# Audit Report

**Global Standard for Food Safety Issue 7: July 2015**

| 1.Audit Summary | | | |
|---|---|---|---|
| Company name | Cambridge Commodities Ltd | BRC Site Code | 6960330 |
| Site name | | | |
| Scope of audit | The repackaging of dry, ambient stable nutritional food ingredients packed into bags for further manufacturing. | | |
| Exclusions from scope | None | | |
| Justification for exclusion | Justification for exclusion | | |
| Audit Finish Date | 2018-10-11 | | |
| Re-audit due date | 2019-11-05 | | |

| Voluntary modules included | | |
|---|---|---|
| Modules | Result | Details |
| Traded Goods | Passed | Trading of a range of nutritional food ingredients including herbals, vitamins, minerals, amino acids, enzymes, probiotics, antioxidants, oils, gums, sweeteners and dietary supplements. |
| FSMA Preventative Controls and FSVP Preparedness | Passed | The repackaging of dry, ambient stable nutritional food ingredients packed into bags for further manufacturing. |
| Choose a module | Choose an item | |

| 2. Audit Results | | | | | |
|---|---|---|---|---|---|
| Audit result | Certificated | Audit grade | AA | Audit type | Announced |
| Previous audit grade | AA | Previous audit date | 2017-11-01 | | |

| Number of non-conformities | | |
|---|---|---|
| | Fundamental | 0 |
| | Critical | 0 |

| | | |
|---|---|---|
| | Major | 0 |
| | Minor | 2 |

## 3.Company Details

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

## 4.Company Profile

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

| | |
|---|---|
| Subcontracted processes | Yes |
| Other certificates held | FEMAS, Organic, Halal, Kosher, ISO22000, Informed Sport, ISO14001, ISO9001 2015 |
| Regions exported to | Europe<br>Africa<br>North America<br>Choose a region<br>Choose a region<br>Choose a region |
| Company registration number | N/A |
| Major changes since last BRC audit | None |

## 4.Company Profile

Company Description

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

## 5.Product Characteristics

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

| | | | | | |
|---|---|---|---|---|---|
| High care | No | High risk | No | Ambient high care | No |

| | |
|---|---|
| Justification for area | All goods are ambient stable and risk assessment is based on BRC decision tree. |

| 5.Product Characteristics | |
|---|---|
| Allergens handled on site | Cereals containing gluten<br>Crustaceans<br>Molluscs<br>Egg<br>Fish<br>Soya<br>Milk<br>Celery<br>Sulphur dioxide and Sulphites<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen |
| Product claims made e.g. IP, organic | Organic, Halal, Kosher, gluten free. |
| Product recalls in last 12 Months | No |
| Products in production at the time of the audit | The repacking of powdered products. |

## 6. Audit Duration Details

| | | | |
|---|---|---|---|
| On-site duration | 18 man hours | Duration of production facility inspection | 4 man hours |
| Reasons for deviation from typical or expected audit duration | The BRC audit was shorter than the expected duration because it was a simple operation with well laid out QMS. The duration of the production facility inspection was less than 50% of the duration of the BRC audit due to simple repacking operation. | | |
| Next audit type selected | Announced | | |

## Audit Duration per day

| Audit Days | Audit Dates | Audit Start Time | Audit Finish Time |
|---|---|---|---|
| 1 (start date) | 2018-10-09 | 08.55 | 17.22 |
| 2 | 2018-10-10 | 07.50 | 16.25 |
| | | | |

| | Auditor (s) number(s) | Names and roles of others |
|---|---|---|
| Auditor Number | 135059 | S.Brookes |
| Second Auditor Number | N/A | |

## 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 1.1.9)<br>Name / Job Title | Opening Meeting | Site Inspection | Procedure Review | Closing Meeting |
|---|---|---|---|---|
| Tom Stevens/Operations Director | X | | | |
| Joel Scott Paul/Operations Manager | | | | X |
| Phil Barnhill/Quality Manager | X | X | X | X |
| Hannah Pritchard/Quality Manager | X | X(part) | X | X |

| Present at audit | | | | |
|---|---|---|---|---|
| | | | | |

# Non-Conformity Summary Sheet

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

| Critical | | | |
|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Anticipated re-audit date** |
| | | | |
| | | | |
| | | | |

| Major | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| Minor | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| 1 | 3.9.2 | Batch details are not recorded for LPDE bags. | Pcode and batch details of the LPDE bags are now logged in our PS (bespoke purchase/sales system). Newest delivery of bag batch numbers have been noted and we have changed the clean | The bags will now be ordered by the purchasing team who will log this through PS. | QM07.FOR07 - Clean & check record Issue 5 completed 05/11/18 | 2018-11-08 | S.Brookes |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | and check record to include a section for bag Pcode and bag batch number. | | | | |
| 2 | 4.15.1 | Storage against walls was noted in the good unloading area. | Items were moved so that they are no longer stored against the walls. | The warehouse team have been retrained regarding storage of items against walls in the warehouse through a toolbox talk. This will be added to the GMP audit to check monthly. | HSM07.01.31 Perimeter of warehouse in and out training record dated 19/10/18<br><br>Photos of area | 2018-11-08 | S.Brookes |
| | | | | | | | |
| | | | | | | | |

| Comments on non-conformities |
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| |

# Voluntary Modules Non-Conformity Summary Sheet

| Critical | | | |
|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Anticipated re-audit date** |
| | | | |
| | | | |
| | | | |

| Major | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| Minor | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| | | | | | | | |
| | | | | | | | |

# FSMA Module Non-Conformity Summary Sheet

| Critical | | | |
|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Anticipated re-audit date** |
| | | | |
| | | | |
| | | | |

| Major | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| Minor | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| 1 | 117.20 | No lighting survey has been conducted in order to support lighting is adequate. | Lighting survey completed and compared results to the regulations. | Added to yearly schedule to check during GMP audit. | Lux level report October 2018<br><br>Lighting at work HSE guidelines | 2018-11-08 | S.Brookes |
| 2 | 117.305 | QMO7.FOR15 – Clean and check record – MCR version 8 does not include a time of check | Record template changed to include magnet time check. | New form in place. | QM07.FOR15 - Clean & check record MCR Issue 9 completed 06/11/18 | 2018-11-08 | S.Brookes |
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# Detailed Audit Report

## 1. Senior management commitment

### 1.1 Senior management commitment and continual improvement

There is a documented food safety policy signed by Quality Manager and Operations Director and dated 30/07/18 which is in the shared folder on the system with all staff having read access. It is also included in the induction information given to all new employees.

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

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

2018
Reduce the complaints raised due to CCL by 5%. 2017 1.26% YTD 1.13%
Increase supplier audits to 20 per year. Slightly behind due to resourcing.
Increase Internal audit team to 10. 100% Achieved.

2019
Reduce the complaints raised due to CCL by 5%.
Source and purchase a metal detector
Increase supplier audits to 20 next year
HACCP level 2 and external allergen training for all.

These are reported monthly and reviewed at the Management Review meetings held monthly.

Management Review meeting agendas include all elements of 1.1.3. Last Management review meeting was held on 19/09/18. Other meetings held include; Monthly quality meetings covering H&S and quality. Minutes reviewed for 13/09/18.

The site is kept informed of the points listed in 1.1.6 by members of Campden BRI, FSA alert, membership of ESSNA, European Pharmacopeia sources of information and legal foods. These are reviewed by quality team on ongoing basis and before approval of any new product. Last update received 27/09/18.

The 4 non-conformities raised at last year's audit have been resolved and there was evidence that root cause has been identified and actions instigated to prevent recurrence.

## 1.2 Organisational structure, responsibilities and management authority

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

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

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

Goods in procedure – QM07/SOP05 issue 6 dated 27/10/18 (Includes magnet checks)
FTIR testing – QM08/SOP12 issue 5 dated 30/10/17
Repacking – QM07/SOP01 issue 17 dated 27/05/18
Vehicle inspection procedure - QM07/SOP22 issue 2 dated 10/11/16

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

**Details of non-applicable clauses with justification**

| Clause reference | 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 9 and dated 25/09/18.

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

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

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

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

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

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

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

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

There is one flow process diagram QM02/GEN04, currently at version 10 and last verified by the team on 15/08/18. Meeting minutes reviewed.

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

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

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

No CCPs have been identified as limited handling of products on site. The key controls are product approval before starting supply; products are release based on intakes QA testing including rare earth magnet checks and Fourier Transformed Infra-Red check (FTIR) against a previously accepted delivery.

A corrective action procedure is in place.

Verification is carried out during internal audits and the daily verification checks performed. Verification reviews are carried out annually and are based on a review of the system documentation, records, internal audits, deviations and corrective actions, complaints and incidents.

The HACCP plan is reviewed at least annually (last reviewed on 15/08/18), when relevant changes or if a recall occurs. Detail any changes – Update plan to include justification for HACCP ratings – completed. PRP3 (Facilities Maintenance) and PRP7 (Training) updated

**Details of non-applicable clauses with justification**

| Clause reference | Justification |
|---|---|
| 2.9 | No CCPs |
| 2.10 | No CCPs |

## 3. Food safety and quality management system

### 3.1 Food safety and quality manual

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

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

Goods in procedure – QM07/SOP05 issue 6 dated 27/10/18 (Includes magnet checks)
FTIR testing – QM08/SOP12 issue 5 dated 30/10/17
Repacking – QM07/SOP01 issue 17 dated 27/05/18
Vehicle inspection procedure - QM07/SOP22 issue 2 dated 10/11/16

### 3.2 Documentation control

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

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

Vehicle inspection – QM07.FOR06 issue 1
Repack record – QM07.FOR07 issue 4
Foreign body control QM04.POL06 issue 5 dated 23/08/18

### 3.3 Record completion and maintenance

Records are completed manually and electronically and are stored electronically (manual records are

scanned) and backed up daily to three servers.

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

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

## 3.4 Internal audit

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

SM, HLP, JO (Quality) JO – Internal auditor ALCUMUS 23/24/07/18, JSP (Operations), NMS (Procurement) Internal lead auditor ALCUMUS 27 to 31/10/14, PB – Lead auditor ISOQAR 27th to 31st Oct 14. CW – internal auditor ALCUMUS 7th and 8th Dec 2016.

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

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

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

Product release process – 01/03/18 – KK, SM – 2 observations and 1 N/C (COA) NCR 105 (QM08/FOR13) completed 29/03/18
Glass and hard plastics – 24/04/18 – MV, SB – 1 observation raised.
Non-Conformance system – 20/07/18 – SM – 3 observations raised.
Supplier and product approval – 24/09/18 – JO, HS - 3 observation raised – awaiting sign off.

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

Monthly hygiene/fabrication and GMP inspections are carried out, based on risk assessment. Reports reviewed included those for August and September 2018 – 2 minors closed 20/09/18 (QM08.FOR27).

## 3.5 Supplier and raw material approval and performance monitoring

### 3.5.1 Management of suppliers of raw materials and packaging

A risk assessment of raw materials has been carried out, last reviewed 08/10/18 with products assessed for allergen, foreign body, chemical, microbiological and substitution/fraud risks. The assessment is also based on nature of material (e.g. herbs), volume, type of certification and historical issues with risk-based testing regimes in place. With the controls in place all suppliers are assessed as low risk.

Suppliers of products are approved and monitored by the Quality Manager (PB) using supplier and product approval procedure (QM07.SOP08 issue 5 dated 12/07/18) and assessment of suppliers is based on risk, quality and historical compliance.

An approved supplier list is in place which is a IT live list. This lists supplier, manufacturer, date of approval, approved by, basis of approval or non-approval and due date.

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

Examples of supplier approvals reviewed included;

Blueberry Juice Powder supplier – NNG - Audited 01/04/16 by Quality Manager, 4 minors raised and closed within 30 days. ISO 22000 HACCP expires 09/08/20. QM07.FOR04 dated 25/04/17
Wheatgrass Powder supplier – TIG – BRC for Spirulina and chlorella supply – Site code ****439 expires 02/08/19 - (ISO 22000 for wheatgrass powder expires 19/08/19). FDA registration – 13145650044 - Audited 21/04/15 by Quality Manager 2 majors and 2 minors – closed within 30 days. QM07.FOR04 dated 27/04/18. QM07.FOR09 (wheatgrass) signed 16/12/16.
Fenugreek Extract supplier VEA - FSCC 22000 expires 23/10/19, QM07.FOR04 signed 08/10/18.
Turmeric supplier – SAQ – BRC agent - manufacturer PL – BRC 7 including traded goods, site code ****267 expires 24/06/19
LDPE bags supplied by Polybags ltd - ISO9001 expiries 14/9/18 (awaiting new cert). QM07.FOR04 signed 10/10/18.

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

BRC certificate for Spirulina and chlorella from site code ****439 was checked during the audit via the BRC database and found to be genuine and valid.

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

Suppliers' traceability procedures have been assessed by the Quality Manager via SAQ.

Agents and brokers are used and details of manufacturing site are obtained. Examples reviewed for;
Turmeric supplier – SAQ – BRC agent - manufacturer PL – BRC 7 including traded goods, site code ****267 expires 24/06/19.
Spice supplier/agent SAQ – BRC 7 including traded goods, site code ****267 expires 24/06/19.
Herb and spice supplier/agent CABD – BRC Storage and distribution including wholesale and BRC 7 site code ****303 expires 08/09/19.

Ongoing monitoring of supplier performance is via non-conformance system.

Exceptions are covered under supplier and product approval procedure (QM07/SOP08). Products are tested before use if purchased from unapproved suppliers.

### 3.5.2 Raw material and packaging acceptance and monitoring procedures

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

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

An example of a material intake issue was seen for PO228009, P01102, complaint ref S237/18, 1000kg NCR 115 - returned to supply due to FB continuation.

### 3.5.3 Management of suppliers of services

Service suppliers are approved and monitored by Quality Department using supplier approval and monitoring procedure doc ref QM06/GDE01 issue 2 dated 08/10/18 and have appropriate contracts.

These were reviewed for suppliers of laundry (SL) signed 28/1/14 and haulier (Malco freight) signed 06/11/15.

### 3.5.4 Management of outsourced processing and packing

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

The companies used are either;

NVR – BRC site code ****101 expires 17/06/19 – POs stipulate processing requirement and terms and conditions. Example reviewed for Product P29015, PO 226265NVRP - Technical agreement signed 01/11/17.

PBD - approved by site audit by Quality Manager 23/10/15 and has MHRA GMP certification MIA37212 expires 10/11/18. Technical agreement signed 21/08/15

WPB – BRC 7 site code ****080 expires 05/03/19

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

On receipt back to site the products are checked by FTIR testing to ensure it is similar to last batch made.

Example of records seen for P29015 batch 16673 FTIR tested 01/08/18, External Lab micro test results within specification – Concept Life Sciences UKAS 1549 dated 08/08/18.

### 3.6 Specifications

Copies of suppliers' specifications are held for all raw materials and packaging.

Manufacturing instructions/specifications are available at workstations and confirm compliance with finished goods specifications.

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

Specifications are agreed with customers by email example reviewed for customer (BIT) for P05056 dated 19/12/16, customer SAQ dated 21/03/18. Customer (VIA) for P23020 dated 03/09/18, customer SAQ filled 15/01/16.

The following specifications were reviewed and found to be compliant;

Raw material
Blueberry juice powder (spec not dated) - CoA reviewed against spec on each delivery
Wheatgrass powder v3 dated 25/04/17
Turmeric supplier spec dated 12/01/18

Finished product
Blueberry juice powder dated 19/09/17
Wheatgrass powder GF dated 19/10/18
Finished product spec v4 dated 28/03/18

Packaging
LDPE bags DOC V2005/1

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

## 3.7 Corrective and preventive actions

Corrective action procedure is part of complaints procedure doc ref GM08/SOP09 issue 6 dated 08/10/18. Non-conformities that result in a risk to product safety, legality or quality are investigated and recorded in line with clause requirements. This includes the assessment of the consequences of the non-conformity by the quality team and verification of corrective action by the Quality Manager.

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

Examples seen for Internal audits and complaints;

Supplier complaint - Product P19251 225kg complaint ref S356/18 dated 08/08/18 – closed 14/09/18. Supplier blacklisted.
Supplier complaint (informal) – Product P0307 150kg ref S315/18 dated 03/07/18 – closed 28/09/18
Customer complaint – Product 02171 25kg ref 18/206C dated 20/04/18 – closed 28/06/18 – NCR – 127 Allergic reaction.

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

## 3.8 Control of non-conforming product

Non-conforming products are identified by hold stickers with reason of non-conformance and quarantined on the PS system. The Quality department is informed and are responsible for the holding and release of

products. All incidents of non-conforming product are recorded on QM08.FOR04 version 7 as detailed in procedure QM08/SOP01 issue 2 dated 24/10/16. A concessions procedure is also in place QM08/SOP04 issue 4 dated 27/10/17.

Examples reviewed for 2 items held in location 4 of the goods in area; P30087, Pack ID 1338330, batch 100003191 (2 x 5l) and P0902, Pack ID 1337491, batch 201804144 (1 x 25kg) both damage related.

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

## 3.9 Traceability

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

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

Traceability systems of suppliers approved via questionnaire only are verified by Quality Manager (PB) via QM07.FOR02 issue 2.

No rework.

The company carry out an annual traceability challenge including mass balance, and this was undertaken forwards and backwards on Chondroitin Sulphate P03240 batch CS20170470 on 18/09/18. Mass balance 1000kg – 100%

A traceability challenge and mass balance was undertaken during the audit on product Wheatgrass Powder GF, P23020, batch 20171120. The exercise was completed in <4 hours. Mass balance for batch - 2500kgs from supplier TIG – 1697kg dispatched including 11kg to customer VIA, 803kg are pending and 3kg samples. See minor N/C

Minor N/C 1, clause 3.9.2. Batch details are not recorded for LPDE bags.

## 3.10 Complaint handling

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

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

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

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

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

In 2017 – Customer complaints – 612 (158 quality related mainly OOS) and raised 475 supplier complaints.
YTD – Customer complaints – 453 (140 quality related mainly organoleptic/visual) and raised 449 supplier complaints.

Examples reviewed for;

Supplier complaint - Product P19251 225kg complaint ref S356/18 dated 08/08/18 – closed 14/09/18. Supplier blacklisted.
Supplier complaint (informal) – Product P0307 150kg ref S315/18 dated 03/07/18 – closed 28/09/18
Customer complaint – Product 02171 25kg ref 18/206C dated 20/04/18 – closed 28/06/18 – NCR – 127 Allergic reaction.

Quarantined product;
P30087 – Pack ID 1338330 – batch 100003191 (2 x 5l) ref S289/18 raised 20/06/18.
P0902 – Pack ID 1337491 – batch 201804144 (1 x 25kg) ref S445/18 raised 27/09/18

## 3.11 Management of incidents, product withdrawal and product recall

The company has comprehensive procedures doc ref QM08/SOP02 issue 10 dated 21/09/18 and an out of hours contact list for all key members of staff, customers and organisations including the Certification Body. The requirement to notify the Certification Body within three days of the decision to issue a recall is included. There is a business continuity plan QM02/GDE01 issue 2 dated 26/10/17.

A recall challenge is undertaken by the company with the product traced to the customer. The last challenge was undertaken on Product P03240 batch CS20170470 on 18/09/18. The requirement to review the recall/withdrawal procedure is included within the report. Exercise started 9.55 and completed 10.40.

## 3.12 Customer focus and communication

There are no customer branded goods and no specific customer requests.

## Details of non-applicable clauses with justification

| Clause reference | Justification |
|---|---|
| 3.9.4 | No rework. |
| 3.12 | No customer specific requests |

## 4. Site standards

### 4.1 External standards

The site occupies approximately 9200 $m^2$ and production and storage buildings occupy 7400 $m^2$.

The site was constructed in 2015 as a purpose built.

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

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

### 4.2 Security

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

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

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

There are no tanks or silos with external openings.

Staff are trained in site security procedures.

A documented security assessment has been carried out QM02/FOR02 issue 3. A security review was carried out on 27/09/18 and the necessary controls are implemented with reporting to site for all visitors and contractors.

### 4.3 Layout, product flow and segregation

The site is classified as low risk/enclosed and these areas are defined on the site plan doc ref QM06/FOR08 issue 6. The area is divided into two separate risk areas- white for clean room where products are packed and are open and amber for warehouse and lab.

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

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

There were no temporary structures noted.

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

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

Floors are coated and impervious.

There are no suspended ceilings or roof voids.

There are no external windows within the production areas.

Internal windows are plastic and all lights are covered and protected.

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

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

External doors are either key pad secured, alarmed (fire exits) or kept closed/screened except when in use for material movements.

## 4.5 Utilities – water, ice, air and other gases

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

Report seen for Concept Life Sciences – sample date 18/09/18

Changing room water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, TVC@22C for 72 hours 1cfu/ml, TVC@37C for 48 hours 51cfu/ml)

Lab main water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, TVC@22C for 72 hours 128cfu/ml, TVC@37C for 48 hours 238cfu/ml)

Wet room water (presumptive coliform <1cfu/100ml, E. coli <1cfu/100ml, TVC@22C for 72 hours 3cfu/ml, TVC@37C for 42 hours 69cfu/ml)

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

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

## 4.6 Equipment

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

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

## 4.7 Maintenance

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

## 4.8 Staff facilities

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

There are no high risk/high care facilities.

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

There is a no catered canteen.

Staff are provided with vending machines, microwave and refrigerators which were clean and temperature monitored and recorded on doc ref QM08.FOR29 (Fridge temperature record).

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

## 4.9 Chemical and physical product contamination control

### Raw material handling, preparation, processing, packing and storage areas

### 4.9.1 Chemical control

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

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 5 dated 23/08/18 with a registration system for scissors and cutters. These are issued to operator and signed back on a daily basis.

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

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

### 4.9.3 Glass, brittle plastic, ceramics and similar materials

Monthly glass and brittle plastic audits are carried out by the assistant Quality Manager doc ref QM08.FOR25 issue 2. An appropriate glass breakage procedure QM08.SOP13 issue 3 dated 13/09/17 is in place which includes isolation, cleaning and authorised clearance inspection procedures. Breakages are recorded on form QM08.FOR28.

No breakage incidents have been recorded for the last 12 months – NCR report checked.

### 4.9.4 Products packed into glass or other brittle containers

No products are packed into glass

### 4.9.5 Wood

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

## 4.10 Foreign-body detection and removal equipment

### 4.10.1 Foreign-body detection and removal equipment

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

Foreign body control policy QM04.POL06 issue 5

### 4.10.2 Filters and sieves

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

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

### 4.10.3 Metal detectors and X-ray equipment

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

### 4.10.4 Magnets

A rare earth magnet is used for raw material sampling only to check material received and is not as foreign body control or removal equipment. Magnet certificated by Greenwood magnetics dated 28/09/18 – gauss 5277 (required 5000).

### 4.10.5 Optical sorting equipment

No optical sorting equipment is used.

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

No rigid packaging.

### 4.11 Housekeeping and hygiene

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

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

Repack procedure details that all used utensils and waste from previous product handling activities are removed from the area and this is verified by buddy check documented on Repack record – QM07.FOR07 issue 4. Example reviewed for trace challenge 31/08/18 P23020.

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

Start-up hygiene checks are documented for all key processes and equipment and are documented on repack record QM07.FOR07 issue 4 within the repacking area. Environmental swabbing is carried out quarterly e.g. hand swabbing and surface swabbing, with records retained. Last hand wash and repack surfaces report dated 18/09/18.

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

Limits of acceptable and unacceptable cleaning are defined by visual clean. Cleaning is verified by documented second checks listed as buddy check for each product changeover.

### 4.11.7 Cleaning in place (CIP)

CIP systems are not used.

### 4.12 Waste / waste disposal

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

Waste is collected from site by licensed contractors BIFFA CBDU104360 expires 23/05/2019. All food waste is sent for anaerobic digestion.

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

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

## 4.13 Management of surplus food and products for animal feed

There are no customer branded products or surplus food products and there are no products on site which are intended for direct consumption.

A range of products are purchased as food grade but may also be used for feed materials; The site has FEMAS certification with KIWA expiry 31/03/20. Site is registered with Cambridgeshire County Council, approval number GB026E216.

## 4.14 Pest Control

External contract with Prokill (BPCA M15/737) consists of 12 routine visits and 4 inspections. Full records of pest control are maintained including site plan dated 03/11/16 (Verified for external BS 11, Internal 28, moth pot 19 and EFK 13), bait data sheets, operative training records e.g. Technician GP - RSPH level 2 04/01/11, records of inspections and treatments. The last visit to site was carried out on 09/10/18 with no recommendation although increased external activity was noted and some external toxic baits have been introduced. Other records reviewed included; 03/10/18 follow up re mouse sighting and discovery of flour beetle (Supplier issue) one off incident. 12/09/18 – boring insects on incoming pallets – pallets removed from site.

EFKs are situated throughout the site and catch tray analysis is performed quarterly.

In-depth pest control surveys are undertaken at a frequency based on risk and the last one was 12/9/18 – 6 housekeeping issues raised all completed 24/09/18.

All toxic baits are secured. All recommendations are completed by the company in a timely manner. No evidence of infestation was found or has been identified during visits. No issues highlighted through trending reports.

Employees have been trained to understand the signs of pest activity and to report any evidence of pest activity to the Quality team.

## 4.15 Storage facilities

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

Minor N/C 2, clause 4.15.1. Storage against walls was noted in the good unloading area.

Products are long shelf life and are stored on site. There is no outside storage.

FIFO systems are managed via PS stock control system to ensure products are used and despatched in correct order.

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

## 4.16 **Dispatch and transport**

Traceability is maintained during transportation by logging the batch of the goods against the sales order and is recorded on the product label.

Vehicle checks are recorded for loading and unloading of vehicles. QM07.FOR06 issue 1 example reviewed for traded good trace challenge 03/09/18 for customer arranged haulier S.

Approved third party hauliers are used and detailed contracts in are place which include security of load, cleaning, breakdown and maintenance and meet the requirements of this section. Example of contract seen for Malco Fright Ltd signed 06/11/15.

**Details of non-applicable clauses with justification**

| Clause reference | Justification |
|---|---|
| 4.2.3 | No external storage tanks or intake pipes |
| 4.3.5 | No high risk/care areas. |
| 4.3.6 | No high risk/care areas. |
| 4.3.7 | No high risk/care areas. |
| 4.3.9 | There are no temporary structures. |
| 4.4.4 | No high risk/care areas. |
| 4.4.6 | No suspended ceilings in production areas. |
| 4.4.8 | No glass windows which pose a risk to product. |

| | |
|---|---|
| 4.4.13 | No high risk/care areas. |
| 4.5.3 | Only potable water is used. |
| 4.5.4 | Ice, steam and gas are not used. Compressed air is used for machinery operation only. |
| 4.7.5 | No high risk/care areas. |
| 4.7.7 | No engineers workshop |
| 4.8.4 | No high risk/care areas. |
| 4.8.5 | No high risk/care areas. |
| 4.8.10 | No catering facilities provided |
| 4.9.1.2 | No strongly scented or taint forming materials are used. |
| 4.9.2.2 | No staples etc. |
| 4.9.4 | No product packed into glass or brittle containers |
| 4.10.1.2 | No foreign body detection or removal equipment used |
| 4.10.1.3 | No foreign body detection or removal equipment used |
| 4.10.1.4 | No foreign body detection or removal equipment used |
| 4.10.3.2 | No metal detection or x-ray on site |
| 4.10.3.3. | No metal detection or x-ray on site |
| 4.10.3.4 | No metal detection or x-ray on site |
| 4.10.3.5 | No metal detection or x-ray on site |

| | |
|---|---|
| 4.10.5 | No optical sorting equipment used |
| 4.10.6 | There are no jars, cans and other pre-formed rigid containers. |
| 4.11.3 | No high risk or high care areas |
| 4.11.7 | No CIP |
| 4.12.3 | No unsafe or trademark waste |
| 4.13 | No surplus food or product for animal feed |
| 4.14.3 | Pest control is contracted externally. |
| 4.15.4 | No controlled atmosphere storage areas required. |
| 4.15.5 | No outside storage required for product. |
| 4.16.3 | No temperature-controlled transport required. |
| | |

## 5. Product control

### 5.1 Product design/development

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

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

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

### 5.2 Product labelling

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

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

No customer branded products produced on site.

## 5.3 Management of allergens

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

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

All allergens are identified on the raw material specifications (PS system). Allergens are stored together with non-allergenic products however this practise has been carefully risk assessed via the HACCP plan and both warehouse practises and product packaging (double bagged) such that the risk of cross contamination is adequately controlled. There is a Spillage control procedure HSMO5 issue 1 dated 30/10/17 in place.

Visitor questionnaires include questions relating to allergens.

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

All products are single ingredient, there is no rework.

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

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

They are validated by extensive external lab testing across various batches e.g. ALS UKAS 1282 P23020 batch 20150428, dated 28/10/15, Alta bioscience UKAS 245 ref 5838 batch 20160318 dated 30/06/16 and ref 9453 batch 20160718 dated 30/05/17 and Concept Life Science UKAS 1549 batch 20170505 dated 14/07/17 all results <5ppm. Supplier testing of each batch as documented on CoA, seen for batch 20171120 as part of trace challenge, CoA <5ppm gluten. Supplier BRC 7 expires 02/08/19.

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

## 5.4 Product authenticity, claims and chain of custody

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

A documented vulnerability assessment QM02.FOR02 has been carried out as part of the HACCP study.

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

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

Halal cert ref CCL/FI/B/006798 expires 01/05/19
Kosher cert ref 37386 expires 09/12/18
Organic (Soil Association) licence number DA18397 (GB-ORG-05) expires 31/03/19.

Single ingredient products with full segregation.

## 5.5 Product packaging

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

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

All dry products are double bagged and sealed with black cable ties. Bags are typically 50mu gauge LDPE clear as customers would like to see product on receipt.

## 5.6 Product inspection and laboratory testing

### 5.6.1 Product inspection and testing

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

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

Example reviewed for; Product P35056 – Micro – Supplier testing via Eurofins China dated 09/05/17 tested for Aerobes 60cfu/g, Coliforms <10cfu/g, Salmonella not detected/25g, E.Coli <10cfu/g, mould 65 cfu/g and yeast <10 cfu/g.

Example reviewed for; Product P23020 – Micro – Concept Life Science dated 13/07/17 tested for Presumptive E.Coli <10cfu/g, Coliforms <100cfu/g, Salmonella not detected/25g, Staph aureus <20cfu/g, mould 120cfu/g and yeast <20 cfu/g.

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

Example reviewed for; Product P35056 – Pesticides – Eurofins China dated 09/05/17 – all results within tolerance.

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

The following tests are carried out on site; FTIR for every batch. Example seen for trace challenges during the facility inspection for P35056 batch 210712046 dated 18/06/18 >99% match and P23020 Batch 20171120 dated 18/06/18 – 99.8% (Herbals >95%, Chemicals >98%). A visual check against photo and CoA verses specification check are also conducted.

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

Example micro report was seen for the following by Concept Life Science (UKAS 1549) Product P08059 - tested on 04/05/18 for life extension and tested for presumptive Coliforms <10cfu/g, E.Coli <100 cfu/g, Aerobes 10, Salmonella not detected/25g, mould and yeast <20 cfu/g and Bacillus cereus <20cfu/g. Water activity 0.453 dated 08/05/18.

## 5.6.2 Laboratory testing

The external laboratories used are accredited as follows: Concept Life Science (UKAS 1549) Eurofins China/Germany and ALS (UKAS 1282)

There is a FTIR room only.

## 5.7 Product release

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

## Details of non-applicable clauses with justification

| Clause reference | Justification |
|---|---|
| 5.2.3 | No nutritional/suitability or consumer claims are made. |
| 5.3.5 | No rework of allergen containing material. |
| 5.3.6 | No warning labelling is used |
| 5.4.3 | No ingredients are of particular risk of adulteration or substitution. |
| 5.4.4 | There are no specific claims (provenance, breed, IP etc.) |

| | |
|---|---|
| 5.6.2.2 | No onsite lab. |
| 5.6.2.4 | No onsite lab. |
| | |

## 6. Process control

### 6.1 Control of operations

Documented process specifications and work instructions are in place e.g. Repack procedure Doc ref QM07.SOP01.

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

There is no in-line monitoring.

Audible alarms and dataloggers are fitted to small storage chiller which is used for specialist ingredients. This is more for product quality rather than food safety. Datalogger is linked to the alarm system which is linked to Quality specialist via PC.

Procedure FTIR testing doc ref QM08.SOP12 is in place in the case of equipment failure or deviation of the process from specification.

### 6.2 Labelling and pack control

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

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

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

### 6.3 Quantity, weight, volume and number control

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

### 6.4 Calibration and control of measuring and monitoring devices

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

Scales are calibrated annually and checked internally daily against test weights calibrated annually by Blake and Boughton. Check weights 5kg, 200gr and 1g calibrated 14/11/17

Calibration certificate seen for:
Ohaus scale D31P60BR, serial number: B418558664 calibrated 14/11/17,
Adam GFK 75 scale, serial number: AE5532866 calibrated 14/11/17
AD FX scale, serial number: 8900389 calibrated 14/11/17

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

The calibration procedure doc ref QM08/SOP11 issue 4 dated 31/08/17 details the corrective action procedure.

**Details of non-applicable clauses with justification**

| Clause reference | Justification |
|---|---|
| 6.1.3 | There are no inline monitoring devices which control process parameters or product quality. |
| 6.1.4 | No variation in processing conditions in equipment critical to product safety & quality. |
| 6.2.4 | No on-line vision equipment is used |
| 6.3.2 | All product quantities are covered by legislation |
| 6.4.1 | No CCPs. |

## 7. Personnel

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

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

Agency staff are supplied pre-screened according to the agency and company agreement.

Example reviewed for K.T (Goods In sampler) induction which includes personnel hygiene, security, pest awareness, food safety, commination control, allergens and HACCP dated 24/09/18.

Detailed individual training records and a list of approved trainers are kept. There are no CCPs.

Staff training records reviewed included:

AT - AD Technician – FTIR testing – 02/10/18, induction which includes personnel hygiene, security, pest awareness food safety, commination control, allergens and HACCP dated 07/08/17. Concessions 2/10/18
KT - Goods In sampler - Goods inspection process 25/09/18
L.W – Cleanroom Assistant - Repacking procedure 4/05/18, Foreign body control 17/09/18, Glass and brittle plastics 09/10/18, Allergens 08/10/18, spillage procedure 01/10/18, glass breakage 01/10/18
J.C – Warehouse team leader – vehicle inspection 14/11/16, Spillage 26/10/15

Staff interviewed during the audit were competent in their roles e.g. Clean room team leader K.L Warehouse team leader JC.

A programme of refresher training on updated procedures is in place via on job monitoring and as part of annual personnel development plan.

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

Personal hygiene standards, which meet clause requirements, are documented and covered during induction training and basic food hygiene training (carried out in house). Site hygiene is detailed in QM06/SOP02 issue 2 dated 26/10/17 and the foreign body control policy doc ref QM04.POL06 issue 5 dated 23/08/18.

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

Blue plasters are controlled via issue log and sign back at end of the day to ensure it is intact.

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

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

## 7.3 Medical screening

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

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

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

## 7.4 Protective clothing: employees or visitors to production areas

Documented procedures are in place for the wearing of protective clothing. Disposable, single use overalls are used by employees. Company issued and externally laundered protective clothing is provided with daily changes. Visitors are required to wear hair nets and disposable coats.

The external laundry, Swiss Laundry, operates procedures which meet clause requirements. Approved via SAQ and contract dated 28/01/14.

Protective clothing is changed daily, based on risk.

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

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

**Details of non-applicable clauses with justification**

| Clause reference | Justification |
|---|---|
| 7.1.2 | No CCPs |
| 7.2.4 | No metal detection on site |
| 7.4.4 | There are no high risk or high care areas |
| 7.4.7 | All items either suitable for laundering or disposable |
| | |

## Module 8 - Traded Goods

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| **Scope** | **Trading of a range of nutritional food ingredients including herbals, vitamins, minerals, amino acids, enzymes, probiotics, antioxidants, oils, gums, sweeteners and dietary supplements.** |

### 8.1 Approval and performance monitoring of manufacturers/packers of traded food products

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

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

Suppliers of products are approved and monitored by the Quality Manager (PB) using supplier and product approval procedure doc ref QM07.SOP08 and assessment of suppliers is based on risk, quality and historical compliance.

An approved supplier list is in place which is a live list. This lists supplier, manufacturer, date of approval, approved by, basis of approval or non-approval and due date.

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

Supplier questionnaires are issued every three years and suppliers are required to notify the site of any significant changes in the meantime by updating questionnaire. There is an annual supplier re-approval

form QM07.FOR12 covering specifications, certification checks, changes to material or process and a re-check RASFF/google for any evidence of contamination risk for the material. CoAs are received with each batch and each batch is FTIR tested.

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

Suppliers' traceability procedures have been assessed by the Quality Manager (PB) via SAQ.

Majority of suppliers are the primary manufacturer of materials. Traders, agents and brokers are used for some raw materials. Information (specification, SAQ & CoA) to enable the approval of the manufacturer has been obtained directly from the manufacturing site as per directly sourced materials.

Turmeric supplier – SAQ – BRC agent - manufacturer PL – BRC 7 including traded goods, site code ****267 expires 24/06/19.

The following supplier approval files were reviewed;

Blueberry Juice Powder supplier – NNG - Audited 01/04/16 by Quality Manager, 4 minors raised and closed within 30 days. ISO 22000 HACCP expires 09/08/20. QM07.FOR04 dated 25/04/17
Wheatgrass Powder supplier – TIG – BRC for Spirulina and chlorella supply – Site code ****439 expires 02/08/19 - (ISO 22000 for wheatgrass powder expires 19/08/19). FDA registration – 13145650044 - Audited 21/04/15 by Quality Manager 2 majors and 2 minors – closed within 30 days. QM07.FOR04 dated 27/04/18. QM07.FOR09 (wheatgrass) signed 16/12/16.
Fenugreek extract supplier VEA - FSCC 22000 expires 23/10/19, QM07.FOR04 signed 08/10/18.
Turmeric supplier – SAQ – BRC agent - manufacturer PL – BRC 7 including traded goods, site code ****267 expires 24/06/19

Ongoing monitoring of supplier performance is via non-conformance system.

Exceptions are covered under supplier and product approval procedure doc ref QM07/SOP08. Products are tested before use if purchased from unapproved suppliers.

## 8.2 Specifications

Copies of suppliers' specifications are held for all raw materials.

Example – supplier NNG, Blueberry Juice Powder (spec not dated) - CoA reviewed against spec on each delivery.

Finished product specifications are generated by the company based on raw material specification and are supplied to customers on the company's format. The following specifications were reviewed and found to be compliant:

Raw material
Blueberry Juice Powder (spec not dated) - CoA reviewed against spec on each delivery
Wheatgrass Powder v3 dated 25/04/17

Turmeric supplier spec dated 12/01/18

Finished product
Blueberry Juice Powder dated 19/09/17
Wheatgrass Powder GF dated 19/10/18
Finished product spec v4 dated 28/03/18

Specifications are reviewed on receipt of each delivery or where changes occur.

## 8.3 Product inspection and laboratory testing

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.

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

Testing results reviewed as part of trace challenge on Blueberry Juice Powder P35056, PO234946, batch 201712046

Another example reviewed for Turmeric powder – supplier SAQ P20095. Micro - Concept Life Services UKAS 1549 dated 05/03/18. E.coli <10 cfu/g, Entro <10 cfu/g, Aerobes <10 cfu/g, Y&M <20 cfu/g, Salmonella ND.
Eurofins Germany dated 02/03/18 - Illegal dyes, HM, PAH, Aflatoxin, Ochratoxin A. Results within limits.

## 8.4 Product legality

Product legality is assessed prior to purchase and with consultation with Trading Standards or by obtaining import authorisations.

## 8.5 Traceability

A recording system is in place with all products coded at intake to allow for full traceability through the PS system via bar code scanners. All activity from purchase order to sales and dispatch is logged via the PS system.

The traceability system is computerised and operates on a batch system with a unique batch code assigned based on purchase order.

A traceability challenge and mass balance was undertaken during the audit on Blueberry Juice Powder P35056, PO234946, batch 201712046. Purchased 750kg 16/02/18, delivered 50kg to customer (BIT) 03/09/18. Mass balance = 0.036kg loss.

## Module 9: Management of Food Materials for Animal Feed

| Scope | |
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### 9.1 Management Commitment

### 9.2 HACCP

### 9.3 Outsourced Production

### 9.4 Specifications

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| **9.5 Traceability** |
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| **9.6 Chemical and Physical Product Contamination Control** |
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| **9.7 Labelling** |
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| **9.8 Training** |
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## Module 11: Meat supply chain assurance

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| **Scope** | |
| **11.1 Traceability** | |

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| **11.2 Approval of meat supply chain** |
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| **11.3 Raw material receipt and inspection** |
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| **11.4 Management of cross-contamination between species** |
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| **11.5 Product testing** |
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| **11.6 Training** |
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# Module 12: AOECS Gluten-free Foods

| Scope | |
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## 12.1 Senior management

## 12.2 Management of suppliers of raw materials and packaging

## 12.3 Outsourced production

## 12.4 Specifications

## 12.5 Management of gluten cross-contamination

## 12.6 Management of incidents, product withdrawal and product recall

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| **12.7 Labelling** |
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| **12.8 Product inspection and laboratory testing** |
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## Module 15 FSMA Preventive Controls Preparedness Module

| Item no. | Clause | Module item | Conforms (Y/N) | Comments |
|---|---|---|---|---|
| 1 | 117.20 | Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting. | N | Lighting is generally suitable and sufficient to permit effective cleaning of hands and maintenance of personal hygiene and facilitates the changing of personal protective clothing.<br><br>Minor N/C 1. No lighting survey has been conducted in order to support lighting is adequate. |

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| 2 | 117.37 | The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage. | Y | Water is not used in the process. Domestic piping is as UK building regulations. No backflow or cross-connection from waste water and sewage pipework.<br><br>The site water distribution schematic has been reviewed by Facilities Office with no backflow or cross-connection from waste water and sewage pipework issues identified.<br><br>Water testing in place. |
| 3 | 117.40 | All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant.<br><br>Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact. | Y | All food contact surfaces of plant equipment (tables) / utensils (scopes, sieves) are made of corrosion resistant materials, such as 300-series stainless steel or food grade plastics.<br><br>Seams on food surfaces observed as part of the facility tour were seen to appropriate to standard requirements.<br><br>The site has extensive cleaning procedures which include inspection and verification.<br><br>Micro and allergen cross contact results indicate that there are no installation issues. |
| 4 | 117.80 | Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117. | N/A | No ice is used for the process. |
| 5 | 117.110 | Where defect action levels (DALs) are established for a food, quality control operations must reduce defects to the lowest level possible.<br><br>Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot. | Y | The site inspects incoming raw materials and have established DALs which are lower than the FDA Defect level limits.<br><br>The site has implemented quality control operations to reduce defects to the lowest level possible.<br><br>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 |

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| | | | | exceed site DALs are returned with N/C raised. |
| 6 | 117.130 (a) | The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility:<br>• economic adulterants which affect food safety<br>• environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step<br>• radiological hazards<br>• unintentional adulterants that affect food safety. | Y | Economic adulterants, radiological hazards and unintentional adulterants have been considered as part of the sites food safety hazard analysis and TACCP risk assessment.<br><br>These include; Historic Incidents, Foreign Bodies, Solvent Residues, Heavy Metals, Process Impurities, Pesticide Residues, Adulteration Risk – Producer, Adulteration Risk – Supply Chain, Substitution Risk – Producer, Substitution Risk – Supply Chain, Illegal Dyes, Microbiology, Mycotoxins, Allergens, Nuts / Nut Products, Skin Allergens, Irradiation, GMO, Animal Derivative, Antibiotic Residues, CMR, Bio Security and Security, as detailed in the product technical dossier doc ref: QM07/FOR09 version 22 |
| 7 | 117.130 (b) | All identified, known, or reasonably foreseeable hazards must be evaluated to determine 'hazards that require a preventive control' (i.e., significant hazards). | Y | Significant hazards have been considered as part of the sites supplier approval procedure and as part of the food safety hazard analysis and TACCP assessment. |
| 8 | 117.135 | Establish one or more preventive control(s) for each identified 'hazard that require a preventive control' (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act. | Y | Preventative controls have been established for each of the identified hazards. Established positive release procedures are in place with the QA manager (PCQI) and nominated deputies approving product release. A corrective actions procedure doc ref GM08/SOP09 issue 6 dated 08/10/18: includes preventative controls. |
| 9 | 117.139 | Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: | Y | The site withdrawal / recall procedure doc ref QM08/SOP02 includes notifying consignees of how to return or dispose of recalled product, how to conduct effectiveness checks to verify |

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| | | • notifying consignees of how to return or dispose of recalled product<br>• conducting effectiveness checks to verify recall is carried out<br>• appropriate disposal of recalled product (i.e., destroy, divert, repurpose). | | recall is carried out and appropriate disposal of recalled product procedures Observations following the annual mock recall are used as part of the recall procedure review and discussed at the post recall meeting.<br><br>A recall challenge is undertaken by the company with the product traced to the customer. The last challenge was undertaken on Product P03240 batch CS20170470 on 18/09/18. The requirement to review the recall/withdrawal procedure is included within the report. |
| 10 | 117.145 | Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10. | Y | Monitoring activities are in place for each of the preventative controls in place e.g. Goods In procedure – QM07/SOP05 issue 6 dated 27/10/18 (Includes magnet checks).<br><br>The preventive controls qualified individual (PCQI) and authorised deputies are responsible for conducting or overseeing the review of monitoring records within 7 days from the date of creation. They are members of the site Food safety team, understand FSMA requirements, aware of FDA preventative standards and have extensive technical industry experience. |
| 11 | 117.150 | Establish corrective action procedures when preventive controls are not implemented in a manner consistent with the requirements of BRC sections 2.11 and 3.7.<br><br>Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring). | Y | Corrective action procedures are detailed for each of the preventative controls, for example those detailed as part of the internal audits carried out, in line with the Corrective Action/Preventative Action (CAPA) Procedure doc ref GM08/SOP09 issue 6 dated 08/10/18. A concessions procedure is also in place QM08/SOP04 issue 4 dated 27/10/17. |

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| 12 | 117.160 | Validate all established process controls prior to implementation of the food safety plan, upon changes requiring revalidation or within 90 calendar days of the first food production.<br><br>Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility. | Y | All established process controls including allergen, sanitation and supply chain controls are validated by the PCQI / QA Manager / food safety team prior to the implementation of the food safety plan, and / or changes requiring revalidation. |
| 13 | 117.165 (a) | The PCQI (or authorized designee) reviews the monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification.<br><br>The PCQI (or their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been created. | Y | Monitoring and corrective action records are maintained and reviewed by the PCQI (or their authorized designee) within 7 days. |
| 14 | 117.165 (b) | Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following:<br>• sampling procedure to include method, quantity, frequency, and number of samples<br>• analytical method<br>• laboratory conducting an analysis<br>• corrective action procedure where a pathogen is detected. | Y | The site carry out testing according to a sampling plan and testing requirements are detailed via PS system per WO.<br><br>A product testing procedure FTIR testing – QM08/SOP12 issue 5 dated 30/10/17 is in place which identifies: the method, frequency and number of samples to be tested, the analytical method, |
| 15 | 117.165 (c) | Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following:<br>• adequate number and location of sample sites | N/A | |

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| | | • timing and frequency of sampling<br>• analytical method<br>• laboratory conducting the analysis<br>• corrective action procedure where a pathogen is detected. | | |
| 16 | 117.165 | Devices used to **verify** preventive controls must be calibrated. | Y | The site has a documented list of measuring devices which is updated as necessary.<br><br>On site Product testing – All measuring devises utilized in the associated analytical method are calibrated at appropriate frequencies, with calibration activities recorded. Due to the nature of FTIR analysis results are verified against standards prior to being reported.<br><br>FTIR service visit Agilent Technologies 8/10/18. FTIR calibrated internally on a weekly basis against known reference standard.<br><br>A rare earth magnet is used for raw material sampling only to check material received and is not as foreign body control or removal equipment. Magnet certificated by Greenwood Magnetics dated 28/09/18 – gauss 5277 (required 5000). |
| 17 | 117.180 | Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan.<br><br>Document the PCQI's training or qualifications via job experience. | Y | The company have identified a number of PQCIs including PB Quality Manager at CCL, who has 20 + years' experience in total within various food industries with 8 years of this spent with CCL. He regularly audits suppliers and has experience auditing sites over in China. Courses completed include lead auditor training and HACCP level 2. He has successfully implemented and managed food safety plans and BRC. HP Quality manager at CCL who has 5 years' experience in the food |

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| | | | | supplement industry and previously completed a doctorate in bio-inorganic chemistry. Courses completed include lead auditor training and HACCP level 3. HP has successfully implemented and managed food safety plans and BRC. |
| 18 | 117.305 | All records required by 21 CFR § 117 must include:<br>• the date and time of the activity being documented<br>• signature/initials of individual performing the activity or conducting the record review<br>• information to identify the facility (e.g., name and location)<br>• the identity of the product and lot code where applicable. | N | Records reviewed were generally appropriate, see minor N/C and readily available. The sites traceability system identifies the required records.<br><br>Minor N/C 2, clause 117.305. Incoming raw material form QMO7.FOR15 – Clean and check record – MCR version 8 does not include a time of check. |
| 19 | 117.310 | The owner, operator or agent in charge of the facility must sign and date the written food safety plan initially and again upon any changes following reanalysis. | Y | A documented food safety plan is in place, with annual review. |
| 20 | 117.315 | All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours, with the exception of the food safety plan, which must remain onsite. | Y | Records are retained indefinably and are retrievable within 24 hours. |
| 21 | 117.405 | Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities.<br><br>Where a hazard requiring a supply-chain-applied control is identified **and** the control is applied by an entity other | Y | Extensive supply chain procedures have been established which cover supplier approval and verification controls. Verification can be through review of supplier provided verification documentation e.g. third-party audit results, or second party on site audit. All materials received require certificate of conformance |

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| | | than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control. | | / analysis and are subject to onsite testing and positive release.<br><br>Verification is carried out during internal audits and the daily verification checks performed. Verification reviews are carried out annually as part of the HACCP review and are based on a review of the system documentation, records, internal audits, deviations and corrective actions, complaints and incidents. |
| 22 | 117.420 | Supplier approval must be documented **before** receiving and using raw materials and ingredients.<br><br>Verification activities must be conducted **before** receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers. | Y | Supplier approval is documented before receiving and using raw materials and ingredients.<br><br>Raw materials are subject to testing and positive release prior to use. |
| 23 | 117.430 | One or more supplier verification activities (as defined in 21 CFR § 117.410(b)) must be conducted for each supplier **before** using raw materials and ingredients **and** periodically thereafter at an adequate frequency. | Y | Appropriate supplier controls are in place. |