Audit Report **Global Standard Food Safety Issue 9**

1. Audit Summary			
Company name	Bee Health Ltd	Site code	4098255
Site name	BH1 & BH2		
Scope of audit	BH1: The Manufacture and bulk packing of vitamins, minerals and supplements in tablet, powder, soft gel capsules, liquid and oil forms into bulk bags / lined cardboard boxes / Jerry cans / IBC. BH2: The manufacture of 2-piece capsules. The packing of tablets, 2-piece capsules, powders, soft gel capsules, liquids, oils, Lozenges and tea, into glass or plastic bottles / jerry cans / pouches.		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit start date	2024-06-18	Audit finish date	2024-06-20
Re-audit due date	2025-08-16	Head office	No

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

2. Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit programme	Unannounced - Voluntary
Previous audit grade	AA+		Previous audit date	2023-06-26	
Certificate issue date	2024-07-11		Certificate expiry date	2025-09-29	
Number of non-conformities			Fundamental	0	

2. Audit Results		
	Critical	0
	Major	0
	Minor	4

3. Company Details			
Site address	Lancaster Road Carnaby Industrial Estate Bridlington East Yorkshire YO15 3QY		
Country	United Kingdom	Site telephone number	01262607890
Commercial representative name	Andrew Purvis	Email	andrewp@beehealth.com
Technical representative name	Tricia Johnson	Email	tricia.johnson@beehealth.com

4. Company Profile					
Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3
Shift pattern	4 on 4 off shift system 7 days a week, Monday – Friday 8:00-4:00, 9:00-5:00. Packing hall 06:00-14:00, 14:00 to 22.00 and 22:00 to 06:00				
Seasonal site	No				
Seasonal opening times (Start/end date)	Click or tap to enter a date.	Click or tap to enter a date.			
Other certificates held	Soil Association, Organic: Expiry date 31-01-25 Halal HMC: Expiry date 22-06-24 Kosher KOF-K: Expiry date: 31-12-24 MSC: Expiry date: 26-09-24				

4. Company Profile	
	ISO9001: Expiry date: 16-05-25 Sedex/Smeta
Outsourced processes	Yes
Outsourced process description	Ingredient supply to BRCGS site code 10010699, Lozenge production and return to Bridlington for secondary packing.
Regions exported to	Europe Asia North America Other
Company registration number	GBEY 080 Health mark for products of animal origin for export to EU. Issued by Food services 8/4/2021 by East Riding of Yorkshire Council EHO. Registered company 6653237
Major changes since last BRCGS audit	Removal or tinctures from scope. Currently considering whether tea remains in scope. Propolis now bought in milled, converted to lozenges by third party then returned to site. Slight changes in some job roles. Expansion of soft gel department ready for vegan soft gels. Currently the market has product packed to plastic rather than glass. Legacy Solvitt system being phased out and replaced by Monday.com for parent company INW.

Company Description

Established in 1992 with origins in products from bees. Bee Health Ltd' has USA owner 'INW' since 25 March 2021 with registered company in London. Coastal location. Lancaster Road is a former airstrip. Areas is surrounded by flat concrete. The approach road is straight with several roundabouts. The company has two sites. One is owned, two is leased from a landlord. These two premises are 500 meters apart with attached neighbouring premises in between. Total covered area 7,246m² employing 330 direct staff, no agencies, financial turnover ~£47M, staff churn reducing ~ 50% working 4 on 4 off shift system Monday - Friday. Majority of products are contracted customer own label with a lesser quantity to the company's own brand FSC- Food Supplement Company. Some raw materials and packaging are customer specified /supplied.

Product forms include tablet, powders, soft gels, capsules, oils, contract product lozenges. Activities include manufacture of powders blending, tablets pressing, tablet coating, soft gel manufacture, primary and secondary packaging activities.

Site 1-BH1 has two large tablet machines with 6 smaller ones, 3 coating drums, 3 dispensing weigh areas (including 1 for allergens), a wash room, soft gel manufacture area with 3 machines and its own wash room and 2 polishing machine. 5 gelatine tanks. Product packaging includes Bulk bags, lines boxes, Jerricans and IBC.

Site BH2 South west end of road includes main warehouse, two-piece capsule manufacture, packing of oils, liquids, tablets, capsules, powders with six capsule making/packing machines, 3 packing lines for

4. Company Profile

tablets/soft gel/capsules. Also areas present for hand packing into bottles, powder packing room and liquid packing room. Product packaging includes glass bottles, plastic bottles, jerry cans, pouches.

Brands include Bee Health and MSC, and retailer labelled non-prescription vitamins, supplement and mineral products as tablets (coated or non-coated), powders, in 2-piece capsules, soft gel capsules, also liquids, gels, and creams into glass or PET. Defined in HACCP plan: any risk to a vulnerable group is documented on the specification for the product prior to customer approval and all relevant information is kept on system so all can access as required. Complementary pet feeds are formulated using ingredients detailed on the specification and checked for feed additive compliance during the NPD process. Bee Health sales primarily UK 94%, remainder to Europe, Asia and USA. Company has 5000 raw materials, and 1000 customers offering diverse range of options to their client base as a contract manufacturer and supplier for retailer label products.

Products are not sold as beverages however some products are liquid form and consumed as such for example throat spray, include oils and product containing added water. Unannounced visit, auditor gained access to pack house within 30 minutes.

5. Product Characteristics

Product categories	12 - Beverages 15 - Dried food and ingredients 16 - Confectionery 18 - Oils and fats
Finished product safety rationale	Low Risk Ambient products. Low water activity for powders and preservative potassium sorbate

High care	No	High risk	No	Ambient high care	No

Justification for area	According to standards, ambient storage, considered as low risk
Allergens handled on site	Cereals containing gluten Crustaceans Molluscs Egg Fish Soya Milk Celery Sulphur dioxide and Sulphites Sesame
Product claims made e.g. IP, organic	Organic, some products suitable for vegetarians & vegans, Halal Kosher, Gluten Free, Dairy Free for some products – according to

5. Product Characteristics	
	customers request, MSC (but logo not used), Manuka Honey and extra virgin olive oil.
Product recalls in last 12 months	No
Products in production at the time of the audit	Creatine Tablets, Turmeric Capsules, Vitamin D Soft Gel, Zinc Citrate Tablets. Turmeric Capsules. Peppermint soft gel. English Primrose Oil Soft Gel. No beverages. No liquids. Filling hall Line 1 Vitamin D3 -plastic container Line 2 off for cleaning. Line 3 Vitamin B12-Pouch

6. Audit Duration Details			
Total audit duration	24 man hours	Duration of production facility inspection	14 man hours
Reasons for deviation from typical or expected audit duration	None		
Combined audits	None		
Next audit type selected	Unannounced - Voluntary		

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)

Name	Job title	Opening meeting	Site inspection	Procedure review	Closing meeting
Adam Kitching	Operations Director	On site			On site
Andrew Purvis	Managing Director	On site			On site
Tricia Johnson	Head of Quality	On site	On site	On site	On site
Jenny Anderson	Head of Learning and Development			On site	
Jo Downson	Engineering Controller			On site	

Meg Nangle	Head of Research & Development			On site	
Neil Chambers	Head of Engineering			On site	
Tim Frear	HR Director	On site			On site

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/Unannounced	Pass/Fail
2022/08/16	BRCGS Food Safety i9	Announced	Pass
2023/06/26	BRCGS Food Safety i9	Unannounced	Pass

Document control			
CB Report number	B00266/06/2024		
Template name	F908 Food Safety Audit Report Template BRCF613_Audit Report Food 06/01/2023 v.1		
Standard issue	9	*Template issue date*	2022-12-16
Directory allocation	Food	*Version*	1.1

Non-Conformity Summary Sheet

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

Critical		
Clause	Detail	Re-audit date

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

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
4.6.4	No procedure for the movement of static equipment.	The current engineering SOP has been updated QM.ENG.SOP06 to include the movement of static equipment, which will give priority to the safety of the product and the equipment is maintained.	We will ensure that when reviewing and updating engineering SOPs, that all points within the BRCGS scope are covered and actioned.	As our machinery rarely moves from its location once it is in situ, this wasn't considered when writing the SOP.	2024-07-10	NR
4.9.1.1	Site 2. Meeting room tea cupboard is not the designated location for food grade lubricants. Lubricants were stored there. The location is not a secured location.	The food lubricant has been removed from this cupboard and put in the dedicated lubricant cabinet which is locked in the engineering workshop. The managers have been briefed on the use of the room and storage of the lubricants.	The internal meeting room has been added to the hygiene schedule for checking and cleaning,	The cans of lubricant had been requested for the machinery at site 2 but found to not be needed and instead of taking them to the correct place (engineering workshop) they were put out of site in the meeting room at site 2, this office is locked when not in use and was locked on the day of the audit.	2024-07-10	NR
4.11.1	Warehouse storage area has water-stained walls with	The mould on the walls has been cleaned off and	Discussion with the site landlord to plan to the fix	Roof has a leak on it due to the guttering being	2024-07-10	NR

Minor						
	black mould and wet floors upon which pallets of ingredients are directly stood, noted at bay locations ZAA03B, ZAA23D.	repainted with mould resistant paint.	the roof in the longer term as we have already invested £7500 on the repair of the guttering at our own cost. We have briefed the warehouse team to give them instructions on what to do with the stock in the case of rain coming in through the roof and the cleaning up of the floor area.	blocked, this site is not owned by Bee Health, we are in talks with the landlord regarding the longer term fix of the roof and guttering to prevent the rain water coming in.		
7.1.7	SOP 37 requires packaging to be tared on scales for product weight check. Scales in use without applied load displayed zero. Actual expected tare-7g.	Sop has been reviewed and updated; the staff have been trained on the updated version.	We will ensure that SOPs are robust and monitored with the staff.	There is more than one way to carry out the task of hand packing, this was not detailed in the SOP due to the previous writer not being aware of the various ways of hand filling.	2024-07-10	NR

Comments on non-conformities
Click or tap here to enter text.

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical		
Clause	Detail	Re-audit date

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

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

Audit team

Lead auditor		
Auditor number	**First name**	**Second name**
20817	Neil	Radford

Audit team				Attendance (YYYY/MM/DD, 24hr: MM)			Presence	
First name	Second name	Auditor number	Role	Audit Date	Start time	End time	Remote or physical	Professional recognition number
Neil	Radford	20817	Auditor	2024-06-18	08:30	18:30	Physical	
Neil	Radford	20817	Auditor	2024-06-19	08:30	18:30	Physical	
Neil	Radford	20817	Auditor	2024-06-20	08:30	12:30	Physical	

1. Senior management commitment

Site has a Quality Mission statement from INW site-based document. References compliance with technical and legal requirement of the “Sale Of Goods Act 1995”. Policy references safety, legality authenticity. The policy is approved by the MD. Policy was written by Head of Quality and HR Director. Dated signed 31/1/2024 QM.GEN.Pol07 version 13. Food safety act is not referenced in site documentation. Site maintains that is not a requirement of the standard however conceded that the intent is implemented and would be added to documentation.No NC assigned.

Culture plan in place since April 2020 and has recently been refreshed under the new ownership. The new scheme launched two months ago called champions of change organised by HR (JA) with purpose to enable communication and feedback throughout the works force. Examples of activities and timescales; discussed how departments would prefer communications between departments, types of information that their feedback suggests are not being told and changing the bonus scheme. Survey recently conducted April 2024. Action points brought down from head office (parent company). The new scheme supported by group is being communicated to SLT at the present time. Minutes of last meeting was presented. Referenced the following:

General group discussion around topics:
-Net promoter scores
-Training; Lean manufacturing apprenticeship course starting September. Duration a year.
-Management
-Miscommunication
-Radios
-First change assignments based on feedback from shop floor. Next meeting 13/8/24 at which time the actions and timescales will be further formalised.

Referenced on staff notice board was information regarding site GMP score, H&S committee meeting, Air con for packing hall Sept 2024, PPE feedback review target end of June 2024, Reinvestment in packing hall feedback target sept 2024.

A top-level culture plan document has been prepared by the MD. In addition to that the site has activity reported under Health and Safety action plan. Good overall staff engagement was evident through the audit process noted in discussion with batching and hygiene operatives, and goods inward.
The five minor NC assigned at previous BRCGS audit have not repeated.

Food safety and legality objectives: Communicated monthly to SLT in meetings via share-point access. Site has an excel form called KPI trackers updated monthly collated by (RN) Finance Dept, Points include the following. Noted dated report for April.

RTM leavers % 12 months leavers: 53% April
PPM’s typically >95%
Solvitt stock count variance 0.25% error.
GMP audits: number of audits performed RAG rated. Target no red scores. Reported each month.
CPMU (total) objective is 22 max. Actual 17 (April) Based on previous years equivalent sales.
Customer returns. Typically one per month at present.
For internal audits the Head of Quality presented on internal audits. In April five internal audits x3 minor raised with brief description of the NC raised. So noted issues GMP ingredient container damaged. Supplier NC no issues for April. Top three subjects aim for MHRA (to get MIA license)-this is for pharmaceutical industry though site is not chasing that market customers would like it.

Slides also presented for engineering, also HR and Finance, Learning and Development, NPD, R&D. Noted slides for the net promoter scores.

Management review: Data of last monthly management review was 21/5/24 attended by Ops Director, MD, HR Director, Head of Quality, Head of L&D, Head of R&D, H&S Manager, Domestic sales, Export sales, Financial Controller. Head of Engineering. Last annual review was Feb 2024. Meetings chaired by MD. During meeting was identified complaints from a specific customer and presented to customer what actions are being implemented. This was an MD initiative. This was agreed in morning meeting following a point raised in the management review. Site maintains excel sheet on share-point which is live. Daily discussions on action points for safety stats, quality etc.

Monthly and annual leadership meetings including review of objectives. Head of Quality confirmed that agenda covers effectiveness of systems for HACCP Food defense, authenticity, and the food safety and culture plan.
Quarterly HACCP/TACCP monitoring.
Quarterly NPD meetings.
Annual HACCP review.

Confidential reporting system is hosted via QR codes from TV and notice boards and UKG system (clocking training and documentation) suggestion boxes. In house hosted document dated 24/1/23 also Whistleblowing policy hosted by parent company based in USA. Contact phone numbers are provided for the three Directors.

The Head of Quality confirmed that sufficient resources are provided. The management supports project activity with capex board short and medium terms investments. Listed evidence on capex viewed for items such as industrial washing machine for tooling trays etc.

Information about developments and reviews is coming from Food Standards Agency and monthly reviews of RASFF. Refers to Food gov site, soil association information, FSA alerts, checks against health claim register, EFSA web site.

BRCGS certificate displayed on web site. Site has non- food products that cannot be included in scope of food standard.. Hard copy of the BRCGS standard food interpretation guide is held by the head of R&D and head of quality.

Organisational structure was presented for INW updated 27/2/2024 and detailed MD (AP) with six direct reports including Head of R&D (MN), Sales (CJ) and (GB), Operations Director (AK), HR Director (TF) Financial Controller (RN), and HR Director (TF) with three Direct reports Head of Quality (TJ), Environmental Safety Health (PM), Learning and Development (JA).

Key Personnel ‘Deputy’ cover is referenced on Quality Manual Overview QM.HACCP04
Issue Date: 03-05-23 Version No: 13

Reporting food safety issues is organised through the Head of Quality (TJ) with full support of the company HACCP team. The site QMS includes provision for reporting of non-conformance, has procedures for crisis management, close working with Directors and documented evidence for commitment to continual improvement of the food safety culture.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification

2. The Food Safety Plan – HACCP

Detailed in company plan: “To compile the HACCP, a team of people with requisite skills have been drawn together in order to develop a multi-disciplinary including processing, quality, technical, maintenance, and NPD”

The team leader of the HACCP team is trained to level 4 certification and all other members of the team are trained and certified a minimum of level 3 HACCP plus some department managers that are not on HACCP team. Trained on line one day training High Speed.
Additional people with relevant experience are drafted into the team to assist and advise on issues as required and are documented in the quarterly HACCP meetings.
The Bee Health HACCP team consists of:
Head of Quality - Team leader (TJ)
Quality & Hygiene Manager (EL)
Head of Research & Development (MN)
Soft Gel SME (AT)
Shift Manager (LS)
Head of Engineering (NC)
Operations Director” (AK)

The scope of HACCP plan is clearly defined for the product groups.

Tablets are a mixture of active raw materials, blended with additional ingredients such as excipients and bulking agents, these are then compressed into the customer specification these may be coated using a blend of glycerine HPMC and colouring agents. They are either packed in food contact safe plastic bags and then in bulk boxes and shipped to the customer or they are packaged in bottles / cartons / bags or pouches, labelled, and shipped to the customer.

Two-piece capsules are a mixture of active raw materials, blended with additional ingredients such as excipients and bulking agents, these are then encapsulated into two-piece vegetarian or Bovine capsules, to the customer specification, these may require polishing if they are dusty. They are either packed in food contact safe plastic bags and then in bulk boxes and shipped to the customer or they are packaged in bottles / cartons / bags or pouches labelled and shipped to the customer.

Powders are either pure fill (single active ingredient) or a mixture of active raw materials, they can be blended together with additional ingredients such as excipients and bulking agents, these are then bagged and boxed the customer specification They are either packed in food contact safe plastic bags and then in bulk boxes and shipped to the customer or they are packaged in bottles / bags or pouches, labelled and shipped to the customer.
Soft gel capsule shell is a mixture of glycerine, Water Gelatine or starch and potentially colouring agents. The capsule fill is a blend of liquid and powdered raw materials which is then injected into the capsule shell via the soft gel machine. The wet soft gels are polished to remove the excess oil these are then put into trays to dry. Once dried the soft gels are polished for a second time and then graded. The soft gels are then either packed in food contact safe plastic bags and then boxed to the customer specification

shipped to the customer or they are packaged in bottles / bags / cartons then labelled and shipped to the customer.

Liquids / Oils are a mixture of dry and liquid ingredients which can include, flavours, preservatives, and active ingredients. These are then blended / mixed to the customer specification, once blended, or mixed they are then dispensed into suitable containers. These can then be sent to the customer as bulk or packed and labelled in bottles and shipped to the customer.
The plan makes reference also to Catalogue of feed materials & EC regulation the regulation 183/2013 of the European parliament and of the council on additives for use in animal nutrition, 183/2005 feed hygiene. The European parliament and of the council on additives for use in animal nutrition

Prerequisites are referenced as HACCP 05 dated 13/3/24 and includes supplier approval, RM specs, RM intake, ingredients intake liquids and oils packaging and labels intake, lab testing, potable water supply, stock control, allergens controls, glass and brittle materials control, Health screening and personal hygiene, CAYG, foreign body prevention, knife control, pest control, chemical control, traceability, maintenance training, doc control, waste control, control of NC product, calibration, transport, QMS, q, adulteration and deliberate contamination, external lab services, line start up controls, fabrication, nitrogen gas intake, filter change 1mm muslin filtration, chilled storage. Site has an overall process step generic risk assessment HACCP 0830/4/24. Decision tree x 5 questions. PRP have the relevant control procedures referenced in columns. Shows for PRP parameter, dept, hazard, control, limits, procedure for monitoring verification and corrective action frequency. Observed PRP for allergens. At intake risk for bags split, identification control, controls or warehouse manufacture and packing. Products are consumed and used by a various cross section of the public and as such must protect vulnerable people including allergen sufferers, pregnant woman, babies, the elderly and people with certain illnesses for example those taking blood thinning medication. Any risk to a vulnerable group is documented on the specification for the product prior to customer approval and all relevant information is kept on system so all can access as required.
Complementary pet feeds: these are formulated using ingredients which are fit for human consumption and follow the same approval and intake processes they are designed for the species detailed on the specification and are checked for feed additive compliance during the NPD process.

Process flow diagram:
Three flows: 3/6/24 all in version 9 each individual verified and signed as personalised copies.
1 Manufacture and packing of powders capsules and tablets
2 Soft Gel manufacture and packing. Will be version 10 as is moving upstairs.
3 Liquids and propolis manufacture and secondary packing (lozenges case packing after return to site.

Hazard analysis was documented at each process step with consideration to microbiological, physical, chemical, fraud, malicious contamination and allergenic risks. Risk assessment applied and where significant application of codex decision tree. Radiological hazards were noted within the TACCP system and HACCP study. The plan is reviewed in event of change and at least annually.

Risks associated with:
microbiological (Yeast / mould, E. Coli, Salmonella, Staphs, Listeria),
physical (foreign body issues: glass, plastic, wood, hair)
chemical (radiological hazards / specific statements from each supplier, aflatoxins, ochratoxins, pesticides, heavy metals, chemicals for cleaning) contamination,
adulteration and legality has been considered.

The company has determined 2 CCPs on site, sieving (Number 1) & metal detection (Number 2).

Limits for sieving is 2mm mesh, but a 3mm CCP due to the diagonal of the mesh measuring max 3mm when undamaged for powders being dropped being post blend. Sieving also includes 0.5mm mesh for the liquid production at site 1 and liquid packing at site 2.

Metal detection limits are determined as:
Manufacturing (Tablets & 2-piece capsules): 3.0mm Ferrous, 3.5mm Non-Ferrous & 4.0mm Stainless steel. Soft gel capsules: 2.5mm Ferrous, 3.0mm Non-Ferrous & 4.0mm Stainless steel.
Finished products have been risk assessed as not requiring final metal detection, risk assessment available to view at site. (all containers have foil induction seals).

Procedure if metal detector does not work stop, call QA and area manager to investigate and hold to previous check. Sieves checked per batch. Start and end. Records of integrity, cleaning and any findings and reported to (TJ).

The HACCP plan is verified through internal auditing, with monitoring of HACCP and TACCP quarterly, annual review of plan, weekly review of tasks and team performance for QA Management and Head of Quality, Quarterly reviews of complaints, monthly and annual review of site standards. Date of last HACCP review by the HACCP team was recently on 24/4/24.

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

3. Food safety and quality management system

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

The site food safety policies and QMS implements the requirements of the site Food safety and quality policy singed by the MD. The foundation of the QMS is formalised as the sale of Goods Act though is evident that the site also implemented requirements of Food Safety Act 1990 by application of due diligence principles including risk assessment and quality assurance. For the former the site has a HACCP team and plan for which principles implemented to cover existing operations and any developments and changes. For the latter the site implements ISO9001 and has also a long-term record of certification to the BRC Food standard, then the BRGCS standard. The company evidenced continual commitment to meeting requirements through their internal audit reports, and comprehensive ability to respond to challenge during this BRCGS unannounced audit with information provided in a timely manner.

The content of the Quality Management System (QMS) is accessed as read only by full time key staff, with write access under the control of Technical/ Quality staff. The live version company 'INVU' system holds standard operating procedures, forms with read access to all and write access to authorised persons. That is referenced via the document management system by Agilico Invu Software with occasional printed copy when required for ease of reference.

Manufacturing and Packing instructions and forms are generated from 'SOLVITT' ERP system that contains bill of materials, specifications, variance reports, product specification BOM's that are batch specific issued by Planning and support all processes, instructions and controls from master formulation through to final product.

Documentation control is defined QM.GEN.SOP03 Document Change Control Procedure implemented by quality team with password protected electronic edit access. Observed selection of documents including SOP for hand packing, equipment commissioning sheet, process and packing control records. The documents are identified with title, date of issue, version number, document ref, name of person issuing. Documents in use observed consistent with the index provided. For each document there is at the end a history of change.

Records were maintained to demonstrate effective control of product safety, legality and quality and retained for up to 6 years which relates to the maximum product shelf-life days plus the time period in which a customer or legal complaint could be investigated.

3.4 Internal audits

Audits are managed through scheduling system on Monday.com organised through the head of Quality and is lead auditor locally trained 'Verner Wheelock' positive release. All internal auditors are trained. In total there is six internal auditors. (TJ, MN, PW, EL, ZR, AT, GR and AJ), Target of to cover the BRCGS sections based on risk assessment. All sections are covered once a year. No adverse trend reported. Schedule is shared by clause number. Internal auditor training was performed last in 2023.

Internal audit reports viewed for the following subjects:

Auditor name TJ 11/7/23. This was compliance check against defined procedures. Based on observation. Noted the SOP in use. Audit report observed. Names or the auditee are referenced in the report. Covered some contractors to check their induction on hygiene rules and allergens etc. No NC identified. One recommendation raised that training sign off intervals for refresher are detailed in the procedure. There is a dedicated training person reporting to Head of L&D.

Internal audit report requested for one performed recently to assess NC process. This was for supplier approval. Auditor name (AT)-soft Gel Manager. Date of audit 22/2/2024. Subject of audit 3.5 of BRCGS. Auditee was TJ, MN and EW. Records of assessed documents was noted in the report, and persons involved. One minor NC was raised for bottles water supplier (service) by Country Wise (neighbouring site). The NC was solved and closed out by (PW) internal auditor 10/6/24. Root cause was that sales team did not know that supplier approval was needed for water bottles (as just in offices) but are also in the factory.

In addition to planned systems audits there is GMP audits. Performed by Senior QA members. Frequency is scheduled monthly for all departments in production (four department) and ancillary areas quarterly. Area specific template Noted report for tableting date of audit 13/6/24 auditor name (PP) auditee was manufacturing accompanied by (BF) production supervisor. The audit guide covers first impression of area, is product covered if not in use, labelling or materials, spillages, paperwork completed, waste bins type labelled, correct PPE. Template is updated if other common recurring theme are identified. Findings for the audit was referenced as 92% amber rating. Nc listed x6 minors. If auditor can solve does fix it and still reports it. Is live scoring system. Data collated by admin in to the KPI for management.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

QM.NPD.SOP02 Supplier, Material and Change Approval Procedure. The raw materials risk assessment will form the basis for the raw materials acceptance and testing procedures. There are supplier approval procedures in place (QM.NPD.SOP02, v14). Supplier's approval based on a number of factors: raw materials risk assessment, supplier's performance – carried out annually using Suppliers issues and Self questionnaire (every 3 years), if they do not have any GFSI certificate, along with a number of documents such as, allergens, TACCP, HACCP, traceability exercise, recall procedure and more. All suppliers were risked as low risk suppliers. This risk assessment covers raw materials products, identifies the potential risks of contamination – microbial, chemical, country of origin, physical, rejections, adulteration, substitution - part of VACCP risk assessment and allergens. Products varieties were considered. Raw materials risk assessment reviewed every year or in case of change of raw material or if a new risk emerges. No high-risk materials identified. Reviewed examples for ascorbic acid, gelatine and propolis. The same process, in case of new suppliers and there is a trial period. Suppliers reviewed annually and approved supplier lists were maintained via electronic system. Supplier approval procedure covers the purchase of raw materials or packaging from agents and the site has to identify the last manufacturer or packer. Exceptions relevant to customer branded products are in place and identified to the customer. Supplier approvals reviewed included: Gelatine BRCGS Site code 1454179 exp 20/3/25, Glycerine BRCGS site code 10003250 Exp date 8/11/24, Vitamin B6 site code 1371682 Exp 26/10/24, Evening Primrose Oil IFS Broker Exp date 20/5/25 TUV Nord. Manufacturer is FSSC22000, Vitamin E Vitamin B6 site code 1371682 Exp 26/10/24, Paraffin FSSC 22000 exp 31/5/25, Green Bag BRCGS Exp 23/6/24 site code 1312820 SAI. Suppliers reviewed annually and approved supplier lists were maintained via the electronic system. Supplier approval procedure covers the purchase of raw materials or packaging from agents and the site has to identify the last manufacturer or packer. Exceptions relevant to customer branded products are in place and identified to the customer.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Goods inwards office procedure was described by (DS) Warehouse admin who had an excellent understanding of the computer system and two-year experience in the company. The system called Solvitt is used to book in materials for which orders have been pre-loaded. All materials are identified with exception of hygiene materials that are currently received separately and are put away by the hygiene team into locked up area at site 1 and site 2. It was explained that hygiene materials are due to be included on the system. Located in the good in office was some materials awaiting log in and put away. The items were identified Delga press for EQ Commerce Ltd or a contract packing job. The delivery note detailed Boron cartons and have item code prefixed 52 (customer supplied). Goods arrived 17th June 2024. The procedure requires that if goods are not shown on the Solvitt legacy system then that has to be referred to purchasing and is put on hold until resolved. Materials that are received and not found on Solvitt are put away on a system named Monday.com which is an internet-based database and is being phased in.

Current associated procedures include:
-QM.WH.SOP03 Booking in procedure
-QM.WH.SOP08 Issue Stock to Blending Works Orders
-QM.WH.SOP10 Scanner Gun Usage

Solvitt is the primary system at present until Monday.com has been verified the two are being run together. Solvitt is used for raw materials, packaging, labels, sleeves, equipment except hygiene, not engineering items, not manual handling equipment and not PPE. PPE on order to requisition on Monday.com is then added onto Solvitt system. Observed record for goods in example of Greenshell Mussel powder 500558. 20kg received with 220 Kg to follow from trader with accompanied certificate of analysis. Detailed for compositional, microbiological and heavy metals. Analysis showed all parameters inside specification. Raw material / packaging acceptance procedures have been identified and include raw materials placed on hold until the sampling and assessment of raw materials / packaging by Quality Laboratory staff. Checks and sampling of microbiological or analytical analysis conducted based to plan. All checks recorded to electronic database. As soon as raw materials passed QA checks, further, pallets were booked on system and a label was generated by the system, scanner was used to scan labels barcode and allocate location. As soon as a pallet blocked in system, scanners has a failsafe system to block the pallet and avoid picking to production from Solvitt goods are picked for order process or received returns waiting to be put away. Each individual unit is weighed before returning to stock and labelled according to remaining quantity using a stock system printed label that shows material code, batch number, bar code suppler batch number, if passed or on hold, date and time booked in. Record shows who booked it in. Physical copy of GRN is retained. When put-away QA checks are implemented, and green QA label applied if required. During the storage inspection some slow-moving materials were noted by management that were considered likely no longer required. Management made not to review the item 610670 at bay location 2AD13D. When picked items are transferred to blending there is transfer via air lock. During batching the weighing is managed through the Solvitt system. Packaging intake checks include print verification.

3.5.3 Management of suppliers of services

The approval and monitoring of suppliers of services is part of supplier approval and monitoring procedure in place and detailed on the approved supplier list, which identifies that approval may be based on contract, third party certification or code of practice. Suppliers included pest control, contracted servicing, waste management and laboratory testing. Contracts reviewed during site inspection included:
Waste disposal is by licenced contractors Papilo, third party lab is UKAS for ISO 17025, pest contractor is recognised industry brand leader and BPCA member with annual contract review.

3.5.4 Management of Outsourced processing

Of the large range of products just one activity is outsourced which is bee Health own brand product. That is the production of lozenges under the company own brand care of BRCGS certificated third party confectionery producer.

Risk assessment is referenced in HACCP plan and detailed on process flow for powders capsules and tablets, this is shown of the flow chart dated 22.6.2023 supplied to CB before BRCGS audit. The supply of Propolis to the contract producer is covered by the audit scope.

The propolis is received and subjected to the standard site intake quality assurance checks and dispatch checks in accordance with the outsourced processor. The material has natural antimicrobial properties.

3.6 Specifications

The site maintains specification for ingredients and packaging and products via legacy computer system 'SOLVITT' ERP system that contains bill of materials, specifications, variance reports. A number of specifications were challenged selected from the product chosen by auditor for traceability check; those included Gelatine spec date 20/4/2024, Vitamin B6 dated 10/3/2023, Evening Primrose Oil dated 2/2/2023, Vitamin E dated 15/10/2023.
Paraffin U dated November 2021 Medicinal White Oil Marco 82 NSF H1 registered. This is paraffin used as ingredient in the traced product. the specification from the supplier confirms it can be used as pelletiser and in the manufacture of gelatine capsules., Green Bag spec dated 23/8/2022.All specifications noted were dated / reviewed within three years period. Content of the specifications was suitably detailed and verified by site with appropriate knowledge of food. The R&D Manager also had pharmaceutical qualification. Specification final products are readily available, suitably details and agreed with the brand owner. Product code ref 540083

3.7 Corrective and preventive actions

Procedures were in place - control of corrective actions / internal investigation procedure to ensure that all out of specification product is clearly identified. The requirements are referenced into the individual site SOP's by area. Any issues are escalated to line managers and Quality. The completion of corrective actions (within the defined timescale) is recorded to verify the effectiveness. Non-conformances are required to be monitored and reviewed monthly by the Management team and trend analysis was carried out. Briefly discussed examples for metal detector finding with retained sample from file provided by Quality team.

3.8 Control of non-conforming product

Procedures were in place - control of non-conformity procedure – (QM.QA. SOP08, v9) to ensure that all out of specification product is clearly identified, labelled, blocked into system, placed a label notice form and quarantined. It is responsibility of Head of Quality to release or taking further actions of products.
The labelling of such materials from the bay location system is under the control of the quality team and subject to review consistent with the changes of the internal labelling processes being phased in for all materials. The system can be interrogated for materials on hold. Staff have ability to consider root case and determine preventive action where required.

3.9 Traceability

The company has recording systems linking product to raw materials and packaging batches, and ability to trace back or forward and determine location of materials used and dispatched through implementation of mass balance. Site has recently implemented traceability forward test for Ginkgo Gilboa tablet product that was conducted at the same time and product used for site crisis test 27/3/2024 with verification of no

remaining stock on hand for the product. records included the materials usage, batch number, quantities, tooling , dimensions, weight, DOM, yields, and physical testing of tablet dimensions.

During BRCGS audit the site traceability system was challenged backward with mass balance. A soft gel product Evening Primrose Oil with vitamin B6 was selected on day 1 for traceability test commenced 2pm. Production code 540083, batch 04816-A. Passed 6/3/24 produced. Produced 2/3/2024. C of A noted Date of expiry March 2027. Tooling 26 oblong, In house testing for appearance, fill weight actual 1533mg spec 2016, total weight target 2016mg actual 2018mg, disintegration target <30 mins actual <15 mins, peroxide value target <10meq, actual 4.42 meq O2Kg, TAMC <10 exp 4 CCFU (aerobes), PYMC <10 exp 4 (Y&M), Escherichia coli Abs 1g conforms and Salmonella abs 25g conforms. Traceability commenced 2pm day 1 and ended 5.35 day 1 Outcome presented day 2 by (EL).Date of trace 8/6/24 persons involved AJ and GR backward on Softgel. Exercise completed 3 hrs 35 mins for two trace tests including the mass balance for active agent EPO oil. BOM summary. Shows nine components including bovine gelatine, potable water, glycerine, Vitamin B6, EPO, Vitamin E, Liquid Paraffin, Green plastic bag, shipper (carboard box).

The amount weighed to achieve the order 205,000 based on BOM production, and produced 206,800 and the final output was 200,000 capsules of EPO soft gels was 97.56% yield. 200K/205,000=97.56%.
-Test results for lab testing was presented. Weights, fill weight of each capsule (random three).check shell weights for empty capsules
Disintegration. Water beaker control temperature.
Length and width
Loss of drying.
Above checks performed by (KP) 5/3/24
Green pass label is applied to the bag dolav shipper – for the traced lot a box.
BOM sheet manual record of what was added. Currently running both systems together. Manual scales and Solvitt.
RM exp dates captured on receipt.
Spec for the product at top of page then start up checks recorded to form H&D01 VMS packaging with checks for the scoops used, blend start time, sieve check (Not CCP) is just integrity,
Form encapsulation and polishing section records for the capsule and content.
Filled machine 1, start and end time, last product on, age of gel and fill.
Consumables record and tooling used e.g laundered towels used inside tumblers as polishing / absorbing.
In process control checks implemented. Blue ink operative, red ink QA.
Checking overall weight for shell and fill. Filled weight, destruction and strip less empties weight to give overall fill for ten caps sample. Limits shown on sheet and result recoded manually. Line 1c 03/03/24.
Grading machine. Record machine numbers 1 and 2. Automatic check. Qty bag in a box= 1, 5000 caps a bag, ten boxes a layer, start time and operative initials and end time and initials. Previous product. batch for food grade bag. QA sample to lab confirmation. If dolav used if so then dolav number. (In this case NA). Scan of box label at start and end. Operators putting personal details on the box.
In process control sheet for grading. AQL criteria product type specific. Foreign soft gel, weight variations, foreign particle matter, appearance, incorrect tooling. Excessive oil, mis shapes, bubbles colour, empty or flat, Touch marks.
Quality checks by line hourly and QA random checking for visual, label, AQL limits, initial and route tracking.
Reconciliation page: Estimate at start, web waste, fill waste, downtime, grading waste, final yield. Limits 95-101 but if <97% a comment is required from QA.
DOM plus shelf life recorded.
Shelf life applied and by who.
Production approval initials Green=supervisor or manager. Traced lots signed by (EM) supervisor.
QA approved for the final pass process.
Hygiene record check sheets completed for each batch
Picking list / Works order picking list. performed by W/H. QA confirms yield and check for quantity and enters back to systems. check physical quantity' Warehouse information sheet.

QA random box selection during palletisation before metal detection.
Summary of IPC check by QA.
Stack checks
Drying tunnel traceability.
CCP metal detector challenge test.
Supplier intakes form for RM and PM provided with C of A
Dispatch details for the bulk sent to customer V
Product 540083 54=Gelatine soft gel bulk, 55 is veg 56 is fish gelatine etc.

Bulk Evening primrose oil received 5700 Kg received 15/1/24 Mass balance shows where it has gone. Consumed 5696 Kg. Usages of the oil is recorded. Some went as bulk; some went into packed product all as capsules for this trace. This is evidenced manually. Going forward will be done using the system.

The outcome of the site own test for traceability and incident management and the traceability challenge performed during the BRCGS audit was successful. 5,000 units filled and shipped no remaining stock

3.10 Complaint-handling

Complaints are recorded on electronic log and investigation conducted using root cause analyses. Customer's complaints are categorised based on nature of complaint. Investigation timescales of complaints were in place, mainly 10 working days for investigation. CPMU (total) objective is 22 max. Actual 17 (April) Based on previous years equivalent sales. The monthly measurements are based on previous year sales data and current complaints to try and achieve as precise representation as possible. (NB site packs products into very small and bulk units). Customer returns. Typically one per month at present. Root cause analysis of 5 whys used. Investigation form used QM.QA.FOR17. Mainly the site receives complaints for quality issues and empty capsules, limited number of foreign body issues. Daily and quarterly updates of customer's complaints and trend analysis. Was one investigation for brush fibre for capsule which was concluded isolated instance where the brush used to clear out filler a fibre had detached. No other similar instances reported and no identified adverse trends for complaints.

3.11 Management of incidents, product withdrawal and product recall

Site product recall procedure is adequate for the type of business. QM.QA.SOP21, No incidents have occurred during the current certification period of previous period before that there was notification of positive allergen celery swab results for which a recall was implemented for Nutra-vita capsules which was suitably implemented. In event of a significant food safety incident including a product recall or regulatory food safety non-conformity the procedure states the certification body is to be informed within 3 working days. Further 21 days required to submit evidence to Certification body. The site implemented a test of the recalls system that commenced 27/3/24 09:30 with timeline of persons involved, actions, sequential time log, further action requirement. Crisis team assembled 11:00. The subject was implemented for product delivered 21/3/2024 product was Ginkgo Bilboa 6000mg + iron tablets (two batches) based on scenario of damaged tooling identified. Product quantity packed and dispatched was confirmed. the root cause was reported to cert body at the time. of test communication with customer was also provided for the mock recall.

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

3.9.4	No rework

4. Site standards

4.1 External standards

The site in on an industrial estate. The estate is linear and coastal and was created post war. There is sufficient space and no adverse local activities impacting on finished product integrity. The company operations developed in two locations around 500 metre apart. BH1 and BH2. Reception and main office at BH1. Both units developed to satisfactory standard. Operations in the area being mainly metal / steel fabrication. External areas were observed to be in good order. Waste materials maintained tidy. A large number of containers located in the yard are used for storage of metal, secondary packaging. Raw materials not stored outside. Pest management implemented on the outside of containers. No significant pest activity in the vicinity. Traffic routes noted to be well maintained. The building fabric was considered to be well maintained with adequate proofing observed. The external condition of the site is included on the internal auditing program. Policies and systems are in place for the control of visitors and contractors. There is requirement to sign in at reception during which time the site hygiene rules, allergens policy etc are referenced and health checked.

4.2 Site security and food defence

Predictive models based on risk assessment are implemented to help identify potential hazards and to assist company due diligence. The assessments were conducted by trained staff – all members of HACCP team. The documented site security policy statement dated 24/8/23 version 6 and a physical site security risk assessment was last assessed 12/11/23.
TACCP (Threats) plan last reviewed 8/2/24 currently V10.
VACCP (vulnerability) last review date was 24 April 2024.

Noted training for team member (WCD16/2/2023)-Buyer and (EL) QM level 2 13/2/23 both TACCP trained - High Speed Training, “training also included VACCP” verbally confirmed by (TJ). Certificate for TACCP and VACCP viewed for member of NPD team (MN) dated 9/2/23 training conducted in house by third party learning.ultipro.com. Certificate presented by (TJ).

Provisions for control include requirement for visitors to sign at reception onto an electronic system, on completion of sign in the system takes photo and mails that to host for approval. Management encourage staff to challenge unrecognised persons. Each factory unit has wire fence the condition of which was observed as intact. Fencing for which the site was responsible for was intact.

Doorway entries are key code locked. External storage units were also locked. A number of other security provisions are implemented including CCTV, controlled access barriers, designated key holders, alarm systems. The risk assessment is organised through the following steps; order enquiry to Bee Health (assessed through NPD procedures and trained staff TACCP level 2, Checks of manufacturing and packing of suppliers (assessed through intake procedures, QA checks, cleaning controls, only one product per room at any time, trained staff to avoid cross contamination, CCTV for monitoring of handling, yields assessments for quantity verification, It systems security), raw materials sourced from suppliers (assessed by SAQ, TACCP trained team including procurement, technical assessments of supplied documentation, sampling and external testing, supplier audits, documentation reviews, speciation testing where deemed required, individual risk assessments taking into consideration historic, environmental, or high risk materials such as EVOO or honey. Supplier approval process. Assessments continue through each of the

following steps for raw materials delivery, waste, staff and visitors. To each step the hazards are listed, severity and likelihood multiplied to given overall risk rating then determine if further controls are needed for which the answer had been concluded No for each stage after site own control measures that control likelihood. Assessment is further implemented for the raw materials relative to compliance with reg for pesticides, Polycyclic Aromatic Hydrocarbons (PAH), heavy metals, irradiation, GMO, incorrect storage, other known risks, substitution, fraud, cross contamination. In all cases the risk after site further controls are implemented is determined as low. For suppliers the site used GFSI approved suppliers.

Further assessment is evidenced by company for storage and security of materials review dated 8/2/24 version 10 next due 8/2/25 no change of content. Review included consideration to the intake of ingredients, PPE, Processing, Product storage, ambient storage, despatch, chemical storage, IT systems data, site access, engineering, packaging intake, water intake. Following completion of the risk assessment the site again concluded no further controls needed.

4.3 Layout, product flow and segregation

The company has two sites divided by neighbouring steel fabrication business, the activities of which were segregated with locked doorway. Units 1 and 2 were both surrounded by hard surfaced concrete yard areas. The soft gels department has some internal fabrication work being implemented. That area was currently cordoned off and sealed with plastic sheeting and tape and appears satisfactory. There was not current visible contamination risk from that work which is being conducted toward an objective to make vegetarian based product.

Layout detailed for:
-BH1-001 5/12/22 GF Rev D details location for electrical room, cooling room, soft gel, drying tunnel, mixing vessel, Air con units, soft gel locker room, soft gel changing room, polish room, tooling room, soft gel wash house, drying tunnel, grading line, soft gel machines, engineering office, manufacturing locker room, toilets, kitchen , air lock, boiler room, offices, first aid room, cooling room, manufacturing area.
-BH2-001 Rev B 7/2/23 area plan included good in office, quarantine area, offices, storage, server room, entrance hall, canteen, wash house, lines 1-4, powder room, liquid room.
Overall the company has sufficient space for the operations conducted, some areas where space is tighter but overalls satisfactory. The current facilities are mature and remedial action taken where deemed necessary however only one of the two units is owned so some consideration to future site development was cited.

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

Both units are steel framed and clad and are post WW2. Site 1 has double apex warehouse roof. Site 2 has single apex warehouse roof. There is block wall at low level. Unit 2 Breeze block. Unit 1 brick. No visible damage to walls. Floors have concrete surface with impervious coating for the gels area and non-slip finish for dry powders. Physical condition of floors walls was intact. Open food areas were clean. Stock is warehouse is closed and protected against black dust by plastic covers. Loading and unloading is via doors at ground level. The site does not benefit from raised loading docks. Some issues was noted that appears to be associated roof gullies for which minor NC was raised see clause **NC 4.11.1**

Storage racking is used extensively at unit 1 and some in place at unit 1. Racking was upright, maintained, bay location marked, Some internal ceilings were used as messanine areas for storage and services. No food processing in those areas, with limited access. The production and storage areas has no windows. External doorways were roller shutter with internal strip curtains, well proofed and where damaged suitably maintained. Lighting comprised strip lights with LED units, some fluorescent units being phase out. Lights were functional and clean. Some light units in storage facilities are on motion detectors. Localise dust extraction was provided directed from individual process batch prep booths, running to external DCE units

that were suitably maintained. Ventilation comprised BH1 air handling two banks of 3 pre filters G4's and H11 final filter. Manufacturing BH1 and Encapsulation BH2. Soft gel dehumidified air – through G4s and H9 filters for the drying tunnel. Air filtration is not deemed a CCP.

4.5 Utilities – water, ice, air and other gases

Potable mains water is used for processing, is Yorkshire water supplied, there is steam plant for conductive jackets vessel heating of soft gels (indirect) via tubular exchange and no steam injection, and MAP with bought in nitrogen gas for flush if required by customer. The site has samples of water for potability sent to UKAS accredited lab ALS. The site has no history of problems with the water supply. The suppliers certification relates to surface source. No ice is used in production. Some header tanks are located internally for water for the staff services. Micro checks implemented for compressed air used on site for cleaning and control. No reported issues with the water supply to the site. Micro chemical and organoleptic report for the water supplier over large number of samples for Bridlington 2019 (2801219) water supply zone. Reporting Period: 01-01-2022 to 31-12-2022 was viewed and noted to be satisfactory.

4.6 Equipment

Equipment used on site includes manual handling machinery (leased from contractor Briggs), tote blender, closed coating pans x3, soft gel capsule formers, capsule fillers, linear volumetric filler, tablet counters, counters (grading lines), hand sealing equipment for bags, air filters (air handling and dust extraction DCE's X4) two large for manufacturing and encapsulation, and two for the coating rooms 1&2, for air handling one functions for soft gel one for encapsulation and one for tableting and some dehumidifiers for soft gel x3 (drying tunnels) "DST unit". Packing hall liquid line for dropper bottles range 30-1000ml. Comment on purchase specifications for any new equipment, outlining suitability to meet the site's requirements. Milling machine (Apex Flail) BH076 Model 316 used for rework of tablets and capsules, propolis (used to be milled) is bought in as powder. The site has conveyor system installation. The unit job sheet was defined with checks referenced below. Purchase specification for the Volkmann (auto-feeder) is held on Solvitt system, and copy is on capex system, for PO57671. Date of specification / quotation dated 1/3/24. Equipment design and construction was referenced in suppliers quotation for auto-feeder from supplier Volkmann designed supplier contact name (BF). Included in the specified information was suggested spare parts, proposed on site trials, or trials conducted at machine manufacturer Germany. Equipment commissioning and installation was included in the quotation provided.
Commissioning form QM.ENG.FOR01 and procedure QMEGNSOP006 for new equipment: This covers check if work can be carried out without compromising food safety, whether temporary screens and necessary, if cutting or grinding is required, if there is tainting hazard. The form references wort of work to be performed, if parts have been removed and accounted for, or action taken if not, if the machine has glass parts that can be replaced with Perspex, if working with Perspex, if any damage or intact and action, any temporary repairs, details for lubricants if used, and if machine has been cleaned down. New equipment purchased recently 'Volkmann auto feeder for soft gel line transfers between the pulse scrubber to the two counting grading lines. Form shows check done 14/6/24 signed by LG, Glass audit implemented 14/6/24 updated for the new machine. Hygiene signed by (AJ), and QA signed by (AJ).

Moving/ storage of equipment: Equipment related documents are on system called 'Invu' which is a 'read only' database except for those with write access. No procedure for the movement of static equipment. **NC 4.6.4**

The site has a container for the storage of equipment that is not used. Stored at BH1 Site outside of the production area. Mobile equipment (e.g. forklift trucks, pallet trucks, scissor lifts and ladders) used in open product areas do not pose a risk to the product. Such equipment is short term hire operated by IPAF trained employee. Battery charging is implemented away from open product. No issues were identified in

that regard. The site used lease trucks branded Hyster. Units were observed in good condition and are used between inside and outside for vehicle loading.

4.7 Maintenance

Planned maintenance system is on Excel managed by (JD). Asset list, frequencies monthly quarterly six monthly and yearly. Discussed maintenance for large mixed tank for liquids. Last due May 2024 but was missed due to component failure then fixed and now in use. (Maintenance reported technical issues with heater elements that was replaced, and PSU failed temporary replaced and waiting for part which is on back order). It was noted that the tank lid was slightly out of line, the maintenance team already had action for that.

Requested job card and record or large blender maintenance. Implemented 14/6/24 by SV signed 14/6/24 by MB and co-signed 14/6/24 by (BR).

Noted record for the mill machine, this has list of components checked including bearings, hammers, drive belts screens, guarding, is done a frequency of 6 monthly. Check and grease bearings. Noted report for job last done February 25th, 2024, job done by (RB), then engineering supervisor (MB) signed then hygiene check after (SC). Morris K968 Food grease. Job sheets are being revised to include the type of lubricant used. Statement for lubes allergen free status was known by site,
Maintenance task management is organised for the site and implemented with post maintenance documented check. Parts for tooling were noted to be of a good condition as tolerances to enable equipment to operative effectively left little scope for error and would result in excess product wastage. Following maintenance work there is clearance and then verification sign off.

4.8 Staff facilities

On arrival to work staff are provided with changing facilities, toilets, locker for personal effects, pool stock overalls, disposable PPE items, canteen area with vended cold food items, facilities for heating (microwaves, toaster, kettles for hot drinks, temperature monitored fridges, also tables chairs and TV for canteen, and site staff engagement display screens in corridor areas. Sufficient staff facilities are provided with regards to the number of personnel and are designed and operated to minimise the risk of product contamination. Changing facilities are provided and are suitable. Personal and protective clothing are stored separately within the changing facilities. The changing room was observed to be adequate for the number of staff. Lockers allow sufficient space for personal items and PPE with a single locker system. Overalls for product handling areas are not worn outside of the area. De-robe procedure on exits with step over bench for reminder. Handwashing during the changing procedure is incorporated to prevent contamination of the clean protective clothing. Suitable and sufficient hand washing facilities are provided at the entrance to the production area and at strategic locations throughout. Non-hand operated taps are present with antibacterial liquid soap in use. Hand dryers provided. Post-wash disinfectant is utilised throughout the site. Instructions for hand cleaning are posted. Toilets are adequately segregated from storage, processing or production areas and do not open directly into production. Hand wash signs are displayed.

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

4.9.1 Chemical control

QM.HYG.SOP18 procedure for Control of Chemicals is in place that defines the use, storage and handling of non-food chemicals. Appropriate facilities and procedures are in place to control the risk of chemical or physical contamination of the product. Cleaning chemicals observed to be food grade and purchased from approved suppliers. There is a list of approved chemicals. Safety data sheets were available for Holsolve detergent and Tribac sanitiser. QMS has procedure QM.QA.SOP01 titled Chemical Titration Procedure for checking strength of Holchem supplied chemicals. Chemicals observed fully labelled. Cleaning chemicals are kept in a locked and controlled by the hygiene operatives. No strong-smelling chemicals were noted during the factory inspection. Site also had H&S 010 Chemical / Spillage procedure. PPE is provided and specified for cleaning tasks.

Site 2. Meeting room tea cupboard is not the designated location for food grade lubricants. Lubricants were stored there. The location is not a secured location. **NC 4.9.1.1**

4.9.2 Metal control

A documented blade knife / scissors procedure monitors for condition of fish knives, avoidance of open blades and snap off blades, no stapes or pins were observed. Record for knives issues is maintained. Staff are aware of the need not only to report damage but also loss of knives.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass breakage and audit procedure QM.QA.SOP14. No identified broken or damaged glass observed for the factory inspection with exception of one clear hard plastic cover over gels line where a crack has been identified, marked and being condition monitored. In event of reported breakage the procedure requires reporting to quality, quarantine area and clean area and checked and inspection before return to production. Currently no glass packaging was observed during the factory inspection and management advised glass not currently used. Designated clean up equipment is provided in event of glass breakage-equipment coloured red. The use of glass in production areas was minimised. Glass items included line covers, lighting and EFK units, some line controls, electrical fittings, containers and lids, and controlled tools. Risk based weekly (open product areas), and monthly (facilities) glass and hard plastic checks were implemented. There are windows in production area from offices / low risk area. These are protected and do not open externally. Glass audit implemented 14/6/24 updated for the new machine Volkmann. Hygiene signed by (AJ), and QA signed by (AJ).

4.9.4 Products packed into glass or other brittle containers

Products have previously been filled to glass. Some products are filled to containers, but currently only plastic containers are used. Containers are presented into the un-scrambler then pass through inverter and air blower. If glass containers are used those are manually placed to the feed of the inverter, Unscrambler is not used for glass jars.

4.9.5 Wood

QM.GEN.SOP12 procedure implemented for control of wood and cardboard. Damaged pallets were removed. Wooden materials are not permitted in open product handling areas. Deboxing implemented before ingredients addition to blending. Production areas observed were clear of wood, and floors were visible clean.

4.9.6 Other physical contaminants

Procedures are in place to prevent physical contamination of raw materials by raw material packaging during the debagging and de-boxing process. De-boxing packaging procedure is in place. Dedicated metal detectable pens used in process areas are controlled to minimise the risk of physical contamination by all being individually numbered and issued to staff. Each pen batch tested for metal check. Areas around open product were observed to be clear of potential foreign matter hazards, no loose labels, secure cable

ties. No loose nuts bolts string. Good standard was noted generally for the soft gels area which is segregated from the area where there is construction work with sheeting and tape.

4.10 Foreign-body detection and removal equipment

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

Each process step is referenced as having been risk assessed by HACCP team for foreign body hazards. Metal detection has been deemed a requirement and assessment determine that to be CCP. Products metal detected as the final stage for manufacturing with detector tested to 3.0 mm, Fe, 3.5 mm NFe, and 4mm SS. Soft Gel 2.5mm Fe, 3.0mm NFe, 4.0mm SS. Products were bulk packed into polythene bag lines cases or tied polythene bags in plastic containers for transfer to packing in BH2. CCP is 2 mm sieve post blending of powders in BH1 Metal detection was supported by belt stop and alarm reject which was checked at start and end by QA. Hourly checks are conducted by the operator. The detection is implemented on the cable tied bags before filling. This is the defined last point of control as packs are induction seal with metal film laminated cover.

4.10.2 Filters and sieves

BH1. Sieves are used. CCP1 – Sieving of powders 2mm stainless steel wire mesh for bin fill. Checked per batch. Start and end. Records of integrity, cleaning and any findings. Procedure QA.SOP32. Additionally other sieves and filters are used; 0.3mm-4mm sieve (product dependant) used for de-clumping which may be required for powder materials prior to addition prior to blending. BH1 air handling two banks of 3 pre filters G4's and H11 final filter. Manufacturing BH1 and Encapsulation BH2. Soft gel dehumidified air – through G4s and H9 filters for the drying tunnel. Air filtration is not deemed a CCP. A new unit was observed available for use. Record for sieve checked for EPO traced product noted 2.3.24 sieve intact at start of shift 06:00 and end time 08:00 operative initials (BW). No foreign body found.

4.10.3 Metal detectors and X-ray equipment

Metal detection is implemented on product in bulk bags before filling retail packs due to post pack metal induction seal that would not support detector sensitivity requirements. Detector head site is consistent with bulk dimensions, test sticks 3.0 mm Fe, 3.5 mm NFe, and 4mm SS. Soft Gel 2.5mm Fe, 3.0mm NFe, 4.0mm SS. Products were then transferred to packing in BH2.

Metal rejection comprises belt stop, and alarm verified at start and end by QA. Hourly checks are conducted by the operator. Examples and challenges carried out during Factory tour without any issues and suitable records maintained in traced documentation. No detector failures. Observed checked for hand labelled boxes observed operative (MT) for Evening Primrose Oil detector checked with test sticks ferrous 2.5mm, non-ferrous (Brass) 3mm, stainless steel 4mm. Stop belt and alarm functioned correctly. Recording form QM MET FOR03. Noted record for check implemented. Previous product was Peppermint oil.

Quality Management maintain records of metal detector findings. Observed sample ref 26 fragment of metal from detector. Root cause Was piece of weld powder chipped from tray. No adverse trends for metal.

Observed metal detection for encapsulation deparmentfor encapsulated product Operative (AK), system is stop-belt and alarm with Loma head , limits used 3mm ferrous, 3.5mm non ferrous and 4mm stainless steel. The encapsulation line operates with buckets of powder transferred from blending area. Detector unit calibrated 3/9/23 next due 3/9/24.

4.10.4 Magnets

NA

4.10.5 Optical sorting equipment
Two optical sorting / grading lines installed (Symetix) on soft gel grading for removal of defective products. There is a daily challenging testing and rejects monitored. Rejects are not repurposed. The step is in place primarily for visual quality.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers
Retail containers are transferred to line, auto inverted and compressed air blown before filling. During the audit, it was not observed glass packing, however observing plastic bottles filling, the overall filling was very slow and manual allowing for inspection. Any glass breakages or not during production of glass packing were recorded of line checks papers. The site adopts a practice of marking cracked plastic items with marker pen to determine if crack size increased. Whilst viewing the gels area a hard plastic cover over the gels grader was noted to be marked in that way.

4.10.7 Other foreign-body detection and removal equipment
NA

4.11 Housekeeping and hygiene
There is environmental areas cleaning programmed daily, weekly and monthly cleaning which covers production area, storage area and external areas. Hygiene standard for the open product areas was visibly good with defined procedures for cleaning, details for order of cleaning, chemicals dosing rates and usage. Cleaning in situ with parts removal to wash room for each unit with hoses etc. For each production room / cubicle there is just one product handled at any one time. Cleaning was carried out by operators at the end of the day and at product change over to minimise cross contamination risk and is programmed based on risk assessment. Hygiene operations are undertaken by the team of Operators. Line Operatives operated ‘clean as you go’. Provision of chemicals via contractor Holchem supported the training and controls with documented procedures. During this BRCGS site inspection the hygiene status of one line was checked after cleaning and another checked during cleaning. Record. Line change cleaning was observed for tablets operative (DH) for the ‘Big machine’ GZP4 whereby tooling clean was in progress at the time. No identified issues. Was also noted line cleaning with (AF) who had continued the cleaning from the night shift with hand over. GZP6 tabbing line cleaning that had just been completed from previous product vitamin B1 (non-allergen nutrient vitamin tablets 532472 next product due was Calcium Magnesium Zinc blend. The cleaning had commenced night shift 9pm and ended 10:15am. The machine had been stripped, vacuumed, parts removed to wash up, the room cleaned, and computer records showed the standard and end time. The company has paper documented system to detail what has been cleaned, that process is being migrated to electronic system and is current focus of attention for verification of cleaning. Observed cleaning for GZPS51 that showed cleaning had commenced, this was intermediate clean and was batch change but for same product and is implemented to refresh for fillers to prevent blocking. For storage areas over-head cleaning is done with a long pole and duster. Coating lines observed clean. Product in operation was citrate, magnesium and Bisglycinate 53/963 batch 40924 and weighing out titanium free white coating code 500650. Observed that the areas and contact equipment was visible clean including coating pan fabricated from stainless steel tank with inlet air flow of 200 cubic meters per hour flow at 60°C with air extraction to DCE unit. For cleaning of the liquid room (not in operation) the plant includes Adelphi (water only) and Giusti (used for far phases and waxes etc. CIC had been updated to check if dry before use. Cleaning is with mains water. Cleaning involves use of hose – hot water wheeled into the room and then brought to temperature with steam. Chemicals usage Holsolve and Tribac. Inside of tanks was visible clean, paddles inside the

Giusti observed in good condition and internal tank surface slightly brighter appearance where passing over the steel. Management states that where required EDTA is used as de-scaler.

For the soft gel department the areas was visibly clean and bright. Cleaning was not in progress as lines were in production. Capsules line two of three operate at any one time with the other in preparation / cleaning. Some cut out surplus gel is created by the continuous feed that is directed to waste and taken by third party to make glue.

Warehouse storage area has water-stained walls with black mould and wet floors upon which pallets of ingredients are directly stood, noted at bay locations ZAA03B, ZAA23D. **NC 4.11.1.1**

Externally at front of building the yard areas were tidy, at rear of building a lot of available space with a mature but adequate appearance and no spillages of waste or evidence of pests. As coastal area a lot of gulls activity nearby but seemingly not attracted to the site.

4.11.7 Cleaning in place (CIP)

NA

4.11.8 Environmental monitoring

Swab program subject to annual review or if changes to equipment or process, implemented that covers packing areas, process contact surfaces, hands, trays, washroom, coats etc. Testing requirements and expected standards are defined with procedure to follow in event result is not to expected norms. The swabs are collected by third party. Schedule for micro testing implement through Monday.com. Traditional swabs sent to UKAS 1282 Lab ALS based on the plan based on site risk assessment.

Swab points also cover utensils and tools and gloves. Fail reported for washroom IBC then retest implemented. Checks for TVC, Coliform, E Coli, Salmonella and Staph. Satisfactory report noted for retest 16/4/24. No significant issues reported or noted.

4.12 Waste and waste disposal

Waste materials did not present a risk to the products or processes. The waste management company is license for transfer CBDU 213176 with Papilo for general waste, recycling and food. This is a compactor skip. Plastic waste is also compacted. In the yard area it was noted that there is lock up for gas bottles, and locked containers for equipment, chemicals etc. the site also has a chilled unit for storage of probiotics-Not a requirement but facilitates extended life for the functional ingredient.

4.13 Management of surplus food and products for animal feed

NA

4.14 Pest management

The site Quality and Hygiene Manager is responsible for the management of pest contractor Rentokil to the service standard Pest Net on line. The company has no reported infestation or adverse trends.. Containers used externally for chilled storage (probiotics) and is identified on the site storage location

systems. Storage of some Soft Gel Trays (Always cleaned before use) has been received into container for storage until required. Contractor covers for eight routine visits and four field biologist inspection based on risk assessment there has been no change to the low risk state of the site.. Site is organic registered and therefore follows requirements for that and BRCGS and ISO9001. Bait plan was provided on line date 15/5/23 for external ground and first floor and the other site. Red dot for external toxic baits, green for External non-toxic monitoring, and internally blue for EFK orange for pheromones. The site is rated low risk and currently had no internal rodent detection points/ baits. Radar boxes are identified on the plan e.g radar 6 green dot that reported to Rentokil in event of activity. Checklist for the radar boxes shows no activity for the last year. Some isolated instances prior to that. Trending date monitored nothing to report no evidence of issues anywhere and this goes into the management review. Recent service visit report was observed dated 7/5/24. No issues reported.

4.15 Storage facilities

The company has storage and BH1 and BH2 on sites, the main facility visited first for the BRCGS audit BH2 is racked with bay location system, no third-party storage facilities. Externally on site are some containers used for chemicals and equipment. There is a dedicated area for storage of allergens. Allergens are stored segregated. Any quarantine materials are identified and if necessary segregated otherwise held in the system designated location. There is no controlled atmosphere storage requirement. At intake, issue of product, returns of part used stock all are identified with customised labels. Receipt documentation and labelling are used to facilitate correct stock rotation of goods and storage.

4.16 Dispatch and transport

Good in and out are located at ground level. The transport to customer premises is provided by GFSI certificated hauliers that are customer appointed. Hygiene of vehicles is checked before loading and unloading. Details are recorded and seen during traceability exercise. The site operates a shunter vehicle for transfer of goods between BH1 and BH2. Record for the warehouse information was noted for the traced production lot. Production date 6/3/24. Number of pallets and number of boxes per pallet identified and the date of stickering the pallet. Recording form QM.WH.FOR08. English primrose Oil showing the health mark EHEY080 on the labels. Labels marked Exp March 2027. Product ID 1500 mg.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.7.3	No temporary repairs
4.8.8	Food service is not provided however fridges microwaves toaster provided.
4.9.2.2	No staples, paper clips or drawing pins used in open product areas
4.10.4	No magnets

4.11.7	No CIP
4.13.1	No surplus food or products disposal.
4.13.2	The site does not sell onto the market excepting the brand owner.
4.13.4	By products are not downgraded for animal feed.
4.14.3	Pest control activities not undertaken in-house
4.15.4	No controlled atmosphere storage
4.16.6	No site-contracted despatch vehicles

5. Product control

5.1 Product design/development

Historically the site has been involved in customer led market. MD reports some development activity by NPD to explore new ideas. List of approved EFSA claims. HACCP occurs before launch. NPD considers concepts and changes before approving a concept. Head of R&D (MN). Pharmacology BSc Nottingham Trent. Vitamin and Mineral approved list, for herbals check novel food register, MHRA traditional herbal list, sweeteners with limits, e numbers for colours and additives excipients, UK Pharmacopoeia. All this is referenced in an SOP. There is procedure for scientific reviews and NPD procedure. Product design and development. Own brands and customer brands are verified for copy. If site finds issue with customer supplied artwork or materials queries are referred back to brand owner e.g 'certified in the UK' that question was asked, and customer response queried if received by BRCGS auditor. Response to be provided by the sales Account manager for that customer. Product example 'Mushroom complex' new product ready to produce. New Product development request form-controlled document number QM.NPD.FORm01. version number 13/3/2023 version 15. Requested sign of form on the controlled documents listing. Document management system called Monday.com Quality Manual database. Approval of HACCP team formulation approval section authorised by (MN) also check for health and safety concerns. In event of change that would refer to HACCP team. NPD would stop and call HACCP meeting. So for example in soft fish mollusc allergen does not currently exist so if a mollusc oil was required approval of team would need to be discussed. Would be a full Multi Discipline team discussion. When formulation is approved then trial spec is approved then move to purchase order then manufacturing document allows trials to proceed. Everything goes through process with sticker identified with trails labelling. Development team gives the HACCP team a heads up. NPD states are brought up to the SLT meetings. Referenced in HACCP is that "Shelf life is typically Manufacture + 2 years for tablets and capsules and + 3 years for soft gels, however customers may specify their own shelf life and take responsibility for the stability if none is available from Bee Health the date is displayed as an expiry date".

5.2 Product labelling

For NPD formulation sheet there is description provided of the intended marketfor the product. As country of sale the statement is all conforms to UK and EU legislation. This statement is on the base of all specifications. The current specification is for the bulk product then there is separate specs for the RM and PM on site. Customers will receive that information where requested and as norm tend to do that due to registration requirements for their market. There is transparency for allergenic information, process aids etc.
Procedure for artwork approval is defined called artwork design and approval QM.NPD.SOP07 14.6.23 version 0. Long form called label check sheet supporting the process. Check sheet is files with the reference label on the Invu system.

5.3 Management of allergens

The site has implemented assessment of potential for allergens arriving to site via raw materials, staff food, vended food, lubricants etc. Of the EU list of 14 ten are present with exception of mustard, lupin, peanut and tree nuts. In event of introduction of new allergen to site the approval of full HACCP team would be required. Each ingredient is assessed for each allergen and data maintained on matrix. Discussion with respective warehouse staff during this audit supported good understanding of rules in place. In some areas designated storage area for allergen demarked by tape, in other areas simply the allocation of specific bays via the stock management system in accordance with the respective risk assessment. Bulk fish oil is stored at ground level on wood pallets with tape to exclude persons entering the area. The site does not apply allergen alibi labelling. Allergen claims are not made for own brands Gluten Free, Dairy Free claims are applied in accord to specific customer label demands where the site has verified their ability to meet that claim. Risk of allergen cross contamination is mitigated by planned order of production for example allergen follows no allergen rather than vice versa. There is clean down between every batch and wet cleaning implemented where programmed and when cleaning validation is deemed necessary for allergen changeover then there is periodic allergen swabbing to verify that there is no carry over after cleaning on equipment with previous run allergens. Tablet lines are dry cleaned, brushed, vacuumed, and run through with inert product filler to remove albeit unlikely remaining traces. The nature of the fillers is such that residual materials are unlikely as fill heads are removed, taken away, washed dried and stored in dedicated locations. Verification checks are implemented periodically to check effectiveness of allergen changeover cleaning, the swabs are collected and checked at third party UKAS accredited labs. No issues have been identified. Training of staff for allergens management was evidence through the staff induction records and is covered at induction training for ever new starter and every returning member of staff. None of the processing operations involved rework. For the soft gels cut out strips those are removed from site and used to make glue. Rework is not used.

5.4 Product authenticity, claims and chain of custody

Vulnerability risk assessment considers country of origin, history, testing of materials, nature of materials, economic factors, raw materials sourced suppliers, sampling process, supply chain module and routine testing, availability of raw materials and adulteration, complexity of supply chain. There is a raw materials vulnerability study last review date was 24 April 2024.

If raw materials identified as being at particular risk of adulteration or substitution for the site, these are controlled by the supplier approval procedure and the use of approved suppliers. Any low or medium risk materials controlled by approval Suppliers process and routinely testing by the Site or Suppliers.

According to site VACCP there is no high- risk raw materials identified once the site controls are considered.

The site has access information and historical data, using a number of sources such as FSA, RASFF, DEFRA and Customers web sites. Site maintains certification to support claims made regarding methods of production. That includes:
Soil Association, Organic: Expiry date 31-01-25
Halal HMC: Expiry date 22-06-24
Kosher KOF-K: Expiry date: 31-12-24
MSC: Expiry date: 26-09-24

5.5 Product packaging

Packaging is stored in a designated area, clean and dry and covered once opened. Packaging is purchased from approved suppliers against specification and with appropriate certification. Specifications were available and detailed suitability for use in contact with foodstuffs.

Example was reviewed during traceability of coloured food contact liners that was specified for food use. Any out-of-date materials cannot be picked. Where materials were received and not used historically there will be some items that will be identified and removed.

Blue colour plastic liners for boxes and pallet containers were of suitable grade to avoid tearing and supported by specification and conformity statements. Identification of the food grade bags batch numbers is manually checked and recorded on control forms. For the traced lot noted 414C/126-2

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

Goods received inspection is based on visual checks and suppliers certification and certification of that to agreed specifications. For tablets forming checking integrity of tablets for strength, solubility, weights, surface appearance. For soft gels the weights for fill and shell, disintegration. For bulk powder bulk density, visual appearance. Also density of fluid.

The Site has a small analytical laboratory in place Procedures and controls for calibration implemented; the testing is pertinent to product quality and feedback to line operatives for adjustment where relevant or in event of persistent issues referred to the Head of Quality. Listed procedures:

QM.LAB.SOP02-Dissolution Machine
QM.LAB.SOP04-Density Analysis
QM.LAB.SOP05-pH Analysis
QM.LAB.SOP07-Peroxide

There is sampling plan whereby products are sent to third party ISO17025 UKAS Certificate labs for micro laboratory was used for analysis in accordance to schedule: for microbial analysis. For finished products microbiological testing, sampling based to annual reviews and risk assessment of products. Some noted examples in section 3.9 of this report.

Micrometer used for measuring dimensions of product.

Shelf-life verification was carried out randomly on end of shelf life of product.

5.7 Product release

NA. Vegan society had a hold and release policy based on results of testing by accredited lab Eurofins wolves. The requirement was removed due cost for holding. All products are released following completion of specified in process controls.

5.8 Pet food and animal feed

Bee Health Ltd included in HACCP intended use reference to their complementary pet feeds: these are formulated using ingredients which are fit for human consumption and follow the same approval and intake processes they are designed for the species detailed on the specification and are checked for feed additive compliance during the NPD process. HACCP Policy Statement: “Bee Health Ltd recognises the need to have systems and procedures in place to ensure that foods safety, quality, legality, authenticity and environmental standards are maintained and monitored. To help achieve this, the company has adopted the HACCP principle and will use the process to evaluate every aspect of the production operation. Bee Health Ltd is committed to comply with food safety standards and requirements for all food handling operations. We enforce good hygiene practice and good manufacturing practice in all operations related to food & feed products”. Bovine gelatine is used on site. Waste from that processing operation is remove for glue making. Gelatine is not returned into food chain. No food waste is sent to animal feed.

5.9 Animal primary conversion

NA.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.9	No animal primary conversion performed on site.

6. Process control

6.1 Control of operations

Processes were observed to be well controlled. There is some transition between systems used for materials at present. This primarily affects the intake of materials. There is also some development of the system used for recording cleaning.

Process specifications are pulled from system that are product specific with display boards in production areas for the orders etc. The site has an electronic system, where all recipes for each product code are in place. Moving toward paperless system currently manual noted for BBE of raw materials and those recipe papers (including quantities) following the product up to point of packing. In blending scanners used, and paper documents as well alongside.

Checks on production lines are carried out before commencing production and following changes of product by production operatives.

Each batch was assessed by site quality laboratory– Tablets - Friability, Disintegration, Dissolution, Weight, Visual app. Dimension. Two-piece capsule - Weight, Disintegration, Visible appearance. Soft Gel - Weight, Fill weight, Shell weight, moisture (LOD), Disintegration, Microscopic seam check, Peroxide. Bulk powders - LOD, BD, Visual appearance. Bulk liquid - Relative density, pH, Peroxide, Visual appearance. Quality checks are now conducted on each batch by the operator and defect levels had been set.

Procedures are in place to define actions to be taken in the event of process failure, equipment failure or failure to meet product specifications. Corrective actions have to be defined in the event of deviation of process from specifications. Listed procedures are provided against which staff are trained.

6.2 Labelling and pack control

Procedure for product labelling and coding is in place. Machine operators have the responsibility to ensure that only the packaging for immediate use is available to the packing machines. Records seen during factory visit on pre- start-up checks sheet. Only one product at a time. Documented checks are carried out at product changes to ensure all products and packaging from previous production has been removed from line, recorded on production papers. Cycle checks implemented at end of runs. Documented procedures are in place to ensure that products are packed into the correct packaging and correctly labelled. Labelling checks are carried out (start, during, after batch change, end of packing) and recorded on packaging check sheet . A sample of the labelling is attached to the quality control records. There is no on – line equipment for product labels and printing checks.

6.3 Quantity, weight, volume and number control

Appropriate quantity control systems were in place to demonstrate compliance with relevant legislation. Checks completed to support product weights and count as appropriate to the final product. QA checks completed and recorded. Related work order and batch paperwork produced from Solvitt including the required checks and providing for record. Good system was also seen in the liquid fill area where the density of the product had been checked by the lab and the line were able to convert to a weight. T1 and T2 data were available. Product was seen to be packed to average weight. Site packs tablets per unit and count checks carried out during process.

Powders are sold by weight. Average weight principles are applied due to specific customer requirements. Legal compliance is evidenced by off line net fill weight checks by QA.
The site does not utilise automated weight data or in line check weighers.

Particulates are sold by weight. The procedure requires the carton or jar to be placed on scales and to press tare before adding product to achieve above target weight. Observed for line 1 Vitamin D3 filling 4000 IU ‘Vita Premium’ with packing hall manager (DB). Tipped from bag to hopper. The process was white plastic tub filled by counter. The line counter has four heads, and half hourly there is a physical count for the actual contents. For container filling a shrink tamper evident seal is applied.

For packing vitamin B12 into pouches it was noted that counter fills to container, manual decant to pouch, declared weight 70g, pouch tare 7g, therefore gross weight ought to be 76g. During this production it was noted that the scales did not display a negative number after the packaging was removed from scales. This is indicative or either an error with content of procedure or practice.

6.4 Calibration and control of measuring and monitoring devices

Calibration matrix is defined. Managed is Monday.com. Covers scales, probe, metal detector test pieces, feeler gauge (micrometer and callipers), weight and hardness testers, log tags (temperature and humidity monitors). Data input onto system, live showing green when done, Populated by Tech department. Make model serial number and the location of device, date last calibrated, calibration due date and certificate. Noted example of certificate for Ohaus packing Hall Valor scales date done 5/10/23 performed by Accuweigh, Certificate uploaded to system. Requested evidence for the reference weights. Calibration checks sent away to Accuweigh. Noted certificate dated 22/3/24 covers range 1g 100g 500g 10Kg weights. Collected and return to site by contractor who also repair scales. Metal detector calibration was requested for Soft Gel work done by contractor SNB visited site 15/9/23 units all checked at the same time. Test sticks referenced. All systems are stop-belt and alarmed. Temperature control on site is used for warehouse manually and fridges for food. Also introducing humidity and temperature monitoring. Certificates refer to reference of national standards.

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

7. Personnel

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

New starters are booked for induction before starting work with L&D Manager they then arrive on site for the training duration of two hours. Trainees are then taken through induction. Program covers alcohol and drug misuse, use of only company issued plastersfor site, hygiene rules, PPE, allergens, Code of conduct food safety and quality within the business, glass breakage procedure, pest awareness site security site off and H&S. Talk through about grade of role all start grade 1 and get talked through the SOP training systems for the departments. SOP training is delivered by L&D through videos. The rest of SOP training is done in department by supervisor and manager and buddies for duration of the training. For the packing hall trails being conducted for permanent full time dedicated trainer. Packing hall has most staff across three shifts. Induction is 53 slide with illustrations. History leadership team, site orientation map, T&C hours of work employment grades, hygiene rules.

In addition to induction records provided for the following examples.

Metal detection CCP2 KA and AK. 21/1/2024. Trainer HE. Logs the procedure and version and duration in total 12 hours 34 mins over various sessions. System called UKG.
For AK the training Date 17/5/24 trainer KC time 13 hours and 31 mins visual assessment of competence.

Allergens: AK and KA both covered at induction. For packaging and labelling is based on SOP. There is verification of sign offs. Control is reconciliation.

Training is refreshed annually.

Training: ‘SOP 37’ requires packaging to be tared on scales for product weight check. Scales in use without applied load displayed zero. Actual expected tare -7g. **NC 7.1.7- SOP 37 requires packaging to be tared on scales for product weight check. Scales in use without applied load displayed zero. Actual expected tare-7g.**

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

Personal hygiene rules are defined for all areas, there is definitive difference between the requirements for storage and open product areas. For site 2 brands warehouse area the facility is single apex roof. PPE includes protective footwear, watch and necklaces permitted. For open production areas only plain wedding ban allowed and items where there is specific permission agreed with employee at induction based on health needs. Hi Viz is worn for warehouse areas, Hairnets and snoods are required for open product areas, also ear plugs, overalls, dust masks for designated locations, gloves where preferred and wellies as needed.

Documented company hygiene rules part of induction is adopted by all new staff. Visitors and contractors aware about hygiene rules upon their arrival, procedure: QM.GEN.SOP08 Company hygiene rules. Hygiene rules include the following requirements: no watches to be worn; no jewellery except plain wedding band or medical alert jewellery (approved by occupational health); no rings or studs in exposed parts of the body; fingernails shall be kept short, clean and unvarnished; false fingernails and nail art is not permitted; excessive aftershave or perfume is not to be worn; no clothing decorated with beads etc; no spitting; eating and drinking only in canteen. These points are covered in induction and on visitor questionnaires. Adherence to the hygiene rules were observed during the factory tour

Smoking is prohibited except off site. Plasters ear plugs detectable pens cable ties issued by site of these metal detection check for plasters and observed good visible controls for other items. Plasters new batches checked through metal detector 26/06/2023. The metal detection is implemented in bags closed with cable ties, the risk is minimal due to the nature of the processing and packing operations. Staff are required to report if medicines are required to management for review and permission. Otherwise medicines are not allowed in production or storage areas.

7.3 Medical screening

Medical screening procedures are in place for staff, visitors and contractors and consist of a questionnaire, completed by all new staff. Provisions for control include requirement for visitors to sign at reception onto an electronic system, on completion of sign in the system takes photo and mails that to host for approval. New employees are subject to a self-questionnaire medical examination prior to employment carried out by third party. In the event of reporting of illness, the member of staff is not permitted to work in food handling areas.

7.4 Protective clothing: employees or visitors to production areas

Cotton overalls are provided and laundered by Johnsons and Ellis. The site also has disposable overalls for specific activities where the products handled result in staining.

Correct PPE usage and rules are communicated at induction. There was good supply of overalls in multiple sizes as pool stock at both units enabling at least daily change and as required by changeovers e.g allergens. There is designated laundry bins provided for used overalls to be laundered.

Production areas have captive footwear, requirement for full hair covering with hairnet, snoods and masks, and blue vinyl gloves for operatives. For outside footwear overshoes are provided for visitors.

There is no usage of chain mail and no requirement for the laundering of company issued PPE. There is requirement for usage of Hi Viz for outside and warehousing. Open product areas overalls are not worn out of doors.

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

8. Production risk zones – high risk, high care and ambient high care production risk zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Equipment and maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

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

9. Requirements for traded products
9.1 The food safety plan - HACCP
Not applicable
9.2 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.3 Specifications
Not applicable
9.4 Product inspection and laboratory testing
Not applicable
9.5 Product legality
Not applicable
9.6 Traceability
Not applicable

Module 11: Meat Supply Chain Assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	

11.3 Raw material receipt and inspection
Click or tap here to enter text.
11.4 Management of cross-contamination between species
Click or tap here to enter text.
11.5 Product testing
Click or tap here to enter text.
11.6 Training
Click or tap here to enter text.

Module 13: Meeting FSMA Requirements for Food – July 2022
Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33)
o For sites regulated by 21 CFR Part 117 provide a brief overview of the control measures and procedures in place, commenting on its suitability to meet the requirements
Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)
o For sites regulated by 21 CFR Part 507 briefly summarise the control measures and procedures in place, commenting on its suitability to meet requirements
Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)
o Provide a brief overview on each of the control measures and procedures in place including a summary of the effectiveness of the food defence plan
Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)

o Summarise the control measures and procedures, commenting on their suitability to meet requirements
Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)
o For sites regulated by 21 CFR Part 112 provide a brief overview of the control measures and procedures in place, including a summary of their effectiveness

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