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	2023-04-25	Audit finish date	2023-04-27
Re-audit due date	2024-05-04	Head office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Meeting FSMA requirements for Food	Passed	The repackaging of dry, ambient stable nutritional food ingredients packed into bags for further manufacturing.	None
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit programme	Announced
Previous audit grade	AA+		Previous audit date		2022-03-31
Certificate issue date	2023-06-01		Certificate expiry date		2024-06-15
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@camebridgecommodities.com

4. Company Profile					
Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3
Shift pattern	08:30 – 17:00 (Cleanroom,); 06.30:14.00 and 14.00 – 22:30 Warehouse				
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	Outsourcing is limited to blending and packing of food supplements.				
Regions exported to	Europe Africa Choose a region				

4. Company Profile	
	Choose a region Choose a region Choose a region
Company registration number	AO 021 and GB026/216.
Major changes since last BRCGS audit	There have been no major changes since the last audit.

Company Description

The company is privately owned with a sister site in the US, but the sites run independently. Founded in the 1998, the company has grown rapidly in recent years, moving to the current, purpose-built premises in May 2015. The main customers are on-line based.
The company specialise in supplying ingredients for the sports nutrition, health and wellness, equine and pet sectors, sourcing and stocking a range comprising of around 1200 active different product lines, which are either supplied in original packaging (traded) or repacked (powdered goods only, 5% of total throughput) on site if smaller quantities are required. The wide range of product types are all ambient stable. The company employ circa 150 employees (25 work in production, 20 in quality). There is limited re-packing on site with total re-packing and storage area around 9000m square and the warehouse has 9000 pallet spaces. Production hours are 8.30 am to 5:00 pm day shift with a night shift of 15:30 to 00:30 with a dedicated third-party cleaning team afterwards to clean walls and floor.
The company also undertakes an on-site contract packing service for tabletted nutritional and health food supplements which falls outside the scope of the Global Food Standard. These is undertaken in a completely separate area to the in-scope products.
The company has also commissioned a blending facility which is not currently operational.
Outsourcing is limited to blending and packing of food supplements.

5. Product Characteristics					
Product categories	15 - Dried food and ingredients VM - Meeting FSMA requirements for Food 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 handling of ambient, dry ingredients that have low water activity,				

5. Product Characteristics	
	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	The repacking of powdered products e.g., P02174, PSID 392995.

6. Audit Duration Details			
Total audit duration	19 man hours	Duration of production facility inspection	5 man hours
Reasons for deviation from typical or expected audit duration	The BRCGS audit was shorter than the expected duration because it was a simple operation with well laid out QMS. The duration of the production facility inspection was less than 50% of the duration of the BRCGS audit due to simple repacking operation with 95% of product sold as traded goods requiring storage only. No products are produced for America, so no production time was required for this AVM.		
Combined audits	None		
Next audit type selected	Announced		

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				Onsite
Rebecca Ryder	Head of Quality	Onsite			Onsite
Phil Barnhill	Technical services Manager		Onsite	Onsite	Onsite
Hannah Pritchard	Technical and systems project Manager	Onsite	Onsite	Onsite	Onsite
S.M	Assistant Quality Manager			Remote	Remote
M.B	Senior Quality specialist			Onsite (Part)	
D.B	Clean room Manager		Onsite (Part)	Onsite (Part)	
A.T	AD Team leader		Onsite (Part)	Onsite (Part)	
J.C	Warehouse supervisor		Onsite (Part)	Onsite (Part)	

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

Document control			
CB Report number	256521		
Template name	F908 Food Safety Audit Report Template		
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
None

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**
20336	Simon	Brookes

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
Simon	Brookes	20336	Lead Auditor	2023-04-25	09.15	17.15	physical	
Veronica	Dillon	21905	Witness Assessor	2023-04-25	09.15	17.15	physical	
Simon	Brookes	20336	Lead Auditor	2023-04-26	08.00	16.35	physical	
Veronica	Dillon	21905	Witness Assessor	2023-04-26	08.00	16.35	physical	
Simon	Brookes	20336	Lead Auditor	2023-04-27	08.00	10.00	physical	
Veronica	Dillon	21905	Witness Assessor	2023-04-27	08.00	10.00	physical	

Audit team
• Record auditors present at the audit.

• When the auditor returns on the next day (or additional days), re-enter the auditor details in a new row for each day.
• Additional rows can be inserted by ensuring that functionality (i.e. text fields) are included. Unused rows may also be deleted to improve the visual appearance of the report.
• This list will be used by BRCGS for compliance checks. It is therefore important that the correct full names and job titles are recorded.
• Presence of the auditor shall entered as physical (i.e. physically on-site) or remote for each stage of the audit (e.g Blended audits).
• Record GFSI Professional recognition number of auditor, if available. Leave blank, if not available.

1. Senior management commitment

There is a documented food safety, legality, quality and authenticity policy signed by the Head of Quality 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. The policy includes commitment to continuously improve the site's food safety and quality culture.

The areas covered by this section were discussed with the Head of Quality and Operations Director during the audit.

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

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

The following activities are included in this plan:

- Conduct annual staff performance reviews expressing the importance of quality and food safety. (Every six months). All reviews were last carried out in Dec 22.
- Conduct annual survey (all employees) and manager to review feedback. Survey completed Feb 2023, reviewed 31/03/23.
- Conduct staff meetings regarding quality updates (monthly).
- Reports to the Board regarding quality and performance statistics including but not limited to the following – food safety issues, complaints, testing out of spec vs passes, concessions and deviations, quality compliance (monthly).
- Posters/information in various positions on site promoting the importance of quality and food safety.
- Hold monthly drop in sessions for the sales team re any issues relating to food safety, quality, legality.

The effectiveness is of these activities is reviewed at least annually, with the last review on 31/03/23. Seen for all employee survey completed Feb 2023 and staff meetings conducted 2023.

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

2022 Targets

- Quality compliance based on the number of formal complaints from customers – Target >95%, 2022 99.59%.
- Increased supplier audits – Target increase to 20 in coming year. Not possible in 2022 regarding ongoing country restrictions.
- HACCP level 2 training – Target for all team members where required. 2023 training booked.

Example of 2023 targets

- Quality compliance based on the number of formal complaints from customers – Target >95%, YTD 99.56%
- Drive quality performance - reduce customer complaints YOY by 1% and supplier complaints YOY by 2%
- Drive down the average number of days to release raw materials current ave 65% released within 3 days, target 75% released within 2 days by 30/11/23.
- Customer request sustainability – decrease % of bespoke customer documents
- Increased supplier audits – Target increase to 20 in coming year. YTD 5 planned and 3 completed.

These are monitored and reported monthly to all staff and reviewed at the Management Review meetings held monthly and attended by TS, B.R and the directors.

Management Review meeting agendas include all elements of 1.1.4 of this Standard. Minutes were reviewed for the meeting held on 08/03/23. The output of the meeting included methods for meeting the objectives and targets through the coming year.
In addition, board meetings are held monthly in order to bring food safety, legality, authenticity and quality issues to the attention of senior management.

Other meetings held 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.

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

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

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

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

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

The site uses the BRC Global Standards logo and/or refers to its certification status on marketing materials, website, 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 hygiene approval number is GB026/216.

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

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

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

- Repacking Product Procedure, doc ref: QM07/SOP01, issue 26, dated 13/04/23 – added additional checks and WIs.
- Foreign Body Control Procedure doc ref: QMO4.POL06, issue 8 dated 31/03/23 – added wearable devices.
- Complaints Procedure doc ref: QM08/SOP09, issue 7 dated 31/08/22 – removed ref to quarantine log as onfo accessed on PS system.
- Goods in product inspection and cleaning procedure doc ref QM07/SOP05 issue 13 dated 06/04/23 – added dedicated bins
- Magnet probe handling and cleaning procedure doc ref QM07/SOP26 issue 1 dated 14/10/21
- FTIR testing doc ref QM08/SOP12 issue 6 dated 13/07/22 – updated doc links and section 5 re addition of initials.
- Vehicle inspection procedure doc ref QM07/SOP22 issue 4 dated 13/04/23 – Addition of load security statement.

Job descriptions were challenged for the following roles A.D Technician dated 19/12/22, Clean Room Supervisor, Clean Room Team Leader and Warehouse Supervisor dated 13/09/22.

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.

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

2. The Food Safety Plan – HACCP

The company's food safety plan is based on Codex Alimentarius HACCP principles. There is one HACCP study, currently at issue 14 and dated 31/03/23.
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 and Level 3 HP, 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.R) 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) doc ref QM02.FOR06 issue 1 dated 21/05/21. It is systematic, comprehensive and fully implemented and maintained.

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

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

References to legislation have been made within the study including:

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

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.

There is 1 main flow process diagram doc ref QM02/GEN04, currently at version 10, which was last verified by the team on 04/11/22. There is also an outsourced processor process flow doc ref QM02.GEN06 issue 1 last verified 04/11/22.

The main process flow diagram covers the process steps, which can be summarized as: product approval, receipt, sampling and checks, release procedure, repack (if required), finished goods storage and despatch.

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

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

Allergen hazards considered as a chemical contaminant and include raw material and supply chain risks, risks from allergens handled on site and risks from visitors/workers. Suppliers' complete allergen statements as part of the raw material questionnaire doc ref: QM07 FOR09, issue 30.

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 04/11/22), 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 are responsible for authorisation, changes/amendments and replacement of existing documents.

Electronic documents are stored securely, with access controlled by authorised access, password protection and are backed up daily to an off-site server.

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

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

- Repack Equipment Log, doc ref: QM07.FOR26, issue 4, reviewed as part of site inspection.
- Clean & Check Record, doc ref: QM07.FOR15, issue 12, reviewed as part of site inspection.
- Repack record for L Glutamine P07241, PSID 320247, batch GM2004004 on 16/02/21 as part of the blended product trace P15351.
- Vehicle Inspection Record, doc ref: QM07.FOR06, issue 1, reviewed for 11/01/23 and 09/02/23 as part of trace challenges.

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 on at least 4 different dates, spread across the year with the frequency determined by risk assessment and previous internal audit performance. Each area is audited at least annually.

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

- Technical Services Manager PB – Lead Auditor Training (Alchemist) 17/11/17
- Assistant Quality Manager SM – Lead Auditor Training (Alchemist) 17/11/17
- Sales and Operations Process Manager JW – Lead Auditor Training (Alchemist) 17/11/17
- Head of Process JS – Lead Auditor Training (Alchemist) 17/11/17
- Technical and Project Manager HP – Lead Auditor Training (Alchemist) 17/11/17
- Senior Quality Specialist A.B – Internal auditor training 27/07/18
- A.D Team Leader A.T– Internal auditor training 26/04/19
- Senior Quality Specialist C.W – Internal auditor training 11/01/17
- Customer Care Advisor M.B - Internal auditor training 24/03/22

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

Internal audit records reviewed included: -

- 29/03/23 - Repacking process (bi annually) – audited by A.B and M.B, No N/Cs raised.
- 22/02/23 - Quaratine area – audited by J.C and A.A. 3 Minor N/C raised, all been closed and approved by 02/03/23
- 04/11/22 - Food Defence and Site Security – audited by P.B and S.M. No N/Cs raised.
- 24/02/23 - Supplier and Product Approval – audited by S.M and C.W. No N/Cs raised.

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

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

- 07/03/23 by B.PI – 3 minor N/C raised, all closed by 09/03/23.
- 18/01/23 by A.B and C.R – No N/C raised

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. Example reviewed for external perimeter growth.

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. E.g., raw material P 17470 supplier JHP, 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, issue 14 dated 13/04/23 – updated re no GFSI subcontract haulier approval – doc ref 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 issue 5 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. 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:

- Enzyme P16010 supplier BCQ approved via FSSC 22000 certification expires 30/11/24. Product approval doc ref QM07.FOR12 last reviewed 28/09/22.
- L Glutamine P07241 supplier XNJ approved via BRCGS Food site code ****023 expires 03/02/24. Product approval doc ref QM07.FOR12 last reviewed 14/01/21.
- Product P12884 supplier JIK approved via FSSC 22000 certification expires 10/12/24. Product approval doc ref QM07.FOR12 last reviewed 21/03/23.
- Pea protein P16109 supplier SHLD approved via BRCGS Food site code ****394 expires 25/10/23. Product approval doc ref QM07.FOR12 last reviewed 28/07/22.
- Product P30602 purchased from agent NVR. Manufacturer of Maltodextrin BAO approved via FSSC 22000 expires 17/11/22. Product approval doc ref QM07.FOR12 last reviewed 26/10/20.
- Flavoring P14785 supplier TAH approved via BRCGS Food site code ****158 expires 04/04/24.
- Organic Sunflower Protein P33893 supplier LLR approved via FSSC 22000 TIC 15 160 14038 certification expires 18/09/23. Organic cert expires 31/01/24. Product approval doc ref QM07.FOR12 last reviewed 06/01/21.
- Blue bags from supplier DPL BRCGS Packaging certification, site code ****811, expriy 18/08/23.

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

The following supplier audit reports were checked and found to be comprehensive: P16010 from supplier BCQ, audit carried out by C.A and H.P on 26/01/23.

The following SAQs were reviewed and found to cover all the requirements: Green tea extract P17391 from supplier ARCD, reviewed by the Technical Services Manager on 03/02/23. Traceability records for batch GTE 030/2108/B-13 dated 02/12/21 held on file.

There is a documented, risk-based process for the on-going review of supplier performance, doc ref QM07.SOP08, with the following performance criteria defined: complaint history, site accreditation and volumes purchased. All products must be re-approved at least every three years using doc ref QM07.FOR12, issue 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 re-check RASFF/google for any evidence of contamination risk for the material.

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

Agents, brokers and wholesalers are used. The site knows the identity of the last manufacturer, packer or consolidation place. Example reviewed for agent KRE, re product P09025, manufacturer B FSSC 22000 certification expires 15/02/24.

Suppliers' traceability procedures have been assessed by GFSI certification, or if required supplier audit, by the Technical Services Manager and the Senior Quality Specialist. Supplier audits are carried out by the Technical Services Manager (PB) who is lead auditor trained and experienced in the industry. Supported by Chinese speaking Senior Quality specialist (C.W). Supplier audits can also be conducted by the Technical and Systems Project Manager (H.P) who is lead auditor trained (17/11/14) and experienced in the industry. These are based on the outcome of supplier questionnaire review, quantity supplied, potential adulteration/contamination risk, historical issues and reputation of the company. The supplier audit report is based on BRCGS criteria e.g., product safety, traceability, HACCP and GMP. No active suppliers are currently approved via site audit.
Where supplier approval is done via a questionnaire, traceability is verified by either a trace test, worked example, or a description of the supplier's traceability system on first approval and then every 3 years. Example reviewed for product P17391, supplier ARCD, traceability records for batch GTE 030/2108/B-13 dated 02/12/21 held on file.
For raw materials purchased from agents, brokers or wholesalers, and where supplier approval is done via a questionnaire, the traceability system of the last manufacturer, packer or consolidation place is verified by requesting manufacturer details. Example reviewed for product P09025 supplied via agent KRE. Manufacturer B FSSC 22000 certification expires 15/02/24. Product approval doc ref QM07.FOR12 last reviewed 08/06/22.

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 products.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Raw materials and primary packaging are checked on intake for compliance with purchase orders and certificates of analysis/compliance are received. Every product is sampled on delivery for visual/organoleptic assessment against CoA and put through magnet testing (Powders), which is conducted in the modular clean room within the warehouse. A magnet is put through the sample bag to check any metallic contamination. If metal is found, a report is sent to Quality Manager and supplier informed. Product is put on quarantine. After magnet inspection product is sent for FTIR testing to ensure a close match to previous delivered lots. This is detailed in the Goods in Product Inspection and Cleaning Procedure doc ref: QM07.SOP05.

An example of intake testing was reviewed for a delivery of a flavouring product P16494 batch 61320 delivered 24/04/23 during facility inspection. Visual/Magnetic inspection doc ref Clean and Check Record QM07.FOR15 tested on 25/04/23, FTIR result 99.7%, passed.

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

3.5.3 Management of suppliers of services

Service suppliers are approved and monitored by Operations using the procedure doc ref QM06/GDE01 issue 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
- Haulage from dock to site (T), Service Level Agreement signed 03/11/15
- Laundry supplier Swiss Landry – Service agreement dated 28/01/14, ISO 9001 expires March 2028
- Contracted cleaning SM – Service level agreement signed 29/04/15
- Pest control – Prokill – Contract in place. BPCA Membership No. M15/737 expires 298/02/24

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.

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. Example seen for customer H&B via online portal, which references NVR and HLS.

The company used is outsourced processor/blender NVR, approved by BRCGS Food certification, site code ****101, expiry 24/11/23 and outsourced packaging companies HLS approved by BRCGS Food certification, site code ****2549, expiry 18/01/24 and HEZ approved by BRCGS Food certification site code ****318 expires 03/01/24.

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 and HCT Technical agreement signed 07/10/19.
Traceability is maintained as both parties hold third party certification.

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:

- Green tee extract product code P0736 V15 dated 29/03/23
- Enzyme P16010 V14 dated 02/11/22
- P09025 V3 dated 02/11/22
- L Glutamine P07241 V7 dated 02/06/21).
- P12884 V2 dated 25/11/19, last reviewed 21/03/23
- Pea protein P16109 V9 dated 13/01/22
- Organic Sunflower Protein P33893 V6 dated 10/09/21

Packaging

- Blue bag supplier DPL DQD High slip first grade LDPE dated 22/02/22. HACCP on file dated 26/09/19. Migration report Smithers PIRA report dated 27/11/18. DoC ref 1935/2004, EU10/2011 dated 01/02/22.

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:

- Blended product P15351 V7 dated 12/05/22.

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

3.7 Corrective and preventive actions

Corrective action procedures e.g., internal auditing procedure doc ref QM04.SOP02 issue 3 dated March 2022 – updated to include NCR log, and Complaints Procedure doc ref: QM08.SOP09, issue 7 dated 31/08/22 – removed ref to quarantine log, now managed via ERP system, which include root cause analysis and preventive action, are in place to address failures identified in the food safety and quality management system.

Non-conformities that result in a risk to product safety, 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.

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

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

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

Example of an RCA were reviewed for;

- The NC raised as part of the Quarantine area internal audit dated 22/02/23.
- FB complaint dated 28/02/23, Supplier N/C raised doc ref QM08.FOR03 ref NCR11-23 detailing RC and CA – Supplier JNN to add additional checks and conduct training. Completed 08/03/23.

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

3.8 Control of non-conforming product

A procedure is in place doc ref 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, including product returns. Records of destruction where a product is destroyed for food safety reasons are recorded as per procedure QM08.SOP08 issue 2 dated 22/05/19.

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

Records are in place to demonstrate the investigation, analysis and cause of any non-conforming product. Defined responsibility and actions/timescales are documented. An example was reviewed for QUAR2, P3459 batch 221130-C11 Pack ID 3403665, 6 and 7 quantity 3 boxes due to damage, awaiting disposal.

3.9 Traceability

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

Traceability for all packaging used is recorded and maintained, example reviewed for L Glutamine trace P13605 batch 111005.

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 05/09/22 on raw material Passionfruit Powder P16051, batch code 202203081. Full traceability was achieved in 1hr and 11min. Mass balance was achieved.
Backwards on 28/09/22 on finished product NBB Stevia Blend P12512. Full traceability was achieved in 1hr 42mins.

A traceability test and vertical audit were undertaken during the audit on traded product Green Tea extract, PSID number 384681, product code P0736, batch number 202210018, product quantity 1000kg, delivered

16/12/22 from supplier NNG. Of the 1000kg, 165kg remains in stock with 935kg dispatched to either repack or traded between 05/01/23 and 06/04/23 e.g. sent to customer HLL 150 kg order 384681, on 11/01/2023 and repack 1 kg order 391644 on 06/04/2023. Of the 1000kg, 2kg was repacked 13/01/23 dispatched to customer 13/01/23. 165.15kg remains in stock. Traceability and mass balance was achieved in 27 minutes.

A traceability challenge and mass balance were also undertaken during the audit on a blended product P15351, blend P15351, batch numbers 0421879-R, BB 01/12/23. This consisted of 9 ingredients delivered to CCL between 09/05/20 and 29/06/21. Intake testing reviewed for L Glutamine P07241, batch GM2004004 29/06/20. L Glutamine P07241 batch GM2004004 repacked on site 16/02/21. All products sent to outsourced Blender NVR on 02/03/21 (2994.2kg) returned 16/08/21 (2994.2kg) and 27/08/21 (2996.4kg) returned 07/09/21 (2996.4kg), P14755, batch example 17881-5. Sent to be pouched (HLS) 20/06/22, 1066kg returned 2119 finished pouches 500g = 1059.5kg. Packed product return from HLS – 04/07/22 – quantity 1059.5kg. Goods intake checks completed 05/07/22, FTIR check 05/07/22 – passed. Sent to customer (MGN) 09/02/23 (customer specified blend). The exercise was completed in 2 hours and 38 min.

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

3.10 Complaint-handling

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

Complaint target is set as a monthly product compliance figure (as per the KPI), set 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 99.56% compliance to date.

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

Complaints for 2023 reviewed e.g. 21/03/23 ref 23/044C re FB – batch ending 6040422115 – supplier NCR raised ref NCR 18/23.

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 – added disposition re food safety risk and authenticity and an out of hours contact lists for all key members of staff, customers and organisations including the Certification Body. A Business Continuity Plan is also in place doc ref: QM02.GDE01, issue 3 dated March 2021.

The requirement to notify the Certification Body within three days of a significant food safety, authenticity or legal incident, including a recall or regulatory non conformity, is included.

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, with this done annually.

The last challenge was undertaken on Garlic Extract on 05/09/22, PSID code 364172NNGP, batch number 202203022. Full traceability and mass balance was achieved. Review report dated 07/09/22.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
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 8 of this report.

4.2 Food defence

Personnel engaged in threat assessments and food defence plans are competent via training and experience. Eh PB 13+ in food defence related activities, Lead assessor trained- 17/11/14, HACCP trained level 2 dated 28/07/11. Site also attended BRC 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 04/11/22.

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

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

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, issue 10 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 enclosed at all times.

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

All doors were noted to be in good condition.

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

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. No storage tanks apart from fire system which is separate.

Annual microbiological and chemical analysis is obtained from the supplier for period Jan to Dec 2022 and additional surveillance testing is carried out by an external laboratory, SGS.

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

Tests reviewed included:

- 09/11/22 – Wet room tap water , tested for E. coli. TVC, Coliforms and Entro.
- 09/11/22 – Clean room left hot tap tested for E. coli. TVC, Coliforms and Entro.

All tests were within the required tolerances.

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

Ice/steam is not used.

No gas is used.

Compressed air is not used.

4.6 Equipment

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

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

The following certificates/evidence was seen to confirm suitability for food use for the Stainless-steel scoops which are constructed of SS 316. Disposable powder scoop (goods in only) conforms to FDA 21 CFR 177.1520, 178.2010, EU 10/2011 and EU 1935/2004.

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.

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

Strongly scented/taint-forming materials are not used.

4.9.2 Metal control

There is a documented foreign body control procedure doc ref QM04.POL06 issue 8 dated 31/03/23 with a registration system for scissors, scoops, sieves, spoons, tools, funnels and cutters. These are issued to operator and signed back on a daily basis.

Daily start up checks are performed and recorded on doc ref QM07.FOR26 version 4 records were viewed during the facility inspection.

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

4.9.3 Glass, brittle plastic, ceramics and similar materials

Monthly glass and brittle plastic audits are carried out by the Quality Team. Examples reviewed as part of vertical audit for clean room dated 25/02/21 and 29/01/21. An appropriate Glass Brittle Plastic and Ceramic Procedure doc ref: QM08.SOP13, issue 4, dated 04/06/19 is in place which includes, training of staff, isolation, cleaning, safe disposal of contaminated product and authorised clearance inspection procedures.
No breakages in storage or clean room recorded for the last 12 months.

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

4.9.4 Products packed into glass or other brittle containers

No products are packed into glass or other brittle containers.

4.9.5 Wood

Wood is restricted to finished product pallets, as per the Foreign Body Control Policy doc ref QMO4.POL06.

4.9.6 Other physical contaminants
Procedures are in place to prevent physical contamination by raw material packaging e.g., visual checks of packaging and cleaning if necessary. Staff follow a documented procedure within the Goods-in and Inspection Procedure, doc ref: QM07.SOP05 issue 13 dated 06/04/22 and Repack Procedure doc ref QM07;SOP01, for removal of raw materials from their packaging, to avoid contamination. Pens used in open product areas are controlled. They are consolidated at the end of the shift and are metal detectable and one-piece. No other portable handheld equipment allowed within the clean room, as detailed in relevant policies.
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.
4.10.2 Filters and sieves
Filters are used in the extraction area and are cleaned annually by a third party, last cleaned 24/04/22 by CR. Portable domestic type metal sieves are used occasionally for weight control purposes only. These are stored in the repack area and are subject to area cleaning regimes. Integrity checks are carried out and recorded on the equipment log QM07.FOR26. The mesh size is not specified as these are used for weight control purposes only.
4.10.3 Metal detectors and X-ray equipment
A risk assessment for metal contamination as part of the 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 Greenward Magnetics dated 27/06/22, average gauss 10,240 (design strength 10,000 gauss. Certified to 10,000 +/- 500).
4.10.5 Optical sorting equipment
No optical sorting equipment is used.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers
No products are packed into glass jars, cans or other rigid containers.
4.10.7 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. Full and detailed cleaning procedures are in place for all areas and equipment and include: • Warehouse Cleaning Procedure, QM08.SOP16, issue 4 dated 14/12/21. • Repacking of Product Procedure (which covers cleaning) QM07.SOP001. Cleaning is carried out every day at the end of shift with full machine strip down and surface washing by operatives using a 2-stage clean involving an alcohol spray and wipes. Cleaning is verified by documented visual checks for each product changeover, which includes a buddy check. Limits of acceptable and unacceptable cleaning for food contact surfaces and equipment are defined by visual inspection at start-up. The corrective action to be taken when results are outside the acceptable limits is defined in the relevant procedures. Validation records are available to show that cleaning regimes are effective. These are covered by the environmental monitoring procedure and allergen cleaning validation. Surface swabbing and air plates (micro) are conducted quarterly. SGS (UKAS 1549) micro reports reviewed. • 20/01/22 – Wet room surface and floor – Salmonella ND and Listeria ND • 20/01/22 – sampling scope ACC 10 cfu/g Y & M 20 cfu/g, Entro <10 cfu/g, E.Coli <10 cfu/g, Salmonella ND, Listeria ND • 27/10/22 – sampling scope ACC <10 cfu/g Y & M <20cfu/g, Entro <10 cfu/g, E.Coli <10 cfu/g, Salmonella ND, Listeria ND • 25/03/22 – Repack room work surfaces and utensiles - ACC 10 cfu/g Y & M – <20cfu/g, Entro <10 cfu/g, E.Coli <10 cfu/g, Salmonella ND, Listeria ND • 15/11/21 clean room small scale, no issues. • Air quality settle plates repack rooms last conducted – 05/10/22 — 1 plate for TVC@30°C, Moulds and Yeasts all results <1cfu/ml Start-up hygiene checks are documented for all key processes and equipment. There are colour coded and dedicated cleaning utensils based on usage e.g., Glass breakage red and allergens is pink. These are hygienically stored.

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:

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

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

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

Environmental monitoring report dated 22/02/23 summarises all associated results – all green.

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

4.12 Waste 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 Prokill (BPCA membership number M15/737 expires 29/02/24 covers rodents, flying insects, crawling insects and birds and consists of 12 routine visits and 4 in-depth inspections per year. Full records of pest control are maintained including site plan dated 04/12/20, verified for external BS 5, EFK 13 and internal 34 bait data sheets, operative training records D.H RSPH Level 2 dated 10/12/13, records of inspections and treatments.

The last visit to site was carried out on 11/04/23 no issues noted.

Other reports reviewed included:

- 11/04/23 – EFK service and 06/03/23 no issues noted.

The risk assessment is reviewed when changes to buildings or processes which could impact the pest management programme and any significant pest issues. Latest dated 03/02/21. No changes since that date.

In-depth pest control surveys are undertaken at a frequency based on risk and the last one was 01/12/22. The report details minor proofing/housekeeping activities. All actions closed 19/12/22 apart from replacing door which was closed 09/03/23. Previous visit 15/06/22.

All toxic baits are secured, they are used externally only.
All recommendations are completed by the company in a timely manner.
No evidence of infestation was seen at the audit or has been identified during visits.
Inspection results are analysed for trends annually as a minimum, or when these has been a pest issue.
No issues highlighted through trending reports.
EFKs are situated throughout the site and catch tray analysis is performed quarterly.

The site has identified that there is a risk from birds roosting and/or entering the building. The following prevention measures are in place: spikes.

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

4.15 Storage facilities

No temperature-controlled storage is required.

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

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

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

There is no controlled atmosphere or outside storage.

Packaging is stored away from raw materials and finished goods. Part used packaging is inspected for suitability/cleanliness and covered. The bags/boxes are generic.

4.16 Dispatch and transport

The company has no owned vehicles.

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

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

Transport procedures are in place within the Vehicle Inspection Procedure doc ref: QM07.SOP22, issue 4 dated 13/04/23 – added load security, covering clause requirements.

Approved third party hauliers are used;

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

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.
4.6.6	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 2 dated 06/04/22 updated to include HACCP team sign off, with HACCP a key part of the development procedure. 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.

Full development systems are in place based on a development checklist which needs to be followed prior to launch and includes a HACCP sign off. Example reviewed for a capsule, initial sign off 07/07/22,

formulated and buddy checked 08/07/22, finished product spec P16595 HACCP signed 14/09/22 and customer signed 26/09/22.

Documented recipe development and production trials are undertaken – seen for the above.

Shelf life is determined and validated through EOL testing, based on the conditions expected throughout the life of the product, recorded on the Shelf-Life Record, which will include start of life, end of life with comparison analysis. An example reviewed for a product P07168 (Glucosamine Vegetation) batch 202108002 – SGS micro report dated 29/03/23, no issues noted (extension code E230321). FTIR report dated 29/03/23 – 99%. Original BB date 03/08/23, following testing shelf life extended to 20/05/24 – CoA updated and supplied to customer. FTIR is used as a fingerprint and overlays the original batch to detect any difference in the composition through the life of the product and post life for potential shelf-life extension.

5.2 Product labelling

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

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

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

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

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

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

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

All allergens are identified electronically and are fully labelled. There is a spillage control procedure HSMO5.01.22 issue 6 dated 14/04/23 – updated to include non-food spillages.

Visitor questionnaires include questions relating to allergens.

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

All products are single ingredient, there is no rework.

Allergen warnings are not considered necessary because of the controls in place.

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

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

5.4 Product authenticity, claims and chain of custody

Personnel engaged in vulnerability assessments are competent via training and experience. E.g. 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. This has resulted in a vulnerability assessment plan. The plan is kept under review to take into account 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 09/02/23.

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 31/03/24.

Documented mass balance tests are carried out on a 6-monthly basis as a minimum. The last challenge was carried out 20/09/22 on product Organic Spirulina, P19211.

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 cert ref 5648 expires 08/12/23

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 DPL DQD High slip first grade LDPE dated 22/02/22. HACCP on file dated 26/09/19. Migration report Smithers PIRA report dated 27/11/18. DoC ref 1935/2004, EU10/2011 dated 01/02/22

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.

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

- Green Tea Extract P0736 Phytocontrol ETO report dated 19/10/22.
- Green Tea Extract P0736 Concept Life Sciences (SGS) – UKAS 1549. Micro report dated 22/09/20, Listeria and Salmonella ND.
- Finished Product P14755, Concept Life Sciences (SGS) – UKAS 1549. Micro reports dated 05/03/21 and 27/09/21 - Listeria Enumeration and Listeria monocytogenes <10 cfu/g, Salmonella spp N.D.

Other test reports reviewed included: -

- P17391 Green Tea extract; Alchemist ID Test report dated 27/03/23 confirming non adulteration, Camden BRI heavy metal test report dated 19/04/23, no issues. Phyto control (ISO 17025:2017 accredited) PAH report dated 28/03/23, no issues noted, Phyto control ETO report dated 27/03/23, no issues noted and SGS Micro report dated 16/03/23, no issues noted.

External labs include: -

- Concept Life Sciences (SGS) – UKAS 1549 is used for micro
- Eurofins DAKKS (Germany and Neogen, UKAS1906 is used for allergen testing
- Inform Sport Testing is used for prohibited sports substances (enhancement testing), UKAS 1187
- Eurofins, UKAS DAKKS (Germany) is used for chemicals such as Heavy Metals etc
- Campden BRI (UKAS 1079) is used or inorganic arsenic and other specialist tests
- Achalimist is used for ID testing using HPLC (A2LA certificated)

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

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

The following tests are subject to legal limits E.g. pesticides, aflatoxins, heavy metals.

- Green Tea Extract P0736 Phytocontrol pesticide report dated 01/09/22.

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 customer.

Shelf life is validated and routinely verified by the approval process, specification and testing. Suppliers are required to detail the stability details to show the life of the product. A shelf-life extension guidance doc ref QM08.SPO03 issue 4 dated 30/10/17 is also in place which details risks and testing required. An example reviewed for a product P07168 (Glucosamine Vegetation) batch 202108002 – SGS micro report dated 29/03/23, no issues noted (extension code E230321). FTIR report dated 29/03/23 – 99%. Original BB date 03/08/23, following testing shelf life extended to 20/05/24 – CoA updated and supplied to customer. FTIR is used as a fingerprint and overlays the original batch to detect any difference in the composition through the life of the product and post life for potential shelf-life extension.

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 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 issue 3 dated 28/07/22.

6.2 Labelling and pack control

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

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

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

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

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

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

No on-line verification of product labels is required.

6.3 Quantity, weight, volume and number control

Products are sold by weight, according to customer requirements.

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

The system and records kept meet legislative requirements.

There are no bulk quantities sold.

6.4 Calibration and control of measuring and monitoring devices

No CCPs have been identified.

The site maintains a calibration matrix which identifies the item, location, calibration method, result, responsibility and frequency, 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 B4-18558664 (60kg), last calibrated 10/11/22 by Blake & Boughton UKAS 0003;
- Scale SN AE5532835 (15kg), last calibrated 10/11/22 by Blake & Boughton;
- Scale SN 8900.288 (3kg), last calibrated 10/11/22 by Blake & Boughton;
- FTIR SN MY2051CU13, last calibrated 12/01/23 by OEM Agilent Technologies;
- Weights various, last calibrated 11/11/22 by Blake & Boughton.

The calibration procedure doc ref: QM08.SOP11, issue 7 dated 11/03/22, 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.

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:

J.B Clean Room Operative:
Repacking Product QM07.SOP01 issue 26 covers labelling and packing process – 14/04/23.

S.B (Modular cleaning room)
Goods in product inspection procedure doc ref QM07:SOP05 issue 13 – 21/04/23

Other staff training records reviewed included:

L.M AD Technician:
FTIR Procedure QM08.SOP12, issue 6 – 24/04/23

W.H clean room assistant
Induction – 17/04/23

N.H UK sales
Induction/Security – 06/03/23

Staff interviewed during the audit were competent in their roles e.g. J.C warehouse supervisor, D.B Clean Room Manager, J.B repack operative, L.M, A.D Technician, M.B Senior Quality specialist and A.T AD Team leader.

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

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

Personal hygiene standards, which meet clause requirements, are documented and covered during induction training and basic food hygiene training (carried out in house). The Guide to CCL Expectations of Staff Hygiene Procedure doc ref: QM06.SOP02, issue 4 dated 19/04/23 documents the site rules and policies. False nails referenced in doc ref QM04:POL06, issue 8 dated 31/03/23.

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

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

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

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 during induction training.

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

A HACCP / Food safety plan is in place which meets the requirements of clause 9.1.1.

The scope of traded products HACCP or food safety plan includes the products and the processes for which the site is responsible. This includes goods receipt, storage and dispatch.

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

The traded products are included in the site's main HACCP plan (see section 2 of this report).

The scope of the HACCP plan includes the traded products and the processes for which the site is responsible, including goods receipt, storage and despatch.

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

A risk assessment is in place which covers 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.

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

- Green tea extract product code P0736 and Passionfruit powder P16050 from supplier NNG, approved via FSSC 22000 certification, expiry 23/12/25, Product approval doc ref QM07.FOR12 last reviewed 29/04/21.

- Enzyme P16010 supplier BCQ approved via FSSC 22000 certification expires 30/11/24. Product approval doc ref QM07.FOR12 last reviewed 28/09/22.
- L Glutamine P07241 supplier XNJ approved via BRCGS food site code ****023 expires 03/02/24. Product approval doc ref QM07.FOR12 last reviewed 14/01/21.
- Product P12884 supplier JIK approved via FSSC 22000 certification expires 10/12/24. Product approval doc ref QM07.FOR12 last reviewed 21/03/23.
- Pea protein supplier SHLD approved via BRCGS Food site code ****394 expires 25/10/23. Product approval doc ref QM07.FOR12 last reviewed 28/07/22.
- Flavoring P14785 supplier TAH approved via BRCGS Food site code ****158 expires 04/04/24.
- Organic Sunflower Protein supplier LLR approved via FSSC 22000 TIC 15 160 14038 certification expires 18/09/23. Organic cert expires 31/01/24. Product approval doc ref QM07.FOR12 last reviewed 06/01/21.

The following supplier audit reports were checked and found to be comprehensive: P16010 from supplier BCQ, audit carried out by C.A and H.P on 26/01/23.

The following SAQs were reviewed and found to cover all the requirements: Green tea extract P17391 from supplier ARCD, reviewed by the Technical Services Manager on 03/02/23. Traceability records for batch GTE 030/2108/B-13 dated 02/12/21 held on file.

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

Monitoring records doc ref QM07.FOR12 for the above suppliers of traded products were reviewed.

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. Example reviewed for customer V assessment questionnaire completed 17/04/23.

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

- Green tea extract product P0736 V15 dated 29/03/23
- Enzyme product P16010 V14 dated 02/11/22
- Product P09025 V3 dated 02/11/22
- L Glutamine P07241 V7 dated 02/06/21).
- Product P12884 V2 dated 25/11/19, last reviewed 21/03/23
- Pea protein P16109 V9 dated 13/01/22
- Organic Sunflower Protein P33893 V6 dated 10/09/21
- Passionfruit powder P16050 V1 dated 22/08/19 – last reviewed 26/01/22

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. This involves sampling of every product/delivery, visual/organoleptic assessment against CoA/Specification and magnet testing. This involves shaking a rare earth magnet through the bagged sample to assess the level of metal contamination.

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

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

- Green tea extract, PSID number 384681, product code P0736, batch number 2022100168, delivered 16/12/22 from supplier NNG. Magnetic inspection doc ref Clean and Check Record QM07.FOR15 tested on 16/12/22, FTIR including visual check tested 19/12/22, passed. Supplier COA checked 16/12/22.

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

Tests carried out by third party laboratories include:

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

Example of test reports reviewed;

- Green Tea Extract P0736 Phytocontrol ETO report dated 19/10/22.
- Green Tea Extract P0736 Concept Life Sciences (SGS) – UKAS 1549. Micro report dated 22/09/20, Listeria and Salmonella ND.

Certificates of conformity/analysis are provided by suppliers. These are supported by independent analysis, with a frequency determined by risk and carried out by an external laboratory.

Examples of test results seen for products which are supplied with CoC/CoA.

- P17391 Green Tea extract; Camden BRI heavy metal test report dated 19/04/23, no issues.

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

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

- Soil Association, licence number D18397, expiry 31/03/24;

- Halal cert ref CCL/COM/CCL/009213W expires 01/05/24
- Kosher cert ref 5648 expires 08/12/23

Documented mass balance tests are carried out on a 6-monthly basis as a minimum. The last challenge was carried out 20/09/22 on product Organic Spirulina, P19211.

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.
The last tests were as detailed in section 3.9, where some of the product was traded and some was repacked, with full traceability and mass balance achieved within 4 hours.

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

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

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)

Adequate lighting was observed in the handwashing and staff areas. As a benchmark a full site Lux level survey was conducted October 2018.

No outdoor bulk vessels.

Water systems have been installed to prevent backflow from, or cross-connection between, piping systems that discharge wastewater or sewage. There is a plan of the water distribution system dated 21/03/22. Sample points have been identified using risk assessment based on usage. Water testing in place.

Food surfaces of plant, equipment and utensils used in food areas were corrosion resistant and seems on food contact surfaces were suitably constructed and/or maintained to minimise accumulation of food particles, dirt, and organic matter, to minimise the risk of cross contamination from microorganisms.

No ice is used for the process.

RMs and other ingredients are inspected, segregated and handled to ensure they are clean and suitable for processing and stored to protect against allergen cross contact and contamination and to minimise deterioration.

RMs and other ingredients that are found to adulterated are disposed of to protect against the contamination of other foods.

No by-products.

The site inspects incoming raw materials and have established DALs where applicable, which are lower than the FDA Defect level limits. The site has implemented quality control operations to reduce defects to the lowest level possible. The site does not mix (dilute) product with defect levels at or exceeding the maximum limit with product containing minimum defects. All raw materials that exceed site DALs are returned with N/C raised.

The hazard analysis covers economic adulterants, radiological hazards, or unintentional hazards which affect food safety. There are no RTE products, all products require further processing.

All known or foreseeable hazards identified are evaluated to determine those requiring preventive controls. This is managed via the HACCP system, which is reviewed annually, or on change. The last review was 04/11/22. No CCPs have been identified.

The site has systems in place for preventive controls. Root cause analysis investigations are carried out where necessary to establish the preventive action required.

The Recall and Withdrawal Procedure is updated on change and contains procedures to notify the consignee of how to return or dispose of the recalled product. Effectiveness checks are carried out following the meeting to ensure that any non-conformances are closed out and used to shape future practice. The procedure details the appropriate procedures for product disposal or rework, i.e., placed on quarantine until the recall team liaises with the supplier and a decision Is made. The last challenge was undertaken on raw material Garlic Extract on 05/09/22, PSID code 364172NNGP, batch number 202203022. Full traceability and mass balance was achieved. Review report dated 07/09/22.

The supply chain program has procedures covering the receipt of RMs from unapproved suppliers which include preventative control management actions and responsibilities. Include – CAs taking into account supplier N/Cs, review of records, reanalysis.

Monitoring activities and procedures are in place for each preventive control required. There are no CCPs, but controls are detailed for both OPRPs and PRPs, for example at step 130 – Goods Release a hazard is detailed as physical, chemical or biological contamination resulting in loss of product, complaint from customer or harm to end user. Prevent action controls established include the positive release of all items dispatched from the site, based on test results (different according to each product).

Corrective action procedures are detailed for each of the preventative controls, for example internal auditing procedure doc ref QM04.SOP02 and complaints procedure doc ref QM08/SOP09. Although no CCPs have been identified, there are QCPs procedures which detail corrective actions. For example, Goods in product inspection and cleaning procedure doc ref QM07/SOP05, FTIR testing doc ref QM08/SOP12 and Repacking Product Procedure, doc ref: QM07/SOP01.

No critical control points have been established.

Equipment used to monitor preventive controls is calibrated, for example the FTIR machine as detailed in section 6 of the BRCGS report. There are no CCPs.

The Technical Services Manager and the Technical and Systems Project Manager (designated PCQIs) or authorised designee reviews any N/Cs raised within 7 days. Where this timescale has to be extended, the PCQI signs off the justification. Daily meetings are held to ensure the 7-day timescale is adhered to. The PCQI reviews preventive controls, such as calibration, product testing and audits.

The product testing requirements 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. Pathogen testing (including pathogens tested as part of the environmental monitoring programme) is subcontracted to SGS UKAS 1549. Where a pathogen is detected a corrective action procedure is in place. All products undergo FTIR testing at intake as an overlay against the previous sample to ensure nothing has been added/subtracted from the product, FTIR Spectroscopy Procedure doc ref: QM08/SOP12. The procedure details:

- The sampling procedure, including the method, quantity, frequency, and number of samples
- The analytical method
- The laboratory conducting analysis
- Corrective action procedure

An example of intake testing was reviewed for a delivery of a flavouring product P16494 batch 61320 delivered 24/04/23 during facility inspection. Visual/Magnetic inspection doc ref Clean and Check Record QM07.FOR15 tested on 25/04/23, FTIR result 99.7%, passed.

An environmental monitoring program is in place as detailed in clause 4.11.8. The programme includes:

- Sampling protocol, for example ait plate, swab
- Sample locations, for example extraction fin, tables and food contact areas
- Frequency of tests, for example annually, hand swabs 3 times annually
- Target organism, for example TVCs, Yeast, Mould, Entrobacteria, E.coli, Salmonella, Listeria
- Test methods e.g. settle plates
- Recording of results, examples were reviewed for air plate testing
- Details of the laboratory carrying out the analysis.
- Corrective action procedures where a pathogen is detected.

The HACCP Team Leader (one of the PCQIs) and has developed the HACCP plan. The plan is validated annually or in change. The PCQIs has been trained to Level 2 as a minimum and working at the site for a number of years as per Section 2 of the BRCGS report.

Site records detail the date and time of the activity.

The site owner/operator last signed the food safety plan during the last HACCP review 31/03/23. This is resigned on change, or review. Records and documents are held for at least 2 years after the record has been created. This can be verified via the Changes and Amendment Log held electronically. Records are held on-site indefinitely. Where records are stored electronically or off-site, they are fully retrievable within 24 hours. The Food Safety plan is held on-site at all times.

As the site does not currently supply the US, no supply chain has been established.

The site determines and conducts appropriate supplier verification activities as part of the supplier approval process. These include identification of supplier verification activities that may not be acceptable.

No RM hazards have a reasonable probability that exposure to the hazard will result in a serious adverse health consequences or death to humans.

The site does not engage in any financial conflict of interests that influence the results of the verification activities for RMs and other ingredients.

Supplier approval is documented prior to the purchase and use of the raw materials. This is detailed in the Approval/Non-Approval Conformation document, doc ref: QM07.FOR04.

All suppliers are required to present the required document prior to approval. The site is aware that no exceptions are permitted for the US. Only approved suppliers will be used.

Where an onsite audit is required as a supplier verification activity, the audit is conducted by a qualified auditor, considers all applicable FDA food safety regulations and includes a review of the supplier's written plan and its implementation.

All applicable sites supply chain program records are reviewed within a reasonable time frame by (or under the oversight of) a PCQI, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the PCs are effective, and appropriate decisions were made about CA.

Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)

Systems are in place for by-products that are sold or distributed as feed. For example, Whey Protein. Identification labelling is in place. Containers are examined prior to filling. No product is currently sold to the US.

Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)

The defence plan is developed by the PCQI. The vulnerability assessment in place details mitigation strategies. The Plan is reviewed annually. The PCQI, is identified on the sites organisational chart.

The site have a written food defence plan, which includes; A vulnerability assessment identifying significant vulnerabilities and actionable process steps, Mitigation strategies appropriate to reduce the vulnerability and procedures for food defence monitoring, corrective action and verification.

The site obtains information on threats to the supply chain which could lead to adulteration/substitution of raw materials by RASFF, FEMAS, Nutraveris. A documented vulnerability assessment has been carried out for each product produced with FTIR testing for all products, resulting in a vulnerability assessment plan, for example testing frequency. The plan is kept under review to take into account changes in potential risks, and is formally reviewed every 3 years, or on change or if there is an issue. No particular risks have been identified due to the controls in place. The supplier approval process identifies risks. The assessment also details the degree of access to the product and the likelihood of potential contamination or from an internal or external attacker. The assessment details mitigation controls in place to reduce the risk to an acceptable level.

Where mitigation strategies are detailed, justification is in place to show how the strategy minimises or reduces vulnerability,

A documented risk/threat assessment was carried out via the Food Defence and Site Security document, doc ref: QM02.FOR02, which considers both internal and external threats and risks from deliberate contamination or damage and covers activists disgruntled employees, all areas of the site, product on-site security and site IT systems. Controls are detailed. There are no areas or products deemed as a higher risk due to the monitoring controls in place which include: 24-hour CCTV, a security team monitors the site through the night with registration numbers taken for cars on site post 18:00, all site members have area restricted key fobs. Entry doors to production are fitted with key fob access systems. There is reporting system for all visitors and contractors. Staff training is in place on site security and food defence.

Corrective action procedures are in place to detail failures in the mitigation controls for the food defence system. No products or areas of the site have currently been highlighted as being of significant risk.

Documented verification procedures will be implemented to ensure that monitoring activities and corrective actions are carried out in accordance with the relevant.

The Food Defence plan is reviewed on an annual basis or on change, as per clause requirements. This information is detailed within the Food Defence and Site Security document, doc ref: QM02.FOR02. Last reviewed 04/11/22.

Records retained as part of the Food Defence plan doc ref QM02.FOR02 detail the time and date of the activity being documented and signature of the person performing the activity, the name and location of the site, with identification of the batch/lot code of the product.

The owner, operator or agent in charge of facility has signed and dated the written food defence plan 31/03/23.

Records for the food defence plan are retained on site indefinitely once the record has been created. Where records are stored off-site, or electronically, they are retrievable within 24 hours. The food defence plan remains onsite.

Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)

N/A as the site does not currently supply the US.

Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)

N/A

14.1 Additional Specifier Requirements
14.1 Traceability
N/A
14.2 Environmental Monitoring
N/A
14.3 Product inspection and laboratory testing
N/A
14.4 Protective clothing: Employees or visitors to production areas
N/A