Audit Report Global Standard Food Safety Issue 9

1. Audit Summary			
Company name	Cambridge Commodities Ltd	Site code	6960330
Site name	Cambridge Commodities Ltd		
Scope of audit	The repacking of dry, ambient stable nutritional food ingredients packed into bags for further manufacturing. The outsourced blending and packing 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	N/A		
Audit start date	2024-04-09	Audit finish date	2024-04-10
Re-audit due date	2025-05-04	Head office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose a module	Choose an item		
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit programme	Announced
Previous audit grade	AA		Previous audit date		2023-04-25
Certificate issue date	2024-04-30		Certificate expiry date		2025-06-15
Number of non-conformities			Fundamental		0
			Critical		0
			Major		0

2. Audit Results		
	Minor	0

3. Company Details			
Site address	203 Lancaster Way Business Park Ely Cambridge CB6 3NX		
Country	United Kingdom	Site telephone number	01353 667258
Commercial representative name	Tom Stevens	Email	tom.stevens@cambridgecommodities.com
Technical representative name	Phil Barnhill	Email	Phil.Barnhill@cambridgecommodities.com

4. Company Profile					
Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3
Shift pattern	08:30 – 17:00 (Cleanroom); 06.30 - 14.00 and 14.00 – 22:30 Warehouse. Monday - Friday.				
Seasonal site	No				
Seasonal opening times (Start/end date)	Click or tap to enter a date.	Click or tap to enter a date.			
Other certificates held	FEMAS, Organic, Halal, Kosher, Informed Sport, ISO 14001, ISO 22000 and GMP+				
Outsourced processes	Yes				
Outsourced process description	Outsourced blending and packing of dry, ambient stable nutritional food ingredients.				
Regions exported to	Europe Africa				

4. Company Profile

	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	None

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, 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, from 2500 ingredients, which are either supplied in original packaging (traded) or repacked (powdered goods only, 5% of total throughput) on site if smaller quantities are required. The wide range of product types are all ambient stable. Site turnover £55 million. The company employ circa 160 employees (20 work in production, 20 in quality of which 30 are based on site). 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 repacking hours are 08:30 – 17:00 with a dedicated third-party cleaning team afterwards to clean walls and floor. Warehouse 06.30:14.00 and 14.00 – 22:30. Monday - Friday. The company has also undertaken for several years 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 separate area to the in-scope products. The company is also commissioned a blending facility which is not currently operational. Outsourcing is limited to blending and packing of food supplements.

5. Product Characteristics

Product categories	15 - Dried food and ingredients Category Category Category Category Category 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 Appendix 2 of the Standard. Site operations are limited to the				

5. Product Characteristics	
	handling of ambient, dry ingredients that have low water activity, which do not support microbial growth. Products are stored in fully sealed containers and repacked in a cleanroom environment.
Allergens handled on site	Cereals containing gluten Crustaceans Molluscs Egg Fish Soya Milk Celery Sulphur dioxide and Sulphites Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	Organic, Halal, Kosher and Vegetarian
Product recalls in last 12 months	No
Products in production at the time of the audit	Vitamin D 0.03kg, Kola extract 0.1kg, Corundum Sulphite 3kg, 10g chamomile extract

6. Audit Duration Details			
Total audit duration	17 man hours	Duration of production facility inspection	5 man hours
Reasons for deviation from typical or expected audit duration	The BRCGS audit shorter than the expected duration 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 BRCGS audit due to simple repacking hand packing operation, zero CCP's. 95% of product sold as traded goods requiring storage only.		
Combined audits	None		
Next audit type selected	Unannounced – mandatory 1 in 3 years		

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	On-site		On-site	On-site
Philip Barnhill	Technical Manager	On-site	On-site	On-site	On-site
Hannah Pritchard	Technical Systems and Project Manager	On-site	On-site	On-site	On-site
Shannon McKenna	Assistant Quality Manager	On-site		On-site	On-site
David Bocking	Cleanroom manager		On-site		

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/ Unannounced	Pass/Fail
2023-04-25	BRCGS Food v9	Announced	Pass
2022-03-29	BRCGS Food v8	Unannounced	Pass
2021-05-04	BRCGS Food v8	Announced	Pass

Document control			
CB Report number	264311		
Template name	F908 Food Safety Audit Report Template Kiwa Agri Food ref version 3		
Standard issue	9	*Template issue date*	2022-12-16
Directory allocation	Food	*Version*	1.1

Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements			
Clause	Detail	Critical or Major	Re-audit date

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Comments on non-conformities
Zero non-conformances raised, organised QMS, small re-packing area, all hand packed, zero CCP's.

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Audit team

Lead auditor		
Auditor number	**First name**	**Second name**
20192	Rachel	Gallop

Audit team				Attendance (YYYY/MM/DD, 24hr: MM)			Presence	
First name	Second name	Auditor number	Role	Audit Date	Start time	End time	Remote or physical	Professional recognition number
Rachel	Gallop	20192	Lead Auditor	2024/04/09	08:30	17:00	Physical	
Rachel	Gallop	20192	Lead Auditor	2024/04/10	08:00	16:40	Physical	

Detailed Audit Report

1. Senior management commitment

There is a documented food safety, legality, quality, and authenticity policy signed by the Head of Quality and Technical B.R, signed 08/03/23 and the Operations Director (TS), 08/03/23 which is held electronically in the shared folders, where all staff have access. It is also included in the induction information given to all new employees, shared om email and on the HR portal where all documents are reviewed and signed. The policy includes commitment to continuously improve the site's food safety and quality culture.

The areas covered by this section were discussed with Technical Manager, Operations Director and Technical systems and project manager 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, dated 08/03/23, which includes measures needed to achieve a positive culture change. The plan is reviewed and the last review was on 06/12/23. Further review to be completed on review following the survey that has been completed in quarter 1. 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 have been completed reports a have been competed monthly, the last reviews carried out in Dec 23.
Conduct annual survey (all employees) and manager to review feedback. Survey completed Feb 2023, reviewed 31/03/23. Planned completed 2024 quarter 1. Still to review the results for actions and positive feedback, in line with site values purpose, vision, mission and values presentation.
Conduct staff meetings regarding quality updates (monthly). Ongoing.
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). Ongoing.
Posters/information in various positions on site promoting the importance of quality and food safety. Ongoing.
Hold monthly drop in sessions for the sales team re any issues relating to food safety, quality, legality. Last completed Dec 23.
The effectiveness of these activities is reviewed at least annually, with the last review on 06/12/23. Seen for: Survey completed Feb 2023, reviewed 31/03/23. New Survey for 2024 completed quarter 1, this is still to be reviewed. Drop in sessions for the sales team re any issues relating to food safety, quality, legality have been completed to schedule.

Clear objectives/targets are established by the company which are specific, measurable, and achievable and these are:
2023 review:
Quality compliance based on the number of formal complaints from customers – Target >95%, actual 99.51%.
Increase supplier audits to 20 – actual 7.
Specific training of the team (HACCP, Food Safety, Internal audit) – internal audit training has been requested and is HR.
Increase conference attendance across department to expand knowledge base – 3 food conferences attended.
Preparation for BRCGS for FEMAs and GMP+ audits. Zero non-cons.

2024 targets:
Quality compliance based on the number of formal complaints from customers – Target >95%.
Increase supplier audits to 20.
Specific training of the team (HACCP, Food Safety, Internal audit).
Increase conference attendance across department to expand knowledge base.
Preparation for BRCGS for FEMAs and GMP+ audits.

These are monitored and reported monthly to all staff and reviewed at the Management Review meetings held monthly and attended by: Operations Director and Head of Quality and Technical.

Management Review meeting agendas include all elements of clause 1.1.4 of this Standard Minutes were reviewed for the meeting held on 07/12/23. The output of the meeting included Product approval process plan, food defence HACCP plan food safety & quality policy quality culture policy HACCP review 07/12/23 this also includes an internal audit review and concession review. No actions except update the HACCP.

Other meetings held to bring food safety, legality, authenticity, and quality issues to the attention of senior management. These include daily meetings with Customer Care covering customer requirements and issues, weekly quality meeting and quarterly management meetings held with department Heads to discuss quality issues. HACCP and Food Defence meetings are held annually. Monthly quality meeting with the Operations director 13/03/24 the quality team all present, what had been completed that month (Quality team departments QC, QA, AD,) customer care, compliance, and approvals. This will also detail actions.
Board report – January 24 reviewed within this there is a Quality report. This details team activity, analytical costs, quality complaints from 2174 dispatches, 12 customer quality complaints (0.38%), supplier 377 deliveries 17 supplier quality complaints 1.59%, QC release time, supplier approval including new suppliers, QA activity queries and resolved and information requested.
There is also a 10am morning meeting.

There is a confidential reporting system in place on the website which enables staff to report concerns relating to product safety, authenticity, quality, and legality. No contact – no issues. The method of reporting concerns is communicated to staff by people HR and internal internet. Senior management assess any concerns raised. This assessment, and any actions taken, are documented. Assessment to the directors, then would investigate and communicate via email.

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. There is also verbal communication from the operative to manager and where required quality will place on hold.

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.

The site is kept informed of the points listed in clause 1.1.8 of this Standard by Standard by membership of Campden BRI, FSA alerts, 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 zero non-conformities raised at last year's audit.

The site uses the BRC Global Standards logo and/or refers to its certification status on marketing materials, website, B2B packaging, but not on direct consumer product packaging.

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 feed hygiene approval number is GB026/216. Last EHO 28/03/24 by Senior EHO no issues.

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.
Their organogram details on the CEO and then directors and senior manager. The technical team Head of Quality, Compliance team Technical System and Products manager and Technical compliance manager . This details, the responsibly each deputy for Head of quality. The TSM deputy is Senior Quality Special and Assistant Quality manager.

Job descriptions and work instructions are documented for all personnel and processes to communicate duties and responsibilities. Job descriptions were challenged for the following roles: JC warehouse operative and LM Lab Technician.

The following work instructions were challenged during the audit and found to be operational and relevant:
Repack Product QM07/SOP01 issue 27.
Glass and brittle plastic audits are carried out by the QA. An appropriate glass breakage procedure is QM08 SOP13 v4 04/06/19.
Risk-based process for the on-going review of supplier performance, doc ref QM07.SOP08 v14 13/04/23,
Goods in Product Inspection and Cleaning Procedure doc ref: QM07.SOP05. v14 03/04/24.
Supplier and Product Approval Procedure QMO7SOP08 issue 14 dated 13/04/23.

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.

The site does not use any external expertise to assist with food safety, authenticity, legality, or quality.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
1.1.12	Zero non-conformities raised at previous audit.

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 5 and dated 07/12/23. The HACCP team is led by the Technical Services Manager and Technical Systems and Project Manager (PB and HP) who are competent in HACCP having Level 2 training PB Highfield 28/07/11 and Level 3 HP Train 4 Food 15/02/17, both have worked at the site more than 5 years. Other team members are the Warehouse Supervisor (J.C), H&S/Facilities Manager

(AB), both planned for Level 2, Senior Product Compliance and Reg Affairs Nutritionist (C.W) HACCP level 2 dated 12/01/22, 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 and packing). It is systematic, comprehensive, and fully implemented and maintained.

A comprehensive pre-requisite programme v15 is in place covering personal hygiene, transport, allergens, pest control, foreign body controls, site/waste management, supplier approval/monitoring, hygiene and housekeeping, stock control, training, legislation review. OPRP's sampling, magnet check, visual inspection, re-packing, FTIR Spectroscopy.

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 e.g. 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.
Other relevant information includes a copy of previous site HACCP plans, a map of the premises and equipment layout and a water distribution diagram for the site. 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.

Product descriptions are defined as dry powders/food supplements mainly in 25kg quantities (Unless otherwise specified) 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.

Shelf life of the product is determined by the supplier best before.

Products are intended for further processing, so the use of the finished product is not known. There are no expected alternative uses for the product at this stage as the product is for further processing.

There is 1 main flow process diagram doc ref QM02/GEN04, currently at version 11, which was last verified by the team on 07/12/23.
There is also an outsourced processor process flow doc ref QM02.GEN06 issue 1 last verified 07/12/23.

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 algae.
Chemical contaminants cover cleaning chemicals from the food preparation area, pesticides including fungicides, insecticides, herbicides and pedenticides, allergens, 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 as part of the raw material questionnaire doc ref: QM07 FOR09, issue 30.
Malicious contamination and fraud are reviewed at the approval and monitored through TACCP and VACCP plans.

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. 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.
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.
A corrective action procedure is in place. Responsibilities for monitoring the critical limits and for corrective action are defined.
There have been no changes since the last audit that could have affected product safety.
Verification is carried out during internal audits and the daily verification checks performed. Verification reviews are carried out annually and are based on a review of the system documentation, records, internal audits, deviations and corrective actions, complaints, and incidents.
The HACCP or food safety plan and pre-requisite programmes are reviewed at least annually last reviewed on 07/12/23, when relevant changes occur, such as processing changes, emergence of new risk, or if a significant food safety incident E.g. 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 – 2.10	No CCPs
2.12.1	There have been no changes that may affect product safety since the last audit.

3. Food safety and quality management system

3.1 Food safety and quality manual, 3.2 Document control, 3.3 Record completion and maintenance

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.

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 4, dated Mar 2023 – procedures signed off by HACCP team. The Quality Team Originator and approver TSM and Technical System Project manager are responsible for authorisation, changes/amendments, and replacement of existing documents.
Records reviewed during the audit were seen to be legible and genuine and were easily retrieved Change history detailed on the bottom of the document.
QM07.FOR07 Clean and check record v15 correct issue on the log and in use.
Supplier approval procedure v14 13/04/23 change included below requirements for non GFSI contractors.

Records are completed manually and/or electronically and are stored electronically. Every paper document is scanned in and backed up to the offsite server. Backed off 2 locations off site daily. There is a log in on electronic PS system that will track everything.

Records reviewed during the audit were seen to be legible and genuine and were easily retrieved.
The majority of records are electronic. Records reviewed -Intake records, records of testing results of raw material at intake, repack records, cleaning records for workstations in repack, outload information.

Electronic documents are stored securely, with access controlled by authorised access, password protection and are backed up daily to an off-site server. The site log the manufacturing site best before, supplier batch number and best before documents these are kept indefinitely.
Electronic records are retained indefinitely, hard copies are retained for 7 years. Longest shelf life of product is typically 5 years but some items such as salt have no shelf life.

3.4 Internal audits

The internal audit schedule is documented and covers all the documentation and processing systems on site relevant to food safety, authenticity, legality, and quality. Internal audits are carried out throughout the year GMP, glass monthly. Repack, calibration, product release packing room process quarantine twice a year with the frequency determined by risk assessment and previous internal audit performance. Each area is audited at least annually. Schedule in place.
There are 8 trained lead internal auditors who are responsible for the site internal audits. These are externally trained. The auditors cross audit departments to ensure independence from direct responsibility. There are also buddied up with shadow. The site have identified 7 people for internal audit training to be completed.
Internal audit records reviewed included-
Supplier and product approval 29/02/24 BPI and LM. The auditors reviewed 12 products, previous audit, documents reviewed for the approval process and the approval process and the dates of reapproval were recorded. PS QC test no issues. 3 observations no non-cons raised.

14/02/24 Quarantine audit AT / AF review of the quarantine procedure and complaints procedure. Quarantine are 4 products were selected and cross – checked on PS against the physical location. All in locations and NCR has been raised and complaint have been closed out. No non-conformances raised.

Training
BPI – QSL IS9001 11/03/24 Internal audit and continual improvement.
AT – Internal training Auditing procedure issue 3 24/03/22 26 minutes.

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. A summary of the results is reviewed in the management review meetings.

In addition, monthly hygiene/fabrication and GMP inspections are carried out, based on risk assessment. The auditor reviewed the close out of the non-conformity. Reports reviewed included: GMP completed monthly review 07/02/24 and 30/01/24.
Glass and hard plastics monthly, 07/02/24 map in place and if any issue this is logged onto the glass, brittle plastics, ceramics, and similar materials form v13 12/02/24 QM08/FOR26 and then this is signed as completed. No issues.

Results are reported to personnel responsible for the activity/area. Corrective actions from these inspections and timescales for completion are agreed and completion is verified by the auditor. A summary of the results is reviewed in the management review meetings.

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, including primary packaging, has been carried out per product, with products assessed for allergen, foreign body, chemical, microbiological, variety/species cross contamination and substitution/fraud risks, as well as risks associated with raw materials which are subject to legislative control or customer requirements. 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 via HR, legislation requirements for herbs and spices e.g. Pyrrolizidine alkaloids, 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 21 is completed, and supply can commence.

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

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

Risks associated with raw materials which are subject to legislative control or customer requirements include: allergens, pesticides and heavy metals and feed items on the 'Undesirables list' held.

Suppliers of all raw materials and primary packaging are approved and monitored by the Technical Services Manager and the Senior Quality Specialist C.W, using the Supplier Approval Procedure, doc ref QM07.SOP08, subcontract haulier approval QM07.FOR45, 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.

If the supplier does not have an GFSI accreditation they can be approved using the Supplier Evaluation Questionnaire doc ref QM07.FOR02 which includes product safety, traceability, HACCP, product security and food defence plan, the product authenticity plan and GMP, and providing evidence of an effective traceability system. Sites reviewed are GFSI.

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 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.
Examples of supplier approvals looked at as part of vertical audits, as below:
Suppliers reviewed
Aspartic acid FSSC22000 expiry 24/10/26 reg no ***45 risk assessment 11/03/24.
Calcium Ascorbate BRCGS A ***4734 expiry 24/12/24 risk assessment 27/03/24.
Vitamin B1 FSSC22000 expiry 27/06/24 risk assessment 19/11/22.
Plastic bag BRCGS AA ****7811 expiry 18/08/24.

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

The site have not completed any supplier audits recently due to travel restrictions. Supplier audits are not completed for approval these are used to review the process that are in place for the products that are supplied. This is based on volume supplied and history of issues,

There is a documented, risk-based process for the on-going review of supplier performance, doc ref QM07.SOP08 v14 13/04/23, 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 19 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 recheck 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 Technical Services Manager.

Agents, brokers, and wholesalers not are used.

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. No customer branded product.

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. v14 03/04/24. There is a flow diagram within the procedure that details the process.
An example of intake testing was reviewed for a delivery of calcium diphosphate powder FTIR. No issues.
The electronic PS system ensures that any approved changes to raw materials or primary packaging are communicated to intake staff.
Raw materials and primary packaging are checked on intake for compliance with purchase orders and certificates of analysis/compliance are received.

3.5.3 Management of suppliers of services

Service suppliers are approved and monitored by Operations using the procedure doc ref QM06/GDE01 issue 4 dated 19/04/23 and have appropriate contracts.
These were reviewed for suppliers of:
Haulage to customers (M), Service Level Agreement signed 03/11/15 (pallet network).
Haulage from dock to site (T), Service Level Agreement signed 03/11/15 (port to site).
Laundry supplier Swiss Landry – Service agreement dated 28/01/14, service protocol 21/04/23 (part of TSA) Approval 04/10/19.
Pest control – Rentokil – Contract in place. BPCA Membership No. M15/737 expires 28/02/25.
There is a documented, risk-based process for the on-going review of supplier performance (doc ref QM06/GDE01), with the following performance criteria defined: complaints as appropriate.
Quarterly meeting with the haulier, - My CCL track and trace for deliveries. There is a dashboard to review the progress. There is a KPI in place monthly reviewed for Feb 2024. Review number of shipments EU distribution 2023 in place on time deliveries. Customer care will pick up any complaints and deal with them.

3.5.4 Management of Outsourced processing

The only processes outsourced are blending and pouch packaging. The customer is made aware of the outsourcing and has given approval, where applicable.
The company used is outsourced processor/blender NVR, approved by BRCGS Food certification, A, site code ****101, expiry 24/11/24. Approval 07/03/22.

Outsourced blending / packaging companies C approved by BRCGS Food certification, AA, site code ****8454, expiry 11/07/24. Approval 23/02/24.
Risks to product safety, authenticity and legality associated with the outsourced processing form part of the site's food safety plan (HACCP). Service specifications are agreed and documented, which include any specific handling requirements for the products.
Contracts are raised for each order detailing requirements. NVR Technical agreement signed 30/09/19. Audit 29/03/23 acceptable 1 minor. C Technical agreement signed 04/10/19. Traceability is maintained as both parties hold third party certification. Specifications are sent to the outsourced contractor. Reviewed for vitamin B12 spec 08/09/23 delivered to site 13/02/24 checks completed as per standard delivery.

A risk assessment is in place to determine the tests/inspection required for the products when they return to site after the outsourced processing. 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 on site.
Reviewed for:
Aspartic 16/10/16 reapproval 11/03/24.
Calcium Ascorbate 16/03/22.
Vitamin B1 23/11/23.
Plastic bag 20/03/24 migration 29/11/21.

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 product specification was reviewed and found to be sufficiently detailed and compliant:
Vitamin B1 23/11/23.
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 are in place for different actions internal auditing procedure doc ref QM04.SOP02 issue dated March 22 and Complaints Procedure doc ref: QM08.SOP09, issue 7 dated 31/08/22, which includes root cause analysis and preventive action, is in place to address failures identified in the food safety and quality management system.
Non-conformities that result in a risk to product safety, authenticity, or legality, or where there is an adverse trend in quality, are investigated and recorded in line with the requirements of clause 3.7.2 of this Standard.
Non-conformance log in place, internal audit NCR log in place.
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. 5 whys is used.

Root cause analysis, and further corrective action to address the root cause, are carried out, when internal audit, supplier / customer complaints as required. Root cause analysis is carried out by area manager and the auditor.
Root cause preventive and corrective action are detailed on the log reviewed for Internal audit 01/11/23 non con the COA on the system and COA does not match, minor. The log details type non-conformance detail and root cause analysis - the CoA process not followed product placed on hold and re-training of the procedure.

Corrective actions taken are recorded and reviewed during the monthly quality meeting.

3.8 Control of non-conforming product

A procedure is in place QM08.SOP01 issue 3 dated 14/03/23 for managing non-conforming products, which includes all the points referred to in clause 3.8.1 of this Standard.
This also includes non-conforming report supplier, non-conformance report, non-conformance report internal, concession form, quarantine procedure scrapping procedure NCR log Auditing NCR log v3 14/03/23.
All non-conforming supplier complaints (this is then treated as per customer complaints procedure) v7 31/08/22.
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.

3.9 Traceability

A documented traceability procedure is in place which meets the legal requirements in the country of sale or intended use.
All raw materials, in process materials, primary packaging and finished product are coded to allow for full traceability through the system. Batch code and best before through the system. PS system is used for traceability QM08 SOP17 v1 27/09/19.
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 traceability procedure includes traded products (see section 9.6 of this report).
The site carries out traceability and mass balance tests at least annually and these were undertaken as follows:
Forwards on 30/08/23 on raw material Actibio – BC delivered 200kg on 21/06/23 best before 24/05/25 in 5kg packs. Full traceability was achieved in 30 minutes. Mass balance was achieved. Despatched 159.389kg 26/06/23 – 15/05/23 (50kg of this amount was repacked). 40kg on stock. =199.389kg.

Backwards on 30/08/23 on finished product Actibio – BC. Full traceability was achieved in 30 minutes (09:44-10:07) 100kg straight out no re-pack Despatched 26/06/23.

A traceability test and vertical audit were undertaken during the audit on: Vitamin B1 repack 10/01/24 5kg BB 24/04/26 despatched to customer V 10/01/24. Traceability was achieved in 2.5 hours (09:15-11:51).
A mass balance exercise was also carried out on: Vitamin B1 delivery 17/11/23 400kg bb 26/04/26, 400kg used and despatched 24/11/23 to 04/04/24.

Documents and records reviewed during the vertical audit included those pertaining to intake, dispatch, 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 v7 31/08/22. 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 at >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 99.95% for February 24.
Complaints reviewed.
14/02/24 silicon sachet between with the inner bag and outer packaging. Investigation with the supplier - operative error new op closed 19/02/24.
16/10/23 hair. Contacted supplier changed from mop cap to all in one protective suit 23/10/23.
Serious complaints, or significant increases in complaints, are investigated using root cause analysis no EHO complaints reported.

3.11 Management of incidents, product withdrawal and product recall

The site has a comprehensive incident procedure, doc ref: Product recall/ Withdrawal and Incident Management Procedure QM08.SOP02, issue 14 dated 07/03/23. A Business Continuity Plan is also in place doc ref: QM02.GDE01, issue 3 dated March 2021.
The site has comprehensive procedures and an out of hours contact list for all key members of staff, customers and organisations including the Certification Body.
The requirement to notify the Certification Body within three days of a significant food safety, authenticity, or legal incident, including a recall, food safety related withdrawal or regulatory non conformity, is included.
The procedure also includes the requirement to provide corrective action, root cause analysis and preventive action to the Certification Body within 21 days, together with any other information it requests to assess the validity of the current certificate.
There have been no significant food safety, authenticity, or legality incidents, including recalls, regulatory non-conformities and food safety-related withdrawals since the last audit.
A test of the incident management procedures, including product withdrawal and recall, is undertaken by the company with the product traced to the customer.
The last challenge was undertaken on 20/09/23 D-Glucosamine Sulphate 2KCL Vegan (FEMAS) date of manufacture 28/06/23 BB 27/06/23 Delivered to 06/09/23 1000kg (10kg only repack) 860kg outloaded 12/09/23 – 13/10/23 and 140kg on stock. Log in place. Issue highlight 10:00am. Customer care advisor contact supplier of issue and obtain root cause 10:15am. TSM discussed with operations director 10:35. Material put on hold 10:50, product recall team following traceability of the batch11:15 completed 11:45, Recall test 12:15 completed.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.1.5	Agents, Brokers and wholesalers are not used.
3.6.3	No customer branded products

3.9.4.	No rework

4. Site standards

4.1 External standards and site security

The site occupies approximately 9290 m² and production and storage buildings occupy 7432 m². 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. There are no potential risks associated with the location of the site that may affect product safety or integrity. 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 systems. There is reporting system for all visitors and contractors, including drivers. Only authorised personnel have access to production and storage areas. Contractors working in product processing or storage areas are the responsibility of a nominated person. Staff training is in place on site security procedures as detailed in section 7.1 of this report.

4.2 Food defence

The team includes TSM, Technical system & Project manager, HSE and facility manager, ops director, cleanroom manager, assistant QM, senior product compliance & reg affairs, warehouse operative. Personnel engaged in threat assessments and food defence plans are competent via training and experience. TSM - PB 13+ years in food defence related activities, Lead assessor trained- 17/11/14, HACCP trained level 2 dated 28/07/11. Site also attended BRCGS food defence training 2023 1 day seminar via LGC.
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 15/03/24 v6.

The food defence plan meets the requirements in the country of sale or intended use.

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

No areas of the site are at significant risk.

Staff training is in place on food defence see section 7 of the report.

4.3 Layout, product flow and segregation

Production risk zones have been assessed using the definitions in Appendix 2 of this Standard.
A justification is documented for low-risk status dated 12/01/23 which forms part of the QMS system. Site operations are limited to the handling of ambient, dry ingredients that have low water activity, which do not support microbial growth. Products are stored in fully sealed containers to minimise the risk of contamination and handled in a cleanroom environment with an ISO Class 9 rating, subject to stringent controls that prevent any potential contamination.
There are no high risk/high care/ambient high care areas on site.

There is a site map, QM06/FOR08 which includes all the points referred to in clause 4.3.2 of this Standard.

Contractors and visitors, including drivers have signing in procedures which include references to relevant procedures and requirements for the areas visited and prevention of hazards and product contamination.

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 always enclosed.

The process flow and flow of people ensures products are not put at risk from the layout.

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 in the repacking area. 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, access steps or mezzanine floors next to or over production lines which have open products.

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 and no evidence of excessive dust and/or condensation was noted.

All doors were noted to be in good condition.

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

Plastic strip curtains were noted to be in good condition, clean and fitted correctly.

4.5 Utilities – water, ice, air and other gases

Water used on site is potable and mains supplied from Anglian Water. Jan 23 Sept 23 last updated 08/03/24. No storage tanks apart from fire system which is separate.
Annual microbiological and chemical analysis is obtained from the supplier and additional surveillance testing is carried out by an external laboratory. Environmental monitoring 8 points once a year hot and cold taps wet room tap (dishwasher) cleanroom changing area. 06/09/23 TVC coliforms E.coli and enterococci. No issues. TVC monitoring only <1 cfu/ml – 560 cfu/ml
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.
Air plates completed once a year in repack room and sample module clean room for TVC yeast and mould – no issues noted.

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.

There has been no new equipment installed since the last BRCGS audit.

The design and placement of equipment is based on risk, to prevent product contamination. Within the repack room (open product area) there are stainless steel workstations (tables) and scales. The only equipment that is used in direct contact with the product are stainless steel scoops that are used to weigh into bags. There are no drains within the repacking area.

The following certificates/evidence was seen to confirm suitability for food use for the Stainless-steel scoops which are constructed of SS 316.

A risk-based commissioning procedure (doc ref QM08:SOP25 V1 dated 12/04/23) is in place which meets the requirements of clause 4.6.3 of this Standard.

The procedure includes the update of site procedures that are affected by the new equipment and post-installation inspection and hygiene clearance. There has been no new equipment installed since the last BRCGS audit.

The design and placement ensures equipment can be effectively cleaned and maintained.

A procedure (doc ref QM08:SOP25 V1 dated 12/04/23) to manage the movement of static equipment in production areas is in place.
There was no equipment seen that has been taken out of service or that is not currently used.
There is no mobile equipment used in open product areas. Scales etc are retained in the area. Battery charging equipment did not pose a risk to products and was seen to be stored outside open product areas.

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 changes 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.
Facilities manager will organise any repairs to fabrication that might be required. This information is then discussed at the health and safety manager.
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 or Supervisor or Team Leader 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, meeting the requirements of clauses 4.8.4 and 4.8.5 of this Standard.
There is no catered canteen.
Staff are provided with fruit, coffee, tea, and milk. No vending machines. 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 as per the requirements of clause 4.9.1.1 of this Standard. They are stored in a designated storage area with restricted access. The main non-food chemicals used on site are:
Caterclean Spray Technical information sheet available, odourless bactericidal alkaline detergent ready to use spray on wipe off and Azo 70% IPA spray disinfectant / wipes.

Strongly scented/taint-forming materials are not used.

4.9.2 Metal control

There is a documented metal control policy in place with a registration system for sharp utensils and equipment. Repack equipment log QM07/FOR26 v4 scissors, scoops, sieves, spoons, safety knife, tool funnels and metal detectable pens are counted daily with two initials, daily.
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 QA. An appropriate glass breakage procedure is QM08 SOP13 v4 04/06/19. There is a red dust pan and brush in place for breakages.
The procedure includes, training of staff, isolation, cleaning, safe disposal of contaminated product and authorised clearance inspection procedures. No breakage incidents have been 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. Where there is open product wood is not used. The repack area product is transferred on trolleys to the workstation. No issues noted during the site inspection.
4.9.6 Other physical contaminants
Procedures are in place to prevent physical contamination by raw material packaging. Staff follow a documented procedure for removal of raw materials from their packaging, to avoid contamination. This is detailed in the debagging part of the repack procedure QM07/SOP01 27 03/08/23. Pens used in open product areas are controlled. They are consolidated at the end of the shift and are metal detectable and one-piece. Pens only used in open product area. No other portable handheld equipment allowed within the clean room, as detailed in relevant policies. Portable handheld equipment are controlled. Handheld and i-pads used within the sealed product areas. These are checked.
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 food safety plan (section 2), 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. Risk assessment part of the HACCP plan – Pre req supplier approval, metal detected at the supplier or sieve with magnet. The site only repack and scoops are used. No other risk for metal.
4.10.2 Filters and sieves
Portable domestic type metal sieves are used occasionally for weight control purposes only. These are stored in the repack area and are subject to area cleaning regimes. Integrity checks are carried out and recorded on the equipment log QM07.FOR26. The mesh size is not specified as these are used for weight and quality (clumping) control purposes only, not food safety.
4.10.3 Metal detectors and X-ray equipment
A risk assessment for metal contamination as part of the food safety plan (section 2), 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 Magnets Hirst Magnets instruments 22/09/23 cert1690mt. No issues. During the check if any metal finds inform technical.

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.
4.10.7 Other foreign-body detection and removal equipment
No other foreign-body detection and removal equipment used.
4.11 Housekeeping and hygiene
The site and equipment were seen to be maintained in a clean and hygienic condition. Equipment and areas checked for cleanliness during this audit included the repacking room. Operative complete cleaning arts if repack between products and at the end of the shift as detailed in Re-packing product QM07/SOP1 issue 27. This details the areas to be cleaned with cater clean spray followed by 70% IPA spray. Contract cleaner on site for walls, floors etc. 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. Equipment and areas checked for cleanliness during this audit included: workstation, scoops, and scales. Cleaning is carried out every day at the end of shift complete clean down of the work surfaces including the extraction units by operatives. Cleanroom cleaning check this is signed off by the provider and then the site. Any issues are reported to the health and safety / faculties Manager Service Master clean task schedule. The schedule includes none food contact sweep daily, damp wipe white wall and trunking. Reviewed 06/04/23. No issues. 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. These are hygienically stored. Hygiene observed in repack room from one product to another no issues noted, work area checked by a colleague prior to restart.
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 22/02/23 covering relevant pathogens and spoilage organisms.
The programme includes air plate and swabs. Sample locations, extraction units, tables, and food contact areas annually. Hand swabs once a quarter. Target organism, for example TVCs, Yeast, Mould, Enterobacteria, E.coli, Salmonella, Listeria. Appropriate control limits are in place.
Results reviewed for hands wabs 3-4 before work, gloves before work, during work 15/05/23, 11/07/23, 09/10/23, 15/12/23. No issues some TVC noted. (TVC for monitoring only.)

Environmental swabs, 07/03/23, 20/04/23, 08/09/23, 20/09/23, 16/08/23 and 15/12/23. No issues some TVC noted. (TVC for monitoring only.) Sample areas Scales, work stations, scoop, work surfaces 28/02/23 and 21/11/23 no issues.
There are no legal or customer limits.

The programme is reviewed minimum annually, and if there were changes in processing/equipment, where the programme has failed to pick up a serious issue, when out of spec levels are found in products and when the site gets consistently negative results, indicating that the programme is not effective, review completed 14/03/24 no changes

4.12 Waste and waste disposal

Waste is collected from site by licensed contractors Ellgia, licence number CBDU315804, expiry 02/12/25 and the associated food waste transfer note. All food waste is sent for anaerobic digestion.
Animal by-products are stored and labelled for trading, these include whey proteins, which are sold as feed 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. Packaging waste removal from open product areas is managed via bagging to ensure that it does not compromise product safety. 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 traded from the site can be used within the pet trade. No customer branded products. 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 31/03/26. 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 Rentokil M15/065 expires 28/02/25 covers rodents, flying insects, crawling insects and birds and consists of 12 routine visits and 4 in-depth inspections per year. EFK units to be serviced 4 times a year and 1 tube change.
Full records of pest control are maintained including site plan dated Feb 2024, bait data sheets, operative training records, records of inspections and treatments. The last visit to site was carried out on 02/04/24 with 5 actions issues identified all resolved.
The risk assessment is reviewed when 14/02/24. Follow up weekly or internal or based on risk.
EFK change 11/04/23.
Biologist report 14/02/24 SK training BPCA certified biologist 30/03/15.

The has been some external mice and rat activity. Follow ups have been completed by the pest management team Toxic outside Bromtrol COSSH 06/07/23.
In-depth pest control assessments, which include an in-depth inspection and a review of the pest managements in place, are undertaken at least annually at a frequency based on risk and the last one was 14/02/24.
The site have just moved over to Rentokil from Prokill (BPCA membership number M15/737) expires 29/02/24 no issues noted on previous reports.
All toxic baits are secured externally due to activity.
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 quarterly.
No issues highlighted through trending reports.
EFKs are situated throughout the site and catch tray analysis is performed quarterly.
The site has identified that there is no risk from birds roosting and/or entering the building.
When interviewed during the site tour, staff were aware of the signs of pest activity and that they should report any evidence of pest activity to technical department.

4.15 Storage facilities

No temperature-controlled storage is required.

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 4 dated 13/04/23 – added load security, covering clause requirements. Approved third party hauliers are used.
Haulage to customers (M), Service Level Agreement signed 03/11/15 (pallet network).
Haulage from dock to site (T), Service Level Agreement signed 03/11/15 (port to site).
A supplier approval procedure (doc ref QM07.FOR45) is in place for the hauliers, which covers food safety and quality during despatch and transport operations. Approval of hauliers is based on terms and conditions which include security of load, cleaning, breakdown, and maintenance and meet the requirements of clauses 4.16.1 – 4.16.5 of this Standard. Contracts reviewed for the above hauliers. Terms and conditions are reviewed and verified by the Technical Services Manager or Assistant Quality Manager.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.2.3	No products have been identified as being of particular risk.
4.2.4	No areas of significant risk.
4.3.6	No temporary structures.
4.4.3	No Drainage.
4.4.5	No suspended ceilings in production areas.
4.4.6	No elevated walkways, access steps or mezzanine floors adjacent or over production lines which have open product.
4.4.7	No glazing designed to be opened for ventilation.
4.5.3	Ice, steam and gas are not used. Compressed air is used for machinery operation only
4.6.5	No redundant equipment
4.6.6	No mobile equipment.
4.7.6	No engineering workshop on site.
4.8.8	No catering facilities (including vending machines) 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.
4.9.6.3	All types of contamination covered in section
4.10.1.2-.4	No foreign body detection or removal equipment used on site.
4.10.2.	Filters and sieves are not used
4.10.3.2 -.5	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. An NPD procedure is in place, doc ref: QM07.SOP27, issue 3 dated 24/04/23. The procedure also references changes to existing products, packaging, and manufacturing processes, with changes recorded via the change control procedures. The procedure includes the following restrictions to the scope of any NPD: no nuts, no sesame, no glass, or brittle plastics or porous or fibrous packaging materials or anything outside of the site's BRCGS scope.

Documented recipe development and production trials are undertaken at the supplier. Site only repacks into standard packaging. The products will be approved through supplier approval, specification review.

Shelf life is determined by supplier durability information, shelf life testing not completed as 95% traded product and long shelf life. Repack retains the supplier durability date. For blended product testing historical and testing. Extra shelf life to extend shelf life. Information on file. Micro testing at end of life and extending of shelf life. 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. A process to verify that ingredient and allergen labelling is correct is in place which is based on the product recipe and ingredient specifications. This managed as part of the product approval system and technical specifications. No artwork. Finished product labelling information is verified against legal requirements and the criteria listed in clause 5.2.2 of this Standard by PB (Technical Services Manager) and S.M (Assistant Quality Manager). No customer branded products produced on site. No cooking instructions are detailed.

5.3 Management of allergens

Cereals containing gluten, Crustaceans, Molluscs, Egg, Fish, Soya, Milk, Celery, Sulphur dioxide and Sulphites are handled on site.
An allergen policy, procedure and allergen matrix are in place. 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. This is part of the allergen policy QM04/POL01 issue 5 05/09/23 strict procedure to ensure that cross-contamination risk is as low as possible during storage packaging intact and will not contamination during storage. All materials re double bagged to minimise damage risks. During the repacking process only one product at each workstation cleaning before and after each repack. The cleaning methods have been validated to ensure the effective remove of allergenic proteins.
Air quality annually to check particle low enough.
Allergen information for each product is supplied by each manufacturer.

All allergens are identified through the WMS and stored in a dedicated area of the warehouse. Team leader will let the team know if handling an allergen and wear apron and sleeves that will change them. This is from the PS.

Visitor questionnaires include questions relating to allergens.

Allergen warnings are not considered necessary because of the controls in place. FSP on the spec the label – not generic label.

No “free from” or food sensitivity claims are made.

Allergen cleaning methods have been validated by accredited external lab Skimmed milk powder next to maltodextrin 15 kg in repacking area 26/10/20 swabs after clean BLG 0.031ppm and casein 0.2ppm ND in maltodextrin product, skimmed milk product BLG >1.8ppm and casein >14ppm. March 2023 Neogen rapid swabs. SGS Elisa after cleaning working surface and scoop cleaned after skimmed milk 07/04/23 BLG <0.167mg/l after clean, before >4.5mg/l no issues, signed off 22/01/24.

No allergen changeover observed.

5.4 Product authenticity, claims and chain of custody

Personnel engaged in vulnerability assessments are competent via training and experience and via the approval process. TSM and senior quality specialist. TSM- PB 13+ in food defence related activities, Lead assessor trained 17/11/14, HACCP trained level 2 dated 28/07/11. Personnel engaged in vulnerability assessments have also attended the BRCGS Food Defence 1 day seminar via LGC.
The site obtains information on threats to the supply chain which could lead to adulteration/substitution of raw materials by RASFF, FEMAS, Nutraveris, Trello, etc.
A documented vulnerability assessment has been carried out for each product produced, which meets the requirements of clause 5.4.3 of this Standard and includes.
Historical evidence of substitution/adulteration
Economic factors which may increase the likelihood of substitution/adulteration
Ease of access to raw materials through the supply chain
Sophistication of routine testing to identify adulterants
The nature of the raw material.

This has resulted in a vulnerability assessment plan. The plan is kept under review to consider changes in potential risks, following a significant product safety incident where product authenticity is implicated, and is formally reviewed at least annually and according to the requirements of clause 5.4.3. Doc ref Supplier and Product Approval Procedure QMO7SOP08 issue 14 dated 13/04/23 references review on changes and a checking for developing threats of adulteration procedure is in place doc ref QM08:GDE01 V4 dated 07/10/19 which stipulates annual review, last review meeting held 27/03/24.

No particular risks have been identified as all raw materials FTIR tested on intake.
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 31/03/25. The last audit was completed 18/09/23 .
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/009213W expires 01/05/24.
Kosher company code 5648 expires 08/12/24.

The following nutritional/suitability/compositional claims are made vegetarian and vegan and are validated by use of approved suppliers, purchasing records, fully sealed/segregated products.
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.
Blue bag supplier BRCGS AA ****7811 expiry 18/08/24. Spec 20/03/24 migration 29/11/21.
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-100-micron gauge LDPE blue. There is no obsolete packaging as all packaging is generic.

5.6 Product inspection, on-site product testing and laboratory analysis

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 following laboratory tests are carried out by external labs:- 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, HPLC for plant identification, colourants etc. The chemical tests detail legal limits for heavy metals, pesticides etc.
The following laboratory tests are carried out by external labs.
ETO 19/01/24 24/1-009191 Phyotocontrol.
Eurofins Green Tea Pyrrolizidine alkyls 02/05/22 herbal.
Heavy metals green tea Campden 23/04/21.
Heavy metals cranberry extract 23/1-083552 09/05/23 Phyotocontrol.
Micro Fenugreek powder SGS 969367 004 12/12/23.
Micro white tea extract 944127 005 06/10/23.
Aflatoxins Eurofins fenugreek powder 7062020-00193158 from 2020
Flaxseed powder aflatoxins 01/11/23 965699 001.

The only tests are carried out on site are the visual assessment and the FTIR tests. Examples seen for trace challenge and during the site inspection.
The procedure was also reviewed if the product did not get released, placed on hold.

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. Activities associated with out of spec results include E.g. hold product and re-test, inform supplier. (all products are positive released before packing).

External labs include: -
SGS– UKAS 1549 is used for micro.
Eurofins DAKKS Germany.
Phyotocontrol France version 54 07/6/2022 Confrac SLA 16/02/24.
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 test.

Shelf life is validated and routinely verified by the concession process on site that will review the shelf life that has been determined by the supplier and extend if the raw material food safety and functionality is not affected. Analytical team review against spec. 95% of the product is traded product so the shelf life has been determined by the supplier.

Pathogen testing (including pathogens tested as part of the environmental monitoring programme) is subcontracted to SGS UKAS 1549.

The on-site lab and testing activities meet the requirements of clause 5.6.5 of this Standard. The FTIR tests are carried out to assess the actual makeup of the raw material, this is 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. The following tests are critical to product safety, authenticity or legality: ID testing, pesticides, aflatoxins, heavy metals. These are carried out using accredited methods by the external labs referenced above. The reliability of results, other than those critical to safety and legality specified in clause 5.6.6.is ensured by training, SOP and the self-calibration of the equipment.

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 and animal feed

Not applicable – no pet food or animal feed is manufactured.

5.9 Animal primary conversion

No animal primary conversion.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.4	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.).
5.5.3	No obsolete packaging as all packaging is generic.
5.8	No pet food or animal feed is manufactured
5.9	No animal primary conversion

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.
Process specifications and work instructions/procedures are reviewed prior to any changes which may affect food safety, legality and quality.
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, which forms part of the release procedure doc ref QM07.SOP17.

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.

Changeover observed in repack room. Corundum Sulphite 3kg to Kola extract 0.1kg, All product removed from weight up area. Only the number of labels required are printed. No printed packaging. No issues noted.

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, 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 C039161399 (60kg), last calibrated 17/11/23 by Blake & Boughton UKAS 0003.
Scale SN IP8952879 (3kg), last calibrated 17/11/23 by Blake & Boughton UKAS 0003.
FTIR SN MY2051CU13, last calibrated 16/01/24 by Agilent Technologies.
Weights various1g 200g 20000g 5000g, last calibrated 17/11/23 by Blake & Boughton cert number R02W000026.
Magnets Hirst Magnets instruments 22/09/23 cert1690mt.

The calibration procedure doc ref: QM08.SOP11, 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 all 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. Security in company handbook – people HR guide of employees. Induction on the first day with HR. Introduction to each department and the line manager and on the job training.

Agency staff are not used.

Detailed individual training records, which meet the requirements of clause 7.1.6 of this Standard, and a list of approved trainers are kept.

Specific training procedures and records are available and were challenged for the following control measures
JC booking in 21/09/23 10 mins Induction 03/03/14.
SB repacking 22/08/23 15 mins Induction 11/04/22 level 2 food hygiene08/02/23.
KL repacking 22/08/23 15 mins Induction 07/12/15 level 2 food hygiene 16/03/23.
LM FTIR Spectroscopy QM08 SOP 12 24/04/23 15 mins Induction 07/05/19.

Staff interviewed during the audit were competent in their roles e.g. lab technician, repack operative Competency of staff is reviewed buddy checks, one to ones quarterly and performance reviewed annually. A programme of refresher training on updated procedures is in place food hygiene Level 2. in the clean room every 3 years on line.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas
Personal hygiene standards, which meet the requirements of clause 7.2.1 of this Standard, are documented and covered during induction training and basic food hygiene training (carried out in house). Site hygiene policy documents the site rules and policies is detailed in Guide to CCL Expectations of Staff Hygiene Procedure doc ref: QM06.SOP02, issue 4 dated 19/04/23 documents the site rules and policies. Foreign body control v8 31/03/23. Dress code procedures Cleanroom dress policy v4 QM07. SOP25 v4 24/04/22. The correct method of hand washing is clearly displayed at all hand wash sinks and in toilet areas. Plasters are blue and issued out to staff. The use and storage of personal medicines is controlled by manager in office, cannot take into the facility. There were no issues regarding compliance to the documented hygiene policies.
7.3 Medical screening
Employees are made aware of the symptoms of infections, diseases or conditions which would prevent them from working with open food via induction. The restrictions for handling open products procedure, doc ref: QM06.POL13 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.
7.4 Protective clothing: staff 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. Protective clothing is changed a minimum of daily, based on risk. Company visitor coats and kitchen towels are externally laundered. The external laundry, Swiss Laundry, operates procedures which meet clause requirements. Approved via service agreement dated 28/01/14, ISO 9001 expires March 2028. 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	All PPE used by staff in open product areas is disposable.

8. Production risk zones – high risk, high care and ambient high care production risk zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
n/a
8.2 Building fabric in high-risk and high-care zones
n/a
8.3 Equipment and maintenance in high-risk and high-care zones
n/a
8.4 Staff facilities for high-risk and high-care zones
n/a
8.5 Housekeeping and hygiene in the high-risk high-care zones
n/a
8.6 Waste/Waste disposal in high risk, high care zones
n/a
8.7 Protective clothing in the high-risk high-care zones
n/a

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

9. Requirements for traded products
9.1 The food safety plan - HACCP
The traded products are included in the site's main HACCP plan (see section 2 of this report). The scope of the traded products HACCP or food safety plan includes the products and the processes for which the site is responsible. 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. 95% of the business is traded product.

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

The supplier approval procedure QM07.SOP08 covers the process for initial and ongoing approval of suppliers and manufacturers of all products traded. There is one procedure for the site. 95% of the business is traded product. The re-pack product is from product that is also traded product.

A risk assessment is in place for all suppliers / ingredients which covers the requirements of clause 9.2.1 of this Standard and takes into account safety, quality and legality and the ability of the supplier to meet the specifications of the products supplied.

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 GFSI certificates, are kept.
Aspartic acid FSSC22000 expiry 24/10/26 reg no ***45 risk assessment 11/03/24.
Calcium Ascorbate BRCGS A ***4734 expiry 24/12/24 risk assessment 27/03/24.
Vitamin B1 FSSC22000 expiry 27/06/24 risk assessment 19/11/22.

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

The site have not completed any supplier audits recently due to travel restrictions. Supplier audits are not completed for approval these are used to review the process that are in place for the products that are supplied. This is based on volume supplied and history of issues,

There is a documented, risk-based process for the on-going review of supplier performance, doc ref QM07.SOP08 v14 13/04/23, 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 19 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 recheck RASFF/google for any evidence of contamination risk for the material.

9.3 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. Where formal approval from customers is not forthcoming, proof of specification issue and request for acknowledgement is retained. The following specifications for Traded Products were reviewed and found to be acceptable:
Aspartic 16/10/16 reapproval 11/03/24.
Calcium Ascorbate 16/03/22 .
Vitamin B1 23/11/23.
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.

9.4 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. 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. v14 03/04/24. There is a flow diagram within the procedure that details the process.
An example of intake testing was reviewed for a delivery of calcium diphosphate powder FTIR. No issues.
The electronic PS system ensures that any approved changes to raw materials or primary packaging are communicated to intake staff.
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 (as noted in section 5.6): 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
Claims are made about traded products, including Organic, Halal, Kosher. The claims are verified by certificates, traceability challenges, CoA, product testing, evidence from supplier.
Documented mass balance tests are carried out on a 6-monthly basis as a minimum. 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. The results of all checks and tests on traded products are recorded and reviewed by the Analytical Department Technicians. Actions taken on out of spec results include retesting, holding the product while an investigation is carried out with the supplier and the customer is contacted.

9.5 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.

9.6 Traceability

The site's traceability procedure, referred to in section 3.9 of this report, includes details of the traceability system for traded products. This 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. All products are traded and some are repacked. There are no products that are just repacked. The last tests of the product was traded and some was repacked, with full traceability and mass balance achieved within 4 hours.

Forwards on 30/08/23 on raw material Actibio – BC 200kg delivered 21/06/23 best before 24/05/25 in 5kg pack. Full traceability was achieved in 30 minutes Mass balance was achieved. Despatched 159.389kg 26/06/23 – 15/05/23 (50kg of this amount was repacked). 40kg on stock. =199.389kg.

Backwards on 30/08/23 on finished product Actibio – BC. Full traceability was achieved in 30 minutes (09:44-10:07) 100kg straight out no re-pack Despatched 26/06/23.
A 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: Vitamin B1 delivery 17/11/23 400kg bb 26/04/26, 400kg used and despatched 24/11/23 to 04/04/24.

Module 11: Meat Supply Chain Assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	
11.3 Raw material receipt and inspection	
11.4 Management of cross-contamination between species	
11.5 Product testing	
11.6 Training	

Module 13: Meeting FSMA Requirements for Food – July 2022
Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33)
Click or tap here to enter text.
Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)
Click or tap here to enter text.
Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)
Click or tap here to enter text.
Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)
Click or tap here to enter text.
Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)

Click or tap here to enter text.

14.1 Additional Specifier Requirements
14.1 Traceability
Click or tap here to enter text.
14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.