective actions. For example, Goods in product inspection and cleaning procedure doc ref QM07/SOP05, FTIR testing doc ref QM08/SOP12 and Repacking Product Procedure, doc ref: QM07/SOP01
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.	N/A	No critical control points have been established
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	Y	The Quality Managers (designated PCQIs) or authorised designee reviews any N/Cs raised within 7 days. Where this timescale has to be extended, the PCQI signs off the justification. Daily meetings are held to ensure the 7-day timescale is adhered to. The PCQI reviews preventive controls, such as calibration, product testing and audits.

	records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically 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	Y	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure is in place. All products undergo FTIR testing at intake as an overlay against the previous sample to ensure nothing has been added/subtracted from the product, FTIR Spectroscopy Procedure doc ref: QM08/SOP12 issue 5 dated 30/10/17 The procedure details: • The sampling procedure, including the method, quantity, frequency, and number of samples • The analytical method • The laboratory conducting analysis • Corrective action procedure where pathogen is detected Examples reviewed included: Spectral overlay of Magnesium Citrate P13032 batch 12211216, FTIR result 99.7%, passed.
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	Y	An environmental monitoring program is in place as detailed in clause 4.11.8 The programme includes: • Sampling protocol, for example air plate, swab • Sample locations, for example extraction fin, tables and food contact areas • Frequency of tests, for example annually, hand swabs 3 times annually • Target organism, for example TVC, Yeast, Mould, Entrobacteria, E.coli, Salmonella, Listeria • Test methods e.g. settle plates • Recording of results, examples were reviewed for air plate testing Details of the laboratory carrying out the analysis. Corrective action procedures where a pathogen is detected.
13.1.16	Devices used to verify preventive controls must be calibrated.	Y	Equipment used to monitor preventive controls is calibrated, for example the FTIR machine as detailed in section 6. There are no CCPs.
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.	Y	The HACCP Team Leader (one of the PCQIs) and has developed the HACCP plan. The plan is validated annually or in change The PCQIs has been trained to Level 2 as a minimum and working at the site for a number of years as per Section 2

	Document the PCQI's training and qualification via job experience.		
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	Site records detail the date and time of the activity.
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	The site owner/operator last signed the food safety plan during the last HACCP review 06/08/21 This is resigned on change, or review.
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 food safety plan, which must remain onsite.	Y	Records and documents are held for at least 2 years after the record has been created. This can be verified via the Changes and Amendment Log held electronically. Records are held on-site indefinitely. Where records are stored electronically or off-site, they are fully retrievable within 24 hours. The Food Safety plan is held on-site at all times.
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.	N/A	As the site does not currently supply the US, no supply chain has been established.
13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients.	Y	Supplier approval is documented prior to the purchase and use of the raw materials. This is detailed in the

	Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		Approval/Non-Approval Conformation document, doc ref: QM07.FOR04, issue 18.
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	All suppliers are required to present the required document prior to approval. The site is aware that no exceptions are permitted for the US. Only approved suppliers will be used.
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 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.	Y	Systems are in place for by-products that are sold or distributed as feed. For example, Whey Protein. Identification labelling is in place. Containers are examined prior to filling. No product is currently sold to the US.
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	Y	The defence plan is developed by the PCQI. The vulnerability assessment in place details mitigation strategies. The Plan is reviewed annually. The PCQI, is identified on the sites organisational chart Controls are implemented by trained, appointed Qi

	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.		
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 • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification	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.
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	The site obtains information on threats to the supply chain which could lead to adulteration/substitution of raw materials by RASSF, FEMAS, Nutraveris. A documented vulnerability assessment has been carried out for each product produced with FTIR testing for all products, resulting in a vulnerability assessment plan, for example testing frequency. The plan is kept under review to take into account changes in potential risks, and is formally reviewed every 3 years, or on change or if there is an issue, for example Ethyl Oxide in Green Tea, all products purchased from China have been retested. Example of testing reviewed dated 23/11/21. No particular risks have been identified due to the controls in place. The supplier approval process identifies risks The assessment also details the degree of access to the product and the likelihood of potential contamination or from an internal or external attacker. The assessment details mitigation controls in place to reduce the risk to an acceptable level
13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step	Y	Where mitigation strategies are detailed, justification is in place to show how the strategy minimises or reduces vulnerability,

	identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.		
13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.	Y	A documented risk/threat assessment was carried out via the Food Defence and Site Security document, doc ref: QM02.FOR02, issue 5, which considers both internal and external threats and risks from deliberate contamination or damage and covers activists disgruntled employees, all areas of the site, product on-site security and site IT systems. Controls are detailed. There are no areas or products deemed as a higher risk due to the monitoring controls in place which include: 24-hour CCTV, a security team monitors the site through the night with registration numbers taken for cars on site post 18:00, all site members have area restricted key fobs. Entry doors to production are fitted with key fob access systems. There is reporting system for all visitors and contractors, with additional temperature monitoring systems and one way flow system in place. No visitors are permitted on site (other than critical service suppliers). Staff training is in place on site security and food defence.
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	Corrective action procedures are in place to detail failures in the mitigation controls for the food defence system. No products or areas of the site have currently been highlighted as being of significant risk
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	Y	Documented verification procedures will be implemented to ensure that monitoring activities and corrective actions are carried out in accordance with the relevant procedures, should the risk assessment detail the need for this.

	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		
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	The Food Defence plan is reviewed on an annual basis or on change, as per clause requirements. This information is detailed within the Food Defence and Site Security document, doc ref: QM02.FOR02, issue 5. Last reviewed 26/11/21.
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 retained as part of the Food Defence plan doc ref QM02.FOR02 detail the time and date of the activity being documented and signature of the person performing the activity, the name and location of the site, with identification of the batch/lot code of the product.

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 owner, operator or agent in charge of facility has signed and dated the written food defence plan 21/05/21.
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	Records for the food defence plan are retained on site indefinitely once the record has been created. Where records are stored off-site, or electronically, they are retrievable within 24 hours. The food defence plan remains onsite.
13.4.1	Vehicles and transportation equipment must be maintained and 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.	NA	The site does not currently supply the US Vehicles and transportation equipment are maintained and 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 are not used. Forklift trucks, pallet trucks are cleaned and checked according to the warehouse cleaning procedure doc ref QM08.SOP016, with records checked.
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	NA	The site does not currently supply the US

	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.		
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 loader and carrier, which are appropriate for the type of food.	NA	The site does not currently supply the US
13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	NA	The site does not currently supply the US
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.	NA	The site does not currently supply the US
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	NA	The site does not currently supply the US

	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		
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 • Responsibilities of the carrier	NA	The site does not currently supply the US
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.	NA	The site does not currently supply the US
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.	NA	The site does not currently supply the US
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	NA	

	Produce safety standards applicable to an individual's job		
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	NA	
13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.	NA	
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.	NA	
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.	NA	
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	NA	

	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.		
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.	NA	
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.	NA	
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.	NA	
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	NA	

	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.		
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 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.	NA	
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.	NA	
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.	NA	
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	NA	
13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after	NA	

	being made by the supervisor or responsible party.		
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 the site for at least 2 years after their use is discontinued.	NA	
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).	NA	

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 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	NA	