Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	H.E. Stringer Flavours Ltd	Site Code	1462754
Site name	H.E. Stringer Flavours Ltd		
Scope of audit	The mixing and blending of Ingredients and flavourings in powder and liquid formats		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit Finish Date	2020-08-26		
Re-audit due date	2021-10-03		

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

Head Office	No

2. Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit type	Unannounced
Previous audit grade	AA+	Previous audit date	2019-08-12		
Certificate issue date	2020-10-14	Certificate expiry date	2021-11-14		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	1

3.Company Details			
Address	Icknield Way Industrial Estate, Tring, Hertfordhshire, HP 23 4JZ		
Country	United Kingdom	Site Telephone Number	+44 1442822621
Commercial representative Name	Lee Beesley – Managing Director	Email	lee.beesley@stringer-flavour.com
Technical representative Name	Kevin Mc Manus – Operations Manager	Email	Kevin.mcmanus@stringer-flavour.com

4.Company Profile					
Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3
Shift Pattern	Day shifts 0800 hours 6AM to 17.00.				
Subcontracted processes	No				
Other certificates held	The site holds a Soil Association Organic certificate Soil Association Certificate number MD0062895P4242 GB-ORG-05 Expiry 2021-05-30, Kosher Certificate number 34133 Expiry 2021-05-30. Balance exercise as part of the external audit protocols.				
Regions exported to	Europe Asia Africa Oceania Choose a region Choose a region				
Company registration number	GB154E0232				
Major changes since last BRCGSGS audit	New Managing Director, new Operations Manager, both promoted internally. New Technical Manager recruited. Site working to Covid 19 rules.				

Company Description
H E Stringer Flavours Ltd is a private company which manufactures flavourings for the food and non-food industries. The market is mainly in the UK but there is a significant export business within Europe, Australia and Asia. The business model for exports is factory gate pricing and they sell through UK based distribution companies who are responsible for client contact.
There has been a corporate restructuring of the company, with HE Stringer Ltd owning the buildings. The manufacturing arm is under HE Stringer Flavours Ltd, which is 75% owned by HE Stringer Ltd .
Site established: 1967, upgrades; 2004 & 2012/13; management team established 2002, size of 1,130m2 (whole building is 2,400m2 and is sectioned off into totally separate units). Production volumes are approx. 130 tonnes per

year, in line with SME customised production up to 1 tonne IBC.
The manufacturing processes are manual blending and mixing of dry and liquid raw materials to achieve a desired flavour profile.
The products are sold in poly-bottles, poly-bags and IBCs depending upon the format. The company has a flexible approach to manufacturing small batches to order. The workforce is small with 13 people employed. The factory operates a single day shift Monday to Friday - 0800-1700.
The site holds Soil Association Organic certification since June 2013 and Kosher certification, since September 2012.

5.Product Characteristics					
Product categories	15 - Dried food and ingredients Category Category Category				
Finished product safety rationale	Low Aw dried foods - low water activity and high alcohol content, Propylene Glycol depending on product				
High care	No	High risk	No	Ambient high care	No
Justification for area	All areas are designated as low risk ambient – low water activity and high alcohol content				
Allergens handled on site	Cereals containing gluten Milk Soya Fish Nuts Celery Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen				
Product claims made e.g. IP, organic	Organic, Kosher, Halal, Sicilian Lemon and Madagascan Vanilla.				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Weak Vanilla Extract code ET16451.Natural Lemon 13449 – booth 1 – liquid blend Condensed Milk Concentrate – 14312 - booth 2 – liquid blend Natural Coffee Flavour – 13380 – booth 5 – powder blend Natural Almond Flavour – 13641 – ethanol extraction Juniper Flavour – 198546 lot 17041 – powder blend Vanilla Flavour liquid – 12518 lot 108609 - ethanol extraction Lime Oil lot code 108544,				

6.Audit Duration Details			
On-site duration	18man hours	Duration of production facility inspection	9 man hours
Reasons for deviation from typical or expected audit duration	Onsite time 18.5; Deviation of 30mins due to lunch break non auditing time.		
Next audit type selected	Unannounced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2020-08-24	10:30	17:00
2	2020-08-25	08:45	17:15
3(finish date)	2020-08-26	08:45	12:15

	Auditor (s) number	Name	Role
Auditor Number	176047	Philip Irwin	Lead Auditor
Second Auditor Number	N/A		Please select

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Lee Beesley / Managing Director	Yes	Yes (part)	Yes	Yes
Kevin McManus/ Operations Manager	Yes	Yes	Yes	Yes
Daniel Harper / Technical Manager	Yes	Yes (part)	Yes(part)	Yes
Andy Buckingham/Compounder		Yes(part)		
Adam Taylor / Compounder and Logistics Operator		Yes(part)		
Terry Stillman – Consultant		Yes(part)	Yes(part)	Yes

GFSI Audit History

Date	Scheme/Standard	Announced/Unannounced
2018-07-18	BRCGS Food issue 7	Unannounced
2019-08-13	BRCGS Food issue 8	Unannounced

BRCGS Food Safety

Non-Conformity Summary Sheet

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

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**
1	3.5.1.2	Supplier file not up to date. Supplier Approval – QMP27, version 1 dated 2019/11/13 currently being updated to cover suppliers of product contact ventilated sacks.	NCR 904.raised. QST met to review procedure at meeting on 7th September. Updated suppliers of product contact ventilated sacks documentation chased up and received.	Completion of supplier approval and review of Protective Packaging Ltd, with updated specifications and ISO9001 certificates received, along with completed QF07 SAQ and Appendix Training a new Technical Administrator for maintenance of Supplier Approval procedure, as extra dedicated resource. Communications rolled out at monthly meeting.	Unsatisfactory application of current procedure – QST supervision requires strengthening.	2020-09-11	Philip Irwin

Comments on non-conformities

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There is a documented food safety policy – P1, Company Quality and Product Safety Policy signed by the new Managing Director dated 2019/11/13. The policy was reviewed during the last management review dated 2020-07-24, there was an update in the policy as part of re-write of the QMS to address Food, issue 8 requirements, now dated 2019-11-13. The policy also includes references to continual improvement, product safety, legality and quality and customer commitment.
This policy is displayed at the site entrance and in the staff amenities areas. It is also included in the induction information given to all new employees.

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

The senior management participates in meetings which are Weekly, Monthly, Quarterly and QST – Quality, Safety and Technical 3 monthly meetings, with full Management Review agenda.
3 monthly food safety, quality legality meetings were conducted. The minutes of the monthly meetings were sampled and verified 2020-04-01, 2020-05-27 and 2020-07-24, more regular to reflect Covid 19 project. The first Quality Conference was held in April – 2020-04-10 to communicate to all staff the future planning for growth in the business, the development of a Quality Culture and the alignment with the changes and requirements of the Food, issue 8 standard. With refresher and Covid 19 project roll outdated 2020-07-01.

The recent management review under SOP 27, issue 1 is 4 per year, approximately 3 monthly and the meeting were conducted on 2020-07-24. The directors and the QA team were present in the meeting. The minutes of the management meeting include last meeting minutes and actions, dated 2020-07-24, quality policy, objectives, system improvement areas, customer complaints, new product development, New emerging issues related to food safety, product legality and quality, hygiene audits and action points discussed, external changes that affect the quality system found reviewed and decisions and actions were established. Review of the site performance against the standard and objectives set in the standard was conducted. Ongoing investment at site including upgrade of computer systems.

Quality Culture is driven by the Managing Director and Managers on site working with an external consultant with wide experience of improvement of food safety culture, with refresher training rolled put dated 2020-07-01. Supported by the first Quality Conference was held in April – 2020-04-10 to communicate to all staff the future planning for growth in the business, and the alignment with the changes and requirements of the Food, issue 8 standard and the market move towards changes in extraction system methodologies. Updated risk assessment to issue 3 dated 2020-03-17, supported by 3m timescale and monitoring via the QST Meeting and Weekly Planning QMS Meetings (in place of monthly communications meetings) – minuted on QF54, feedback via managers and supervisors and recent Covid 19 roll out dated 2020-07-01, used to reinforce the Quality Culture, minuted on QF55. Supported by staff handbook dated 2018-12-13, with policy, whistle blower definition and how to raise a concern, with supporting confidentiality, external disclose by phone or writing to independent consultant or group chairman or PAWs – Public Concern At Work helpline or website, legal protection and support. Discussed with consultant and new Managing Director, area for further review and development in 2020/2021, with focus upon measuring effectiveness, working with PAWs.

The objectives and KPIs Key performance indicators are reviewed monthly and are part of the 4 pa QST – Quality Safety and Technical Senior Management Meetings (MRM – Management Review Meeting), minutes viewed dated 2019-11-13, 2020-04-01, 2020-05-27, Covid 19 – plan update of 2020-07-01, last one on TEAMs dated 2020-07-24.

The following Objectives and targets are in the KPIs, communicated at QST and weekly operations meetings;

- Justified Complaints under 30 per year and pro rata improvement on 2019 (under 0.5% of invoices). Achieved in 2019 at 30, retained as 2020 target and on target at 5 YTD. Nil YTD related to Covid 19.

- Lead Time – order to despatch to be under 15 working days, and pro rata improvement on 2019. Achieved in 2019 at 14, retained as 2020 target and on target at 11 YTD.
- Internal Defects – Not Right First Time under 40 per year and pro rata improvement on 2019. Achieved in 2019 at under 5, retained as 2020 target and on target at under 5 YTD.

At monthly programme meetings, where any KPI is below the target value, the senior management ask for the explanation and the corrective actions are documented and communicated to the relevant team member and communicated back to the senior management.

All the issues related to food safety, quality and legality were listed, their completion date, responsibility assigned, timelines, budget required and methodology for the completion of the task found documented. The issues related to the product safety and quality found communicated to the team, discussed during the meetings and the responsibilities found assigned to sort out the issues. Customer complaints found sorted and followed up by the senior management. Issues related to the line operation, their food safety aspects, training of the team both internally and outsourced were conducted and assigned for the upcoming months, completed and evaluated in this 2019 and YTD in 2020. The effectiveness of all these activities and their achievements have been recorded into the action plan. There are clear communications from the senior management to the rest of the staff in terms of product specifications, line standards such as visual standards and work instructions. The communication related to the CCP(s) and Pre-requisite programs such as cleaning and sanitisation, pest control, Allergens and their handling methods, Equipment calibration and maintenance were communicated to the line personnel. The communication with the staff regarding the daily issues found communicated both verbally and recorded as the minutes of the meetings via the Operations Manager. Supported by periodic toolbox talks. Key impact is the market move towards changes in extraction system methodologies. Weekly records, examples seen from 2020-07-01, 2020-08-19 and 2020-08-24.

The staff can discuss the hurdles and issues they come across for food safety, quality and product legality aspects, with the directors on site. There is a mechanism for Confidential reporting system or whistle blowing policy. This policy and the contact number displayed on corridors, Notice board etc. Part of Staff Handbook dated 2019-06-13. Schedule 6 denoting contact details for the nominated independent person for confidential reporting, in this case the External Food Safety Consultant.
Recent issue of a Covid 19 handbook dated 2020-07-01
BRCGS logo in use on website and limited stationery.

However, currently updating website and QF46, version 1 dated 2013/03/31 – C of A and Q R, to new BRCGS logo. Minor CAR 1 of 2 raised.

The site is kept informed of changes in legislation via BRCGS website, consultant input, certification bodies and test house, Food Standard agency website and retailers' portals. These are communicated to the team, reviewed by collating and discussing in monthly meetings. The site was aware of BRCGS Position Statements – F8033 - Vulnerability, F837 – Food Culture, P558 Packaging, dated 2019/04/10.
H.E. Stringer flavours maintains the latest scientific literature (EC Legislative requirements), historical and known hazards associated with raw materials and different flavours components such as substitution and fraud etc. Legislation and published material referenced during the development of the plan included the flavouring regulations EC 1334/2008, 889/2008/EC, 834/2007/EC, UK Flavouring Association, European Flavours Industry and Institute of Flavours Industry Guidelines, Codex, FSA, BRCGS, Food Packaging Regulations, Food Solvent Regulations, Allergen Regulations, TSO and EHO. PRPs had been identified and included pest control, hygiene, housekeeping, and training, receipt of raw materials, allergen control and stock control.

All previous 3 non-conformances raised during the external and internal audits found closed out and there was evidence that root cause has been identified and actions instigated to prevent recurrence. Each was revisited to ensure full effectiveness was evident.

1.2 Organisational structure, responsibilities and management authority

There is an established and experienced team of managers based on site with the Managing Director being in overall charge. The day to day operations of the site are shared between the management team (Production under Operations Manager, Quality, NPD and positive release under Technical Manager, Commercial under Managing Director). An organogram is in place dated 2020-01-10.
Roles and responsibilities are covered at induction. The key staff cover that is roles and responsibilities in the absence

of key personnel were defined. Procedures are available on the share drive on all computers. Sampled responsibilities for the Managing Director as the BRCGS Representative, the Operations Manager as the Deputy BRCGS Representative and the Technical Manager as the support BRCGS Representative, the HACCP Team and the Internal Audit Team.

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

2 The Food Safety Plan – HACCP

The company's food safety plan is based on Codex Alimentarius HACCP principles.

The HACCP team is a multidisciplinary team. The HACCP plan, with supporting pre- requisites, is dated 2020-07-24. The team consists of the EC Managing Director as the Team Leader who holds a BRCGS Intermediate Level 3 HACCP certificate – ATP034 dated 2008/06/18,
Managing Director - BRCGS HACCP certificate dated 2014/11/06.
Operations Manager – RSPH Level 3 HACCP certificate number 635/4 dated 2019/11/19
Technical Manager - RSPH Level 3 HACCP certificate number 635/5 dated 2019/11/19
External Consultant as Specialist Resource – BRCGS Food ATP number 018 since 2003-10-09.
The scope of the study includes receipt and handling, processing, storage and despatch and covers all the products produced at the site. It is systematic, detailed and fully implemented and maintained.

H.E. Stringer flavours maintains the latest scientific literature (EC Legislative requirements), historical and known hazards associated with raw materials and different flavours components such as substitution and fraud etc. Legislation and published material referenced during the development of the plan included the flavouring regulations EC 1334/2008, 889/2008/EC, 834/2007/EC, UK Flavouring Association Guidelines, Codex, FSA, BRCGS, Food Packaging Regulations, Food Solvent Regulations, Allergen Regulations, TSO and EHO. PRPs had been identified and included pest control, hygiene, housekeeping, and training, receipt of raw materials, allergen control and stock control.

A detailed pre-requisite programme is in place covering general cleaning, sanitation, pest control, maintenance, personal hygiene, purchasing, calibration, supplier approval, internal audits, site security, chemical control, waste control and manganese removal. All these aspects sampled were properly implemented and managed by the site management and checked during the site inspection and traceability trial.

Product descriptions are defined as:
The raw materials comprise of different component in solid powdered form and liquid form. Raw material characteristics, specification and tolerance have been documented, indented use as a food flavours, processing methods, tolerance for defects for example organoleptic and sensory, visual standards and specification and defects found specified. Extracts are infusions of vegetable matter in alcohol and water, with a minimum alcohol content of 20%. Powders are dry blends on a food grade carrier.

There is no sub-contracting of any part of the process.
Legislation and codes of practice used as terms of reference in the development of the plan included. – Codex, Food Safety Act, Food Hygiene Regulations, Food additives and extraction solvents in Foods Regulations and FSA / Campden allergen guidelines.
Intended use varies and is determined by the brand holder, specifics are given on packaging. All products are not

ready to eat / ready to use, they are used in recipes for consumer meals, which may have “free from” or IP claims (halal, organic, kosher), vegetarian. Un-intended product use found defined for example any allergenic product used by allergy sufferers. The shelf life has been confirmed and varies from 6-12 months for normal packaging systems, extract into small 1litre plastic bottles, 5lt, 10lt plastic containers, 20Kg vented plastic sacks and 1 tonne IBC containers.
Some 24 months in vented foil bag systems. Products are packed in standard ambient barrier packaging and intended as an industrial material for business to business supply, to be used in the manufacture of products intended for human consumption. Verified and supported by the site holds external certification. Soil Association Organic certificate, last on site audit dated 2020-05-29, with Soil Association Certificate number MD0062895P4242 GB-ORG-05 Expiry 2021-05-30, with full traceability balance conducted.
Kosher Certificate with on site audit dated 2020-09-08, with full traceability balance conducted, number 34133 Expiry 2021-05-30.

For food flavourings, colours and extract into small 1 litre plastic bottles, 5lt, 10lt plastic containers, 20Kg vented plastic sacks and 1 tonne IBC containers.
This study starts at goods receipt, decanting/mixing (liquid, powder or steam extraction), filling, capping, labelling, packing, palletising and finished goods to warehouse prior to despatch. Ambient stable ingredients. There is no bactericidal/ bacteriostatic treatment utilised in this manufacturing process.
The frequency of checking at every container change.
3 HACCP studies and Process Flow Diagrams found verified by the food safety team on 2020-07-24;
OP1 – open product liquid and powder, interim, WIP and re-pack (pack off)

OP2 – liquid flavours – bootsh1 to 3, including steam extraction in booth 4, large vessel and open – CCP 1

OP5 – powder flavours – in dedicated booth 5, CCP 2,

All took place on 2020-07-24. Supported by Allergen Risk Assessment Matrix dated 2020-07-24.

Powders CCP- 2 sieves – 1.25mm sieve for blending depending on product.
Liquids CCP 1 – filters - 560-micron.

Hazard analysis and CCP identification has been based on a likelihood x severity basis and the use of a 4-question decision tree. The following CCPs have been identified and critical limits defined:
Hazard analysis and CCP identification has been based on a likelihood x severity basis and the use of a 4-question decision tree. Any hazards rated as high or medium risk were referred to the decision tree. The following CCPs have been identified and critical limits defined.
Powders CCP- 2 sieves – 1.25mm sieve for blending depending on product.
Liquids CCP 1 – filters - 560-micron.
Both based upon risk assessment, range of products and industry experience. Frequency at end of customised blend/extract process at ambient packing to WIP and final. Based upon COA – appearance check prior to use.
Corrective Action of report if damaged sieve / filter or if debris in pack for CAPA report and remedial actions.
Positive released based upon COT – Colour, Odour and Appearance/Taste, Refractive Index and Density check by laboratory.
Periodic bioburden check for cleanliness of class L clean room facilities, sampled; The test report from a third-party Laboratories. ALS Laboratory report number 3636-1 dated 2020-07-29 covering Karl Fisher moisture assay and bioburden based upon TVC, bacteria, yeast and moulds – under 100cfu, staphylococcus, salmonella, E. coli, Enterobacteriaceae – not detected and gamma negative verified and found satisfactory.

Describing the CCP’s;
Powders CCP- 2 - sieve – 1.25mm sieve for blending. Critical limit – no holes or damage to sieve, no contents over 1.25mm to pass through.
Liquids CCP 1 – filters - 560-micron metal mesh filter cone. Critical limit – no holes or damage to sieve, no contents over 560 microns to pass through.
Monitoring points at line set up, container change, line clearance and all detailed on QF01 form to verify completion.
Corrective action would be reprocessed product to ensure no breech of CCP and back to point of confidence on that damaged sieve / filter. No issues to date.
A risk assessment has been completed looking at sieve sizes at manufacturer and on site, risk of wear and tear from machines, filler apertures and any metal associated with packaging (e.g. lids and foils). It was concluded that sieves

were sufficient to control the risk of metal and foreign body contamination on liquid and powder lines. The frequency of the sieve inspection is at least twice per shift, if long run or start and end of the normal customised jobs.

Both validated in 2018-07-11 using seeded powder and liquid blends to ensure captured oversized elements, including undersize controls.
Verified critical limits with manufacturer;
CCP – Filter – Certificate of conformity 2019-01-16 “clamp 90 fine screen filter 1.25mm screen mesh sieve certificate number 27535 - stainless steel, food grade and 1.25mm woven warp/weft mesh, with 5 % tolerance to C21FDA.
To national standards, on full re-calibration frequency of 5 years based upon use and risk assessment.
Certificate of conformity dated 2018-11-30 Clamp pure screen inline filter 560 microns certificate number 27266 -- stainless steel, food grade and 560 microns mesh, to 5% tolerance.
Inspection by production / QA countersigned, and production supervisor checked as part of cleaning schedule to ensure no issues on product changeovers, on Form QF01. Verified by internal audits, complaints / product recall or withdrawal. No issues or trends evident and confirmed verification is working correctly.
Last review and date of each HACCP study, no changes – 2020-07-24.

Details of non-applicable clauses with justification

Clause/section reference	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

The Food safety and quality management system have been fully implemented and the food safety and quality manual found as available dated 2020-01-10. This manual clearly describes the requirements of implemented Global Standard for Food Safety Issue-8. Outline of working methods such as specific work instructions and practices have been clearly defined in this Company Manual in English language. All relevant departments have been distributed the manual and the procedures, accessible in har drive and on computers. A list of all control documents indicates the latest version number and the identification and authorisation of controlled documents. This was sampled as part of the traceability exercise on the day.

3.2 Document Control

Controlled documents are held in the computer system (soft copy) and hard copies as well and control is managed by a procedure covering control of documents, password authorities found documented and communicated at induction and refresher training for the creation, authorisation, changes/amendments and replacement of existing documents. All necessary changes in the year 2019 and 2020 YTD, sampled were found authorised. Key authorisation is by the BRCGS representative and deputy.

3.3 Record completion and maintenance

Document control is communicated to key staff at induction and refresher training. Access is password controlled on the computers. Hard copy specification, forms and works orders are issued for each job. Records are completed manually or electronically and are stored as hard copy and electronically and backed up daily.
Records reviewed during the audit e.g. production report, packaging checks, post maintenance cleaning records and internal audit were seen to be legible and genuine and were easily retrieved. The batch history for the few products verified. The record retention also depends upon the type of records. Records are retained for more than 5 years (longest shelf life of product 24 months.)

3.4 Internal audits

Internal audit schedule 2019/2020 in place under QM17, version 4. BRCGS issue 8 standard is broken into small sections along with customer requirements, mock recall testing, trace tests and agency audit of workshop area. All sections of the BRCGS are audited at least once annually, twice if issues or risk, which is are managed by the Managing Director, using an external consultant across the year and supplemented by the ECManaging Director, the Operations Manager and the Technical Manager, to ensure impartiality. Confirmed the risk assessment of all audits is conducted annually, including timely follow up of actions by auditor, as part of the 4pa, QST (MRM) meetings.
Internal audit reports sampled to issue 8 include;
Section 3.7 corrective and preventative action completed on 2020-06-09 – nil NCRs.
Section 4.8 Staff facilities completed on 2020-06-09 - nil NCRs.

A reverse traceability test internal audit was conducted on 2020-02-05 on Cognac Oil Flavour – C082 made on 2020-01-23 production. The trace test took under 30 minutes. Full mass balance of production quality booked into warehouse, moved into production, quality of units produced and waste. Specific gravity is calculated for point of fill during processing. Positive release by in-house laboratory based upon COT, Colour, Odour and Taste, density and refractive index. Tested on 2020-02-05 and nil NCRs.
Section 5.6 Product inspection and lab testing completed on 2020-08-12 – nil NCRs

Section 2.0 Food Safety Plan HACCP completed on 2020-06-09 with evidence of PRP's, procedures, flows and nil NCRs.
Section 3 QMS dated 2020-08-04 – nil NCRs.

Test of product recall internal audit conducted on 2020-01-20 – Raspberry Flavour – ET12481 from date of production 2020-01-20. Trace test started 09:30 and finished at 11:00, under 90 minutes. Product recall reason is product contamination. Full mass balance of production quality booked into warehouse, moved into production, quality of units produced and waste. Normal loss of up to 2% based upon over bulk adjustment on BOM and MOM, all within specification. Specific gravity is calculated for point of fill during processing. Nil NCRs.

Section 4 – site – dated 2020-08-12 - nil NCRs.

Section 5 and 6 – Product and Process Control dated 2020-08-12 – nil NCRs.
Section 7 – Training dated 2020-06-25 – nil NCRs.

A forward's traceability test internal audit was conducted on 2020-02-05 on ingredient M505 back to Cognac Oil Flavour – C082 made on 2020-01-23 production and 3 other jobs and supporting specifications and clients. The trace test took under 2 hours. Full mass balance of production quality booked into warehouse, moved into production, quality of units produced and waste. Positive release by in-house laboratory. Tested on 2020-02-05 and nil NCRs.

Section 3.6 Specification completed on 2019-11-13, objective evidence of two specifications included within report– nil NCRs.
Section 1.1 Senior management commitment completed on 2019-11-13, with evidence included of quality policy as displayed to staff and Quality Conference – Nil NCRs.

5 auditors onsite including;
ECManaging Director holds a Supplier Assessment and Auditing certificate by PQA dated 1994-05-11 and supporting QF05 Training Record denoting refresher training by External Food Safety Consultant dated 2014-03-12 and 2019-04-10.
Managing Director with QF05 Training Record denoting in-house refresher training by External Food Safety Consultant dated 2018-11-07.
Operations Manager with QF05 Training Record denoting in-house refresher training by External Food Safety Consultant dated 2018-11-12.
Technical Manager with QF05 Training Record denoting in-house refresher training by External Food Safety Consultant dated 2019-04-10.
External Food Safety Consultant holds a BRCGS Internal Auditor Certificate number 0149 dated 2003_10_09.
The internal auditors have received internal audit training and are independent of the area being audited and their own work.
Audit dates and reports reviewed shows evidence of photos, procedures, specifications and hand / typed reports

based on templates provided. The corrective actions NC are logged on end of the report with NC numbers and clearly written in text within the report.
Conducted across the year.

There are monthly GMP audits to cover factory environment and processing equipment and utilise;
• hygiene inspections to assess cleaning and housekeeping performance - Examples seen from 2020-07-01, 2020-08-19 and 2020-08-24
• fabrication inspections to identify risks to the product from the building or equipment - Examples seen from 2020-07-01, 2020-08-19 and 2020-08-24.
Every Monday morning weekly production meeting held with cleaning, QA, finance, production to track outstanding actions.
Examples seen from 2020-07-01, 2020-08-19 and 2020-08-24.
with Operations Manager notes of progress being made on actions outstanding. No open product.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

All products used and that form part of the final product (including packaging) are sourced through approved suppliers and are monitored.
Suppliers are being inducted, monitored and approved as per the procedure Supplier Approval. A risk assessment based on suppliers and food fraud assessment, issue 1 dated 2019-11-13 (reviewed 2020-07-24, no changes) is performed on raw material groups each individual raw material is risk assessed, with products assessed for allergens, allergens on site, malicious contamination, cross contamination risks, physical state, foreign body, chemical, microbiological and substitution/fraud risks, history and any prior incidents with supplier, volume per year, IP, origin / provenance, significance to quality, customer / legislative requirement, economic factors making fraud / adulteration more attractive, malicious tampering and extortion history, emerging risk, country of origin. Products are medium to low risk. The annual review of the supplier's master list – QMP27, version 1, assessment was carried out on 2020-07-24, is conducted at least annually, as part of the 4pa, QST (MRM) meetings, to ensure no Covid 19 raw material and packaging shortage / delay issues.
Confirmed that most of raw materials and primary packaging are purchased directly from manufacturers or agents, who are required to complete the SAQs with GS certificate, GMO, Primary packaging compliance and all other documentation. Where agents or brokers are used, the supplier file denotes the last manufacturer or packer. Sampled Madagascan Vanilla.

The nominated supplier is either audited; self-audited and has been on trial assessment, based on risk related to the products, current accreditation BRCGS, GFSI etc. or Questionnaire. The suppliers must fill the detailed questionnaire, details of their GFSI – Global Food Safety Initiative benchmarked certification, certification validity etc. The majority of suppliers sampled held GFSI certification. One supplier did not hold GFSI certification and supporting supplier B – tertiary packaging transit corrugated box, approval dated 2020-07-24 based upon ISO 9001 : 2015 certification and site audit.
Sampled supplier files, as part of vertical audits;
Ingredient code M093 – Supplier A – with GFSI BRCGS Food Chain certificate number US15/842150 expires 2020-12-02.
Ingredient code V087 liquid – supplier U – QF06 review dated 2019-11-13 with GFSI FSSC ISO 22000 LRQA certificate number 9905 expires 2021-04-26.
Ingredient code M011 – liquid – supplier B – with GFSI FSSC ISO 22000 AIB certificate number 263 expires 2020-10-13.
Ingredient code X11 – liquid – supplier X – with GFSI FSSC ISO 22000 SGS certificate number NL18/86 expires 2021-07-07.
Ingredient code 0013 – onion powder – supplier K – QF06 review dated 2019-11-09 with GFSI BRCGS Food SGS certificate number 059 expires 2021-01-23.
Ingredient code R008 – liquid – supplier D – QF06 review dated 2020-02-03 with GFSI BRCGS Food NSF certificate number A83 expires 2021-05-12.
Ingredient code K505 – liquid – supplier K – with GFSI FSSC ISO 22000 Intertek certificate number 622 expires 2020-12-30.
Ingredient code K505 – liquid – supplier K – with GFSI FSSC ISO 22000 Food Chain certificate number 718 expires 2021-09-21.
Ingredient code A – Supplier K – with GFSI BRCGS Food Chain certificate number 215 expires 2020-12-20.

Ingredient code T liquid – supplier U – with GFSI FSSC ISO 22000 LRQA certificate number 5433 expires 2021-07-18.

Haulage – Abacus Transport – QF06 review dated 2020-04-01 and RHA number 23266, with supplier site audit dated 2019-04-01.
DX Freight - QF06 review dated 2020-07-24, with contact dated 2015-11-30 and supplier site audit dated 2019-11-30.

Packaging – white plastic 5 lire jerry can – supplier F – with GFSI FSSC ISO 22000 NSF certificate number 329 expires 2020-12-03.

CCP Validation:
Powders CCP- 2 sieves – 1.25mm sieve for blending depending on product.
Liquids CCP 1 – filters - 560-micron.
Both from supplier B, with supporting test report to ISO 9044, traceable to national standards number 413828 dated 2020/06/09.

Organic Suppliers on the HESF Purchasing System including authenticity. Flow chart, HACCP – Product Safety Plan Flow, GMO declaration etc. 3 Years SAQ frequency. Low risk supplier. Vulnerability assessment, issue 2, dated 2019-11-13 (in 3m QST and no changes up to 2020-07-24), in place – based upon end consumers – infants, elderly, allergy suffers, Vegetarian, Kosher, Organic and Halal, etc. Part of H E Stringer Flavours Soil Association Certificate number MD0062895P4242 GB-ORG-05 expiry 2021-05-30, with supporting balance exercise as part of the external audit.

Kosher Suppliers on the HESF Purchasing System including authenticity. Flow chart, HACCP Flow, GMO declaration etc. 3 Years SAQ frequency. Low risk supplier. Vulnerability assessment in place, issue 2. Part of
Kosher Certificate with on site audit dated 2020-09-08, with full traceability balance conducted, number 34133 Expiry 2021-05-30.

Vented plastic sack – supplier P - ISO 9001:2015 certificate number 17-442046 expires 2023-07-07 by IEC Limited.
Supporting Declaration of Compliance to 10/2011/EC, supporting Stringer checklist in line with protocols.
Plastic IBC - Mauser with TUV SUD ISO 9001:2015 certificate number expires 2023/08/13 and Declaration of Compliance dated 2011/07/08.

However, Supplier Approval – QMP27, version 1 dated 2019/11/13 currently being updated to cover suppliers of product contact ventilated sacks. Minor CAR 2 of 2 raised.

No head office function. Exceptions would require Managing Director approval and nil to date. The audit frequency is annually under internal audit.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Raw and Packaging are accepted as per the Goods in procedure. Raw materials are checked on intake for compliance with purchase orders and certificates of analysis/compliance are received. The certificates of analysis are mandatory for the acceptance of raw and packaging materials.

The certificate of analysis for the following products were seen, as part of vertical audits ;

Sicilian Lemon – with Lapua Certificate of Origin number 17238 by SGS with SINCERT accreditation number 1880 dated 2019-08-13 (new audit booked).
Madagascan Vanilla – with Madagascan certificate of authenticity number 75853 issued by the Department of Agriculture.

Ethanol – Certificate of Analysis covering appearance, aldehyde, G.C. match, refractive index, specific gravity and flash point.

There are line standards / visual standards, work instructions containing product defects, tolerance and product specification. These were visible and communicated on the lines. The review frequency of specifications is annually, under internal audit, if no changes.

Primary packaging is plastic containers - 1 litre plastic bottles, 5lt, 10lt plastic containers, 20Kg vented plastic sacks and 1 tonne IBC containers.
Packaging is composed of plastic and specifications and migration certificates are available to ensure compliance with 10/2011/EC or other customer / country requirements denoted by the Technical Manager.

3.5.3 Management of suppliers of services

The management of suppliers of services is conducted in the same way as suppliers of raw materials and packaging. Approval is based on questionnaire, any industry specific accreditation or certification, previous experience with the supplier etc. exceptions are the suppliers which are approved by the customers. These suppliers of services were checked;
ALS laboratory – UKAS 1282.

Johnson Apparel Master was audited on 2019-11-14.

The audit frequency is annually under internal audit.

3.5.4 Management of Out sourced processing

No outsourced production or packing.

3.6 Specifications

Specifications are provided by the customers. The specifications are managed by the Technical Manager and are maintained for all raw materials, intermediates (bulk Vanilla extracts) and packaging.
Including primary packaging is plastic containers - 1 litre plastic bottles, 5lt, 10lt plastic containers, 20Kg vented plastic sacks and 1 tonne IBC containers.
Packaging is composed of plastic and specifications and migration certificates are available to ensure compliance with 10/2011/EC or other customer / country requirements denoted by the Technical Manager.
Manufacturing instructions/specifications are available at workstations and confirm compliance with finished goods specifications.
Specifications are agreed with customers. The following manufacturing and packing specifications were reviewed and found to be compliant, as sampled;
Weak Vanilla Extract code ET16451 (dilution from Vanilla Ethanol extract intermediate).
Natural Lemon 13449 – booth 1 – liquid blend
Condensed Milk Concentrate – 14312 - booth 2 – liquid blend
Natural Coffee Flavour – 13380 – booth 5 – powder blend
Natural Almond Flavour – 13641 – ethanol extraction
Juniper Flavour – 198546 lot 17041 – powder blend
Vanilla Flavour liquid – 12518 lot 108609 - ethanol extraction
Lime Oil lot code 108544
Specification review is part of NPD and signed off by the Technical Manager, as sampled;
Mixed Fruit – 16452 – version 2 - special address requirement agreed.
Natural Cherry – 12241 – version 2 - special address requirement agreed. No head office function.
The customer communicates the changes of specification. Specifications are reviewed annually, or where changes occur. All finished product and label specifications.
Specifications for products are requested annually from the supplier to ensure the version on file is the most up to date. Specifications are all approved by the Technical Manager.

3.7 Corrective and preventive actions

Corrective action procedures under SOP 15 are well implemented for non-conformances arising from a few scenarios that result in a risk to product safety, legality or quality are investigated and recorded in line with clause requirements. This includes the assessment of the consequences of the non-conformity and verification of corrective action by an appropriate person. Nil NCRs in the internal audits sampled. 2 raised in 2020 YTD in the NCR log. These Non-conformances raised during the internal audits were properly closed, based upon root cause analysis, corrective action found taken and found to be effective.

3.8 Control of non-conforming product

Complaints and Non-conformance procedure – SOP 15 and supporting QF15 Form. Non-conformances come from external audits, internal audits, during receipt, storage, processing, dispatch and customer complaints. Work instruction on NF15 all non-conformances are recorded on non-conformance database, stock is assigned a unique sequential number to the non - conformance. QA HOLD labels are applied to the materials and any materials place on hold through stock system are unable to be scanned for use.

This is a KPI under;

- Internal Defects – Not Right First Time under 40 per year and pro rata improvement on 2019. Achieved in 2019 at under 5, retained as 2020 target and on target at under 5 YTD.

Due to warehouse facility, there is a limited designated black plastic skip quarantine area in the racking Warehouse stock is clearly identified with hold tape stock cannot be used and only person who can release stock from QA HOLD is QA dept. The non-conformance database is updated with the result of the investigation.

The Technical Manager is overall responsible for deciding and management of NC products, if product should be reworked, released or disposed of, due to the foodstuff's nature of the product and its use in food production. No product in the quarantine area at the time of the site audit.

Database include details of details of NC, Allocated NC number, Reason for NC, Closure of NC actions, 5 whys, Corrective and preventive actions, based upon root cause, including complaints justified, Date of closure and closed out by.

Outstanding non-conformance are reviewed daily at morning operation meeting, via the Technical Manager, non-conformances summaries are reviewed by the Management team against performance indicator and non-conformances summary is an input to management review meetings.

No defective product seen during the audit, no product in the On QA Hold in Warehouse facility, sampled.

For last records of food destruction see waste section.

3.9 Traceability

A recording system is in place on the SAGE manufacturing system with all raw materials, in process materials, packaging and finished product coded to allow for full traceability through the system, this includes rework and primary packaging traceability. No bulk, as all made to order or intermediate Ethanol extract (additional traceability via bonded stores book).

As part of internal Audit Schedule for 2019 and 2020, the site had completed the following traceability exercises;
A reverse traceability test internal audit was conducted on 2020-02-05 on Cognac Oil Flavour – C082

Test of product recall internal audit conducted on 2020-01-20 – Raspberry Flavour – ET12481

A forward's traceability test internal audit was conducted on 2020-02-05 on ingredient M505. All deemed to be effective and a suitable system to track products both forwards and backwards.

Detailed documented traceability procedures in place, includes traceability after rework. There is no rework for many products as end customers often have a no rework policy. For some customers underfills may be returned to the same mix but not reworked into a second batch

The following traceability exercise was conducted, back to samples made earlier in 2020, to check each manufacturing process, during each day of the audit;

Natural Maple Flavour – 13205. Liquid Blend. Works Order number 079 dated 2020-03-18. Made to order and confirmation. Supporting BOM – Bill of Materials with weights confirmed, MOM – Method of Manufacture, Form QF06 - Line before and after checks for clearance, no allergens or suitable allergen deep clean controls in place cleanliness,

hygiene, contamination, tape engineering and packaging. Supporting QF01 – cleaning record form. CCP check by A.B. – confirmation of 560 microns metal filter cone in use, no damage and no issues in manufacturing Booth 1. Certificate of Analysis and Quality Report issued based upon COT, RI, density and weight check, number 268 dated 2020-03-20. Free from 14 prescribed allergens under 2007/68/EC. Pass stamped.
Mass balance; Order for 80kgs (always plus 1% over total produced 80.09kg) any excess stock is disposed to ensure full quantity within specification. This system is used on all orders, except Ethanol extraction due to bonded mass balance log.

Natural Almond Flavour – 13641 – ethanol extraction, made on 2020-04-01.
Certificate of Analysis and Quality Report issued based upon COT, RI, density and weight check. Nuts and nut products – no – contain almond oil. Halal compliant – no – contains Ethanol. Pass stamped.

Natural Onion Flavour – ET11106 – powder blend made on 2020-03-18. To BOM batch number 15596 into vented 25Kg foil sacks by supplier P. BOM – Bill of Materials with weights confirmed, MOM – Method of Manufacture, Form QF06 - Line before and after checks for clearance, no allergens or suitable allergen deep clean controls in place cleanliness, hygiene, contamination, tape engineering and packaging. Supporting QF01 – cleaning record form. CCP check by C.P. – confirmation of 1.25mm metal screen in use, no damage and no issues in manufacturing Booth 5. Pack code M087 on to 4 customers denoted on the SAGE Manufacturing database. Retained white powder sample was available and viewed.

Vanilla Bean Flavour – V035 – ethanol extraction, made on 2020-04-01.
To BOM batch number into food grade metal holding barrel for excess and despatched in PP plastic kegs. BOM – Bill of Materials with weights confirmed, MOM – Method of Manufacture, Form QF06 - Line before and after checks for clearance, no allergens or suitable allergen deep clean controls in place cleanliness, hygiene, contamination, tape engineering and packaging. Supporting QF01 – cleaning record form. CCP check by L.B. confirmation of 560 microns metal filter in use, no damage and no issues in manufacturing Booth 2. Ethanol from bonded cage storage area and supporting cage book denoted E048 stock and 252g removed. Use of potable mains water in the still via the steam generator and hard pipe system. Vanilla beans shredded in dedicated equipment to increase surface area for extraction. To 1 customer denoted on the SAGE Manufacturing database. Retained white powder sample was available and viewed.
Certificate of Analysis and Quality Report issued based upon COT, RI, density and weight check. Halal compliant – no – contains Ethanol. Pass stamped.
Suppliers approved by questionnaire have had their traceability system verified, as part of vertical audits and supplier site audits.

3.10 Complaint-handling

external audits, internal audits, during receipt, storage, processing, dispatch and customer complaints. All complaints are logged onto NC database. As part of investigation Non-conforming record opened which confirm details of non-conformance, barcode number, weight, product, customer, 5 why analysis, root cause, corrective and preventative action, final action date closure and closed out by and details linked into the database system to show closure of NC issue. Technical Manager has overall responsibility for investigation of customer complaints, to ensure suitable systems in place to record and monitor complaints.

Customer complaint trending in place, to support KPIs;

- Justified Complaints under 30 per year and pro rata improvement on 2019 (under 0.5% of invoices). Achieved in 2019 at 30, retained as 2020 target and on target at 5 YTD. Nil YTD realted to Covid 19.
- Lead Time – order to despatch to be under 15 workig days, and pro rata improvement on 2019. Achieved in 2019 at 14, retained as 2020 target and on target at 11 YTD.

Complaints are trending against product categories e.g. despatch issues, declared shelf life. 2019 benefited from a mould improvement project with manufacturer, removing many issues with faulty 5 litre bottle down to neck moulding dip and leakers. 2020 limited trends evident. Part of ongoing improvement project.

Communication to staff is at weekly QMS Planning and Operations meetings detailed on form QF54, version 1 - conducted with dept. heads, complaints and NC list communicated to ensure all staff are aware of issues. Examples

seen from 2020-07-01, 2020-08-19 and 2020-08-24.

3.11 Management of incidents, product withdrawal and product recall

Traceability / Recall procedure – QMP 26, version 1.
Procedure details contact details of Managing Director, Technical Manager and Operations Manager.
(recall committee) both office and mobile numbers with priority of contact details and customer list which is (managed through Managing Director). With supporting crisis management, food defence and BCP planning manual, dated 2020-07-01.

Disaster definitions, risk assessment for managing of situations such as fire, flood, bomb threat, malicious sabotage and energy. Key contact list is detailed within the traceability / recall procedure details QA manager will inform the BRCGS (SGS) within three working days. Details of other regulatory bodies police, DEFRA, hospital, HSE, UK Retailers should be notified within 24 hours. Last tested;

Test of product recall conducted on 2020-01-20 – Raspberry Flavour – ET12481 from date of production 2020-01-20. Trace test started 09:30 and finished at 11:00, under 90 minutes. Product recall reason is product contamination. Full mass balance of production quality booked into warehouse, moved into production, quality of units produced and waste. Normal loss of up to 2% based upon over bulk adjustment on BOM and MOM, all within specification. Specific gravity is calculated for point of fill during processing. Nil NCRs. Recall committee decided this scenario would result in a product withdrawal, based upon risk assessment. Not required as only a test.

Testing of mock recall test is scheduled two a year due to retailer customer requirements and in additional mock recall testing out of hours. Confirmed that the Certification Body (SGS 01021) will be informed within 3 days of the event of a recall.

There have been no recalls or withdrawals in the last 12 months.

Details of non-applicable clauses with justification

Clause/section reference	Justification
3.5.2.3	No live animals

4. Site standards

4.1 External standards

The site was built in 1966 and the building has undergone refurbishment work including zoning.

The building is suitable for the type of operations undertaken; The building is on a small industrial estate of mixed usage. No adverse activities were observed. There are defined entry routes for staff. Visitors etc are required to call reception via an entry system before being allowed access. No potential risks associated with the site that may affect product safety or integrity. Ongoing adequate maintenance of the site supported by monthly fabrication inspections to identify risks to the product from the building or equipment - Examples seen from 2020-07-01, 2020-08-19 and 2020-08-24.
There is a suitable clear zone around the site. No additional buildings to the site. Scope size of 1,130m2 (whole

building is 2,400m2 and is sectioned off into totally separate units – carpet supplier, adhesive tape manufacturer and forwarder of food flavours – purchased from H E Stringer). Building new homes on adjacent land at present.

4.2 Site security and food defence

A security risk assessment has been carried out on 2020-04-01, including annual food defence risk assessment, and forms part of the contingency plan in year 2020.
Different aspects were considered for example trespassing no cases, Vandalism no cases, no arson attacks, no attacks or threats, tampering or malicious damage no actual threat found. CCTV not required based upon risk assessment. The overall score of the site is 6 which means low risk.
The site security plan is suitable, in place and is managed by key fobs and secure doors, remote operation of key doors is fitted to site entrance and production, packing areas, warehouse, loading bays etc. Internal restricted areas have been identified and access is for authorised persons only. Emergency lighting is in place. Training is in place to remind staff to identify and report any unauthorised personnel, part of induction, Quality Culture and refresher training. The side and rear of the site is surrounded by fencing and the main gate is locked out of hours. Doors have access codes and there is a single entry point for all staff and visitors. No issues on the external audit walk.
The site is visited by the local Council - number GB154E0232.
Whole business park is locked down by barriers at night, with supporting CCTV.

4.3 Layout, product flow and segregation

There is a plan of the site, denoting different areas. This area is classified as low risk as defined on the site plan – issue 1 dated 2019-07-12, which is reviewed at each quarterly QST meeting, no changes and is up to date. The plan shows delineation, segregation, access routes for personnel, staff facilities, production process flow and waste removal. There were no temporary structures noted.
There is a plan of the site, zones are developed as per the standards flow diagram. The layout, product flow and segregation have extensively improved as part of the building refurbishment. Key control is 5 class L manufacturing booths, with plastic salted curtain doorways. Booth 5 is dedicated to powders, booth 4 is dedicated to extraction, booths 1 to 3 are dedicated to liquids, to minimise cross contamination risk. Most walls are steel sheet lined for ease of cleaning and improved finish. Goods In is a dedicated room, with rapid door and pedestrian door to the Eastern wall sited storerooms – liquids including bonded cage store, powders and packaging. Each is segregated from production by a plastic curtain slat doorway. Open plan production area. Racking for small ingredients at the Northern far end. Northern far wall is lined with fridges and freezers for storage of high odour ingredients to minimise taint / odour risk. All areas are designated as low risk ambient. All blend and extraction work are in 5 class L clean room production areas, dedicated dry or wet, covering fill and sieve / filter stages with plastic slat doorways to central area holding WIP and finished stock. No temporary structure or refurbishment at present, noted in the lay out.

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

The buildings were suitable for their purpose, following full refurbishment 36 months ago. Walls found constructed from appropriate materials and Internal fabrication is well maintained. Doors are well fitting and brush strips are in place and windows screened where necessary. There were no temporary structures or ongoing refurbishment noted. Walls, floors and ceilings found impervious, sealed and easily cleaned, Equipment such as mixing and blending vessels, agitators, pumps, valves, taps found properly maintained. All drains and drain covers are accessible for cleaning. Covered drainage found in place. Floors are durable and drains are located throughout. No water pooling was noted. There are no suspended ceilings or roof voids. No elevated walkways. There are heat extraction systems in place. Lighting was adequate and protected against breakage. Lights are unbreakable LED lights and few lights have protective cover for fluorescent tubes. Adequate lighting provided for clear working visibility. All infrastructure good condition to control dust and pests. Drainage, ventilation and extraction is suitable for the purpose.
Ongoing adequate maintenance of the site supported by monthly fabrication inspections to identify risks to the product from the building or equipment - Examples seen from 2020-07-01, 2020-08-19 and 2020-08-24.
Under QMP21, issue 1, cleaning records were recorded;
Weekly hygiene/housekeeping audit checklist dated 2020-08-05, back to 2016-12-15 verified.
Daily hygiene/housekeeping audit checklist dated 2020-08-26, 2020-08-05 back to 2018-11-26 verified.

4.5 Utilities – water, ice, air and other gases

The water distribution plan or taps plan for the distribution into the site dated 2019-07-12 was verified. Water used on site is potable and mains supplied. No non potable water on site.

Water is a blend ingredient as ambient or on demand heated by process equipment / steam generator, it is also used for cleaning floors, walls and equipment. Mains water is supplied by Thames Water, with potable water data from 2020-07-08.
There is a water diagram and sampling plan denoting key points in place dated 2019-07-12. Taps are flushed for 2 minutes at key points, determined by risk assessment, on a weekly full sampling basis.

Critical limits have been set for microbiological contamination: TVC <100, E Coli and Coliforms absent. Quarterly sampling is carried out at third party laboratory, to confirm class L room low risk and low bioburden. The system is de-scaled annually. Water testing from ALS laboratory. water testing schedule found developed. E.coli, Enterococci Not detected Coliform Not detected.
Supporting ALS report number 3636-1 dated 2020-07-29 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and moulds, staphylococcus, salmonella, E. coli, Enterobacteriaceae and gamma negative verified.
Gases not used.
Supporting Legionella SHEQ Survey dated 2020-04-30 – all within specifications.
Ice is not used. No other utilities used.

4.6 Equipment

The equipment is relatively simple and fabricated from food grade stainless steel. All open product is handled in dedicated 3m high steel sheeted booths along the Western wall, dedicated to weighing, mixing, blending, Ethanol extraction / distillation and packing. There are clear spaces underneath major equipment and other equipment was mobile. All Gaskets and seals are purchased against food grade specifications and arrive with Certificate of Conformity, relating to equipment materials and food contact.

4.7 Maintenance

A preventative maintenance schedule found developed for year 2019 and 2020 YTD. The schedule for maintenance is based on risk, historical information and manufacturers' recommendations. Preventive and corrective maintenance records are noted down and monitored. There is a daily start up hygiene/line check of all equipment which is completed, and the areas of improvement are highlighted. Sampled records dated 2020-04-30, no issues.
There is no Engineering workshop on site. The third party maintenance records sampled and effective;
FLT – Forkway Group report number 0583766 dated 2019-10-10.
Steam Generator – Certuss report 22452 dated 2020-06-03.

Water Softener – Freeston report dated 2020-04-30 and analysis report - Freeston report – water softener covering alkalinity, total dissolved and total iron dated 2020-04-20.

Contracts book in to new Covid 19 rules and are supervised on site. Sampled; Covid 19 Visitor questionnaire in place QF35 Factory visitors Form Issue 4 – sampled Steam Generator – Certuss engineer dated 2020-06-03, including Covid 19 questions and temperature taken at reception using IR gun under site Covid 19 rules.

All chemicals/lubricants used are suitable for food contact where applicable and details of allergen status has been obtained. Food Grade lubricant MSDS sheet verified; H1 Grease.

There is low risk to the product from the maintenance activity. Food grade lubricants used. Deep clean down by the production team at post maintenance hand back.

Recent toolbox talks to cover temporary repairs. Noted food grade heat sealer engineered hygienic rubber edge covers in place and on walk about checklist monitoring.

4.8 Staff facilities

Staff facilities were found to be satisfactory, way from production and sufficient for the size of the workforce. Due to small site staff facilities were limited, this consisted of rest area for breaks with kettle, tea, coffee, sink and fridges provided for personal food. Storage of personal food in clean hygienic state in fridge areas, but based upon risk assessment and customer requirement, no nuts allowed into the factory. No canteen facilities. Part of monthly facility

GMP audits / inspections.

Working clothing is controlled with hooks in use for “production clothing” and all personal items kept in lockers within toilet facilities. Dedicated production changing room, shoes are changed for production area. Visitors use disposable shoe covers. Main changing area prior to production with hands free mechanism hand wash sinks supplied with hot water, soap and paper towels.

PPE consists of white coat, beard snood, boots, gloves, hair net, safety glasses and 3M Juniper RTU filter kits for compounding areas. All PPE is changed daily unless spillage and more available. Clothing is laundered by Johnsons with contract in place dated 2017-07-30.

Designated toilets both male and female were situated near rest areas, which were not near production areas.

Small smoking area located at rear of car park area however, no staff currently smoke on site. The site is not graded as high care or high risk.

No external catering facilities provided on site. No nuts allowed to be brought onto site. All staff aware, this is part of induction. Segregated waste bins are provided within the staff facilities and checked daily.

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

4.9.1 Chemical control

There is an approved chemicals list in place. Non-food chemicals are risk assessed and managed. Chemicals are clearly labelled and stored in a designated storage area with restricted access outside the production area. Strongly scented/taint-forming materials are not used. MSDS sheets found at storage and usage point. Non-food chemicals are risk assessed and managed. Non-food contact chemicals are approved by review of the MSDS. There is an approved list of chemicals, sampled;
Multi-Purpose Cleaner – version 3.011 dated 2011-09-03.
Caflon soap – yellow neck container and IPS/IPA – green neck container.

The risk for cross contamination from chemicals has been assessed. Work instructions for different operations such as open product liquid and powder, liquid flavours – large vessel and open, WIP and re-pack (pack off), interim, powder flavours, found developed. Supported by Allergen Risk Assessment Matrix. Key control is dedicated booths and QF01 documented checks at line set up, changes and line clearance. Sampled as part of the traceability exercise on the day.

4.9.2 Metal control

There is a documented metal control policy in place, key risk is blades, staples, pins. Knives and scissors are checked at start and end of shift and are company issued. Part of weekly site GMP audit. Snap off bladed knives are prohibited and this is communicated to staff, visitors and contractors.
There are three company issued safety knives on site in the production area. These are numbered and controlled in the goods out area. These are weekly monitored, and last record checked for 2020-08-24 sampled. Supported by monthly external audit on QF26 – General and Housekeeping, WAM – Walk About Management . Also checked sign off on QF01 on each job, before and after, as part of the traceability exercise on the day.
One pair of scissors in production and 4 knives solid blade, in the goods out storage area only, well controlled and no issues noted during the site visit.

Staples, pins etc are not used in open product areas or packaging. The risks of metal are controlled using sieves/ filter which is a CCP.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass breakage procedure. No WIP or finished product is packed in glass. Some raw materials are received in glass and these are kept in a designated locked store. These are inspected for condition when used and a record, maintained on the production sheet. The items are then signed back to the store. A glass register is maintained of all

glass and brittle items on site. Only windows are high windows in the production area or in doorways, protected from breakage via use of plastic films. Weekly checks of glass and hard plastic are completed, part of site GMP inspections. Glass check records for 2020-08-24 sampled. The site has a breakage procedure which requires any breakages to be reported to a director/manager. Any potentially affected product is segregated, and a sample of the broken material retained. The glass is swept into a box for disposal. Clothing and footwear are checked for contamination. Supported by monthly external audit on QF26 – General and Housekeeping, WAM – Walk About Management . Also checked sign off on QF01 on each job, before and after, as part of the traceability exercise on the day.

4.9.4 Products packed into glass or other brittle containers

Some raw materials are received in glass and these are kept in a designated locked store. These are inspected for condition when used and a record, maintained on the production sheet. The items are then signed back to the store.
No WIP or finished product is packed in glass or other brittle containers.
Sampled as part of the traceability exercise on the day.

4.9.5 Wood

No wood is permitted in the production area. Plastic pallets or metal trollies are used. Wood is allowed in the warehouse. Sampled as part of the traceability exercise on the day.

4.9.6 Other physical contaminants

Raw materials physical contamination by packaging materials are prevented or minimised by enclosing the packaging in a separate storage area and issued to production as part of order build. Includes debagging. Pen control in place supported by sieves / filters.

Updated IBC lid system in the racking, when dispensing with supporting toolbox talk, covering replaced lid. Work instruction covering in use IBC and new fabricated plastic shroud covers for open IBCs under reissued QF26 High Level Audit Form and supporting reissued QMP07 storage of materials and packaging. Part of regular checklist, Audit Forms QF05 & QF26 with specific inspection instructions, for ongoing monitoring.

4.10 Foreign-body detection and removal equipment

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

A risk assessment has been completed as part of the HACCP study. All product is passed through sieves as a CCP. QF01 Batch Inspection Sheet in each job bag. Any sieve/filter tailing is recorded on QF01. All non-conformances are recorded. No issues to date.

4.10.2 Filters and sieves

Based upon a detailed risk assessment. All product is passed through sieves or filters as a CCP, at packing stage and where packed to WIP temporary packing status.
Sieves are used on;
Powders CCP- 2 sieves – 1.25mm sieve for blending depending on product.
A risk assessment has been completed looking at sieve sizes at manufacturer and on site, risk of wear and tear from machines, filler apertures and any metal associated with packaging (e.g. lids and foils). It was concluded that sieves were enough to control the risk of metal and foreign body contamination on liquid and powder lines. The frequency of the sieve inspection is at least twice per shift, if long run or start and end of the normal customised jobs.
Supporting QF01 Batch Inspection Sheet. Any sieve/filter tailing is recorded on QF01. All non-conformances are recorded.
QF01 also specifies the actions required if any aspect fails and is retained as a critical part of each Works Order Record as documentation of the performance of the sieve or filter.
Both validated in 2018-07-11 using seeded powder and liquid blends to ensure captured oversized elements, including undersize controls.
Verified critical limits with manufacturer;
CCP – Filter – Certificate of conformity 2019-01-16 “clamp 90 fine screen filter 1.25mm screen mesh sieve certificate number 27535 - stainless steel, food grade and 1.25mm woven warp/weft mesh, with 5 % tolerance to C21FDA.
To national standards, on full re-calibration frequency of 5 years based upon use and risk assessment.
Certificate of conformity dated 2018-11-30 Clamp pure screen inline filter 560 microns certificate number 27266 - - stainless steel, food grade and 560 microns mesh, to 5% tolerance.
Inspection by production / QA countersigned, and production supervisor checked as part of cleaning schedule to

ensure no issues on product changeovers, on Form QF01.

Staff working on the CCP have demonstrated the required level of competency.

4.10.3 Metal detectors and X-ray equipment

Not applicable as sieves are present.
Risk assessment included absence of metal detectors. Sieves deemed most applicable due to number of customised mixtures in liquid and powder format and 100% checks at packing stage by operative.

4.10.4 Magnets

No magnets installed.

4.10.5 Optical sorting equipment

No optical sorting equipment installed.

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

Only new containers are used - small 1 litre plastic bottles, 5lt, 10lt plastic containers. Containers are manually inverted prior to filling, as part of the COA – Colour, Odour and Appearance operator check stage to ensure no homogeneous or contamination issues. Sampled as part of the traceability exercise on the day.

4.11 Housekeeping and hygiene

There is a clean as you go policy under QMP 21, issue 1 – Housekeeping and Hygiene. Part of daily hygiene cleaning record on the Batch Sheet, supporting Line Clearance. Site and equipment were seen to be maintained in a clean and hygienic condition. The Cleaning of Production Areas and Equipment Procedure and Policy was verified. Cleaning is completed by production staff. The method, responsible person, cleaning equipment and any chemicals is detailed on the work instruction.

The Cleaning of Production Areas and Equipment Procedure developed and implemented, to ensure safe and clean storage of equipment and the positioning of fixed equipment for adequate cleaning.
Fixed equipment allows access for adequate cleaning.
Cleaning is completed by production staff. The method, responsible person, cleaning equipment and any chemicals is detailed on the work instruction.
Work instructions were viewed for allergen cleaning, dry blenders, reflux vessels, small items and utensils and floor.

As this is a small batch process with manual handling, there is cleaning of booth and equipment at the start and end of each job, it is strictly controlled based on production plans so no cross contamination can occur.
Cleaning equipment is colour coded: blue – food contact, red non-food contact.
It includes daily cleaning procedure using Caflon soap – yellow neck container and IPS/IPA – green neck container.

Cleaning chemicals Caflon soap, IPA were approved for the use on site.
A list of approved cleaning chemicals with details of where they can be used is maintained. Data sheets were viewed for;
Caflon Soap – version 1 dated 2018-07-19.
Hypochlorite – version 3 dated 2020-07-10.
IPA – version 7 dated 2018-07-17. Swabbing is carried out after cleaning for validation. The records are trended for July 2020 verified and found satisfactory.
Swabbing is carried out after cleaning periodically for validation. The swab results as part of ALS laboratory report Supporting ALS report number 3636-1 dated 2020-07-29 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and moulds, staphylococcus, salmonella, E.coli, Enterobacteriaceae and gamma negative verified, to confirm effective housekeeping, hygiene and overall low bioburden and found satisfactory.
Environmental swabbing schedule location type of sample frequency 3 monthly. Viewed surface swabs expiry date of 2021-08-31 and water test swabs.
Supporting ATP machine for background cleanliness / ATP bioluminescence verification. Ribbon blender, ethanol still and beans shredder equipment were inspected for cleanliness during the traceability audit process, with supporting sieves in washroom. No trends evident.

4.11.7 Cleaning in place (CIP)

CIP is not applicable. The whole equipment is simple design, fully taken apart out and washed, scrubbed, cleaned and sanitised.

4.11.8 Environmental monitoring

Environmental monitoring and swabbing are carried out after cleaning periodically for validation. The swab results as part of ALS laboratory report Supporting ALS report number 3636-1 dated 2020-07-29 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and moulds, staphylococcus, salmonella, E.coli, Enterobacteriaceae and gamma negative verified, to confirm effective housekeeping, hygiene and overall low bioburden and found satisfactory.
Environmental swabbing schedule location type of sample frequency 3 monthly number of samples. Viewed surface swabs expiry date of 2021-08-31 and water test swabs. Supporting ATP machine for background cleanliness / ATP bioluminescence verification. Ribbon blender, ethanol still and beans shredder equipment were inspected for cleanliness during the traceability audit process, with supporting sieves in washroom. Out of specification would go jot the CAPA system and product isolated to determine root case and if recall / withdrawal action required. No out of specification to date. No trends evident.
Last annual review dated 2020-07-29, no changes to site procedures.

4.12 Waste

Waste bins are clearly identified and emptied by a third party contractor – all streams Grundon with licence number CBDU 147323, not used for animal feed .
Waste is handled; moved and stored in a hygienic way.
No trade-marked waste is handled.
If recall / withdrawal / large return then specific requirements, including licenced use in animal feed would be explored. No required to date.

4.13 Management of surplus food and products for animal feed

Not applicable due to limited potential surplus due to mass balance based formulas, customised production to individual orders and monitored as a KPI on production efficiency by the Operations Manager. Part of normal waste disposal stream. The products are produced as per the plan from major customers so there is no surplus product. Verified and part of traceability exercise on the day.

4.14 Pest management

The site control pest management with a pest contractor in place using Rokill. Risk assessment in place dated 2019-02-01 and defined schedule of 8 visits per annum (site is not seasonal), 2 EFK services, 2 field biologists visits and 1 annual review trend meeting held. BPCA certificate number M15/246 expires 2021-02-28. Organic statement held and file dated 2019-02-04 and confirmation statement of shatterproof UV tubes. Bait plans in place with confirmation of external, interior, insect monitoring and Electronic Fly units, site map dated 2020-01-28. Data sheets held on file for non-toxic baits Contract Blox – Bell dated 2017-07-01.

All bait boxes were secure and appropriately numbered. Doors are carefully controlled for goods in and out. No evidence of birds reported on site. No records of pest activity evident, no issue with recent building work adjacent to the site.

Last Biologist visit dated 2020-06-10 (actions resolved and supporting photographs) and 2019-10-14. Last technical visits dated 2020-04-20, 2020-05-04, 2020-06-10 and 2020-07-28, no pest activity reported, all paper records held on site in file.

Checked technician and biologists' certificates; field Biologist Level 2 with RSPH passed 2018-09-07.

Technician Level 2 with RSPH passed 2018-11-06.

Trending in place for each year, 2020 e.g. rodents, insects, birds, with monthly trending no issues reported to date for 2020. Annual review meeting held between contractor and site and minted notes reviewed on FSK trends dated 2020-04-29 and at annual review dated 2020-05-04.

Pest awareness training as part of induction manual titled “pest awareness induction”, checked for latest employee – Sales Operations Manager completed 2019-06-25, which consisted of photo training of pests and importance of reporting issues to management. Product risk assessment would be made in the event of a sighting or infestation, nil to date.

Preventive systems are in place to prevent bird roosting and entry.

4.15 Storage facilities

Packaging is stored away from raw materials and finished goods. Part used packaging is inspected for suitability/cleanliness and covered or returned to store at the end of run.
There is no temperature control all finished products are stored in ambient conditions and products are made to order and dispatched within 24 hrs of production.
No temperature control required.
Some volatile ingredients are stored at chill to maintain shelf life, reduce potential odours and prevent loss of material. Temperatures are monitored and recorded, every working day. Sampled weekly log covering units U1 to U13, with fridges set at under 8 degrees Centigrade and freezers set at / under minus 4 degrees Centigrade. Last records were up to date and within specification. Raw materials are used on a FIFO basis. Where product is approaching its expiry date, the Technical Manager is responsible for assessing the material and extending life or authorising disposal. Materials in glass containers are stored in a secure facility. Packaging materials are stored in a separate area of the warehouse and part used materials are covered. Storage facilities were seen and verified during the factory tour.
No outside storage. Storage is on FIFO – First In First Out basis and stocks are kept low. Recent increase to reflect Covid 19 project.

4.16 Dispatch and transport

There is a documented procedure in place to manage the dispatch and transport of all products. Reference Goods out procedure. The company has no vehicles of their own. Traceability is maintained during transportation by despatch records. The dispatch records, including loading and delivery, were verified during the traceability exercise conducted in the audit.
Third party hauliers for raw materials and finished products are normally contracted by the customer. In their absence tend to use;

Haulage – Abacus Transport – QF06 review dated 2020-04-01 and RHA number 23266, with supplier site audit dated 2019-04-01.
DX Freight - QF06 review dated 2020-07-24, with contact dated 2015-11-30 and supplier site audit dated 2019-11-30.

Supporting pre-despatch hygiene check based upon traceability, ambient COA, as part of despatch note, stamped and signed by the warehouse manager - And supporting QC Stamp on the despatch note – confirmation order denoting trailer checked lorry /van number, HE Stringer Flavours signature. Witnessed delivery of raw materials on day 1, with supporting use of daily quarantine hold area and witnessed despatch on day 2, Weak Vanilla Extract code ET16451 (dilution from Vanilla Ethanol extract intermediate), with supporting use of marshalling area.

Details of non-applicable clauses with justification

Clause/section reference	Justification
4.7.6	No workshop on site

4.8.8.	No catering facilities
4.9.4	No WIP or finished product is packed in glass or other brittle containers.
4.10.3	No metal detectors or X- ray equipment installed.
4.10.4	No magnets installed.
4.10.5	No optical sorting equipment installed.
4.11.7	CIP not applicable
4.12.3	No trademarked waste
4.13	Not applicable due to limited potential surplus due to mass balance based formulas.
4.15.5	

5. Product control

5.1 Product design/development

QMP14 New product and process development covers both product, packaging and process development. No new processes have been introduced recently and product is a variation of existing lines. The originator has to submit QF03 with a commercial justification for NPD after checking/offering an existing solution, commercial product development checks for any relevant earlier work in the company record. The project is assigned to a qualified person by the Technical Department. Annex 3 of EC1334/2008 if the material is in the list is used and to ensure verification of H E String Flavours product claims, e.g. organic. Most product claims are by the customer on finished product and fall under their NPD process. The product is referred to HACCP if any significant changes from existing product is introduced. The company will offer items from the existing portfolio to customers where possible. Small batch samples are produced in the laboratory. Any new materials required are sourced from existing suppliers where possible. Technical documents are produced and submitted to the customer with the sample. Shelf life is based on existing product. All are signed off by the Technical Manager. Sampled the shelf life study for Liquid and powder flavours, Shelf life validation dated 2012-07-19. Liquid flavour 12 months, Liquid flavours 6 months life, Powder flavours six months life. Reviewed and updated 2019-11-19, to include up to 24 months if powder in vented foil sacks. Specifications found updated, signed off by the Technical Manager. Minimum reviewed annually with specifications reviewed whenever any requirement is changed.

Trials (when required are conducted based on 8-hour shift pattern to ensure this fit within current process and stock provided to customer for micro and organoleptic testing as customer responsibility within launch gate) and are validated by the Technical Manager.

Full organoleptic test kitchen on site under the Technical Manager as an organoleptic specialist. Key project is review of extraction solvent systems in recipes, to offer customer a wider selection of options.
Sampled; Mixed Fruit – 16452 – version 2 - special address requirement agreed.
Natural Cherry – 12241 – version 2 - special address requirement agreed.

5.2 Product labelling

Product Labelling is reviewed before the production to meet legal requirements. There is ingredients information, allergen advice, Batch number and Best Before Date. Finished product labelling information is verified against legal criteria.

Labels are produced on site and contain details of allergens and MSDS warning symbols, to ensure in line with legal requirements. No cooking instructions, as product is an ingredient for customer recipes.
Final product label and nutritional claims are the responsibility of the customer under their NPD and specification updates processes. Customers may have requirements such as plain labels (no logo) but no product is produced under a customer brand. Part of product specification and sampled as part of the traceability exercise on the day.
Product is used as recipe ingredient in the onward customer process.

5.3 Management of allergens

Allergens on site are cereals containing gluten, fish, soy, milk, cheese, milk, nuts and celery. Allergen oils (almond, celery, cod liver, soya bean) are refined and unlikely to contain protein but are treated in this company as an allergen. A register of allergens approved for presence on site is maintained with supporting Risk Assessment Matrix. The organisation has properly implemented the Allergen management as their legal requirement. Ingredient and allergen labelling and policy verified during the audit.
The allergen policy in place and reviewed under HACCP. A Codex Alimentarius list of allergens found maintained and communicated to the staff as awareness. Visitor questionnaires include questions relating to allergens. The raw materials data base on a software system is used to assess each raw material for the presence of allergens. A risk analysis of each raw material based on a 3x3 matrix has been used to determine high, low or medium allergen risk. Allergens are stored in a segregated store if high risk and controlled storage if low risk. Utensils and equipment are inspected before and after use and a wet clean followed by a solvent rinse is carried out and recorded.

All employees are trained in site procedures for allergen handling. Employees remove work wear before eating. The risk assessment also considers ALBA 17, 18, 35 and 36 as well as the EU allergen list. Products are labelled with allergens only when used in the formulation, no allergen labelling. Production is scheduled to enable allergen cleans between products. Cleaning processes have been validated with swabs for allergens.
Swabbing is carried out after allergen cleans for verification. Records were viewed for Elisa swabs as part of the traceability exercise on the day, no issues noted. Supported by periodic testing by third party Laboratory. Reports for Eliza testing for the allergen in PPM for the month were verified. There is no Reworking. Only use of part formulations as ingredients and repack as part of the normal process. Allergen ELISA Swabs for monthly allergen checks. Sterile swab wands for process hygiene verification based upon bioburden and tested off site by ALS. All held in the fridge to meet storage limits of 2 to 8 degrees Centigrade on the labels.

Staff training for the allergen has been conducted in year 2019 for example Food Safety and Allergen Management was a part, dated 2019-04-10 and refresher training dated 2020-07-01. Staff were interviewed during the site inspection for allergen handling and were found competent. Raw materials and finished product specification were checked
An allergen policy, procedure and allergen matrix are in place. All raw materials, products and the process have been risk assessed dated 2020-04-01.

Supplier declarations are obtained for raw materials. Staff and visitors may not bring nuts on site.

Cleaning equipment is dedicated for allergen use with colour coded equipment for both floors and machinery and protective clothing (red). Dishwashers are total discharge and have been assessed for allergen transfer. Air handling units are independent and do not transfer allergens. Allergen specific swabs are used when transferring from one allergen to another and to confirm cleaning methods for allergen removal validation. Records were viewed for Elisa swabs as part of the traceability exercise on the day, no issues noted.
Visitor questionnaires include questions relating to allergens.

The site is designated nut free staff cannot bring these products on to site. Allergen management training is the part of food safety training which has been conducted.

5.4 Product authenticity, claims and chain of custody

Raw materials vulnerably assessment based on VACCP for different raw materials as per the threats to the supply chain which could lead to adulteration/substitution of has been carried out using historical trends, industrial practice and codes etc. Vulnerability assessment, issue 2, dated 2019-11-13 (in 3m QST and no changes up to 2020-07-24), in place – based upon end consumers – infants, elderly, allergy suffers, Vegetarian, Kosher, Organic and Halal, etc. The

site obtains information on raw materials by monitoring of websites, alerts and legislation, including EC/1334/2008 - flavourings and certain food ingredients with flavouring properties for use in and on foods.
A food fraud assessment is performed on ingredient groups (oils, Sugar syrups, Dry Sugar, flavours etc.) and Provenance (Sicilian Lemon, Madagascan Vanilla, Kosher, Halal and Organic) which considers economic factors, accessibility to raw material, sophistication of testing, historical incidents, adulteration, substitution, length of supply chain supplier confidence and country of origin. Food fraud assessment, issue 1 dated 2019-11-13 (reviewed 2020-07-24, no changes).High-risk event due to crop sensitive changes of Refractive Index and Specific Gravity due to crop variations on various flavours found documented. Specifications updated, signed off by the Technical Manager.
As per the risk assessment, various products are included and are high and low risk as well.
Vulnerability assessment, issue 2, dated 2019-11-13 (in 3m QST and no changes up to 2020-07-24), in place – based upon end consumers – infants, elderly, allergy suffers, Vegetarian, Kosher, Organic and Halal, etc. part of annual review.
Sampled;
Organic Suppliers on the HESF Purchasing System including authenticity. Flow chart, HACCP Flow, GMO declaration etc. 3 Years SAQ frequency. Low risk supplier. Vulnerability assessment in place, issue 2. Part of H E Stringer Flavours Soil Association Certificate number MD0062895P4242 GB-ORG-05 Expiry 31-05-2021, with supporting balance exercise as part of the external audit.
Kosher Suppliers on the HESF Purchasing System including authenticity. Flow chart, HACCP Flow, GMO declaration etc. 3 Years SAQ frequency. Low risk supplier. Vulnerability assessment in place, issue 2. Part of
Kosher Certificate with on site audit dated 2020-09-08, with full traceability balance conducted, number 34133 Expiry 2021-05-30.
Sicilian Lemon – with Lapua Certificate of Origin number 17238 by SGS with SINCERT accreditation number 1880 dated 2019-08-13 (new audit booked).
Madagascan Vanilla – with Madagascan certificate of authenticity number 75853 issued by the Department of Agriculture. Supporting C – BRCGS Food certificate number 10648 expires 2020-10-17 (new audit booked) and G – FSCC 2200 certificate by LRQA number 10110259 expires 2021-06-18.
The following claims are made:
Organic, Halal and Kosher. Sicilian Lemon and Madagascan Vanilla.
The site holds external certification. Soil Association Organic certificate, last on site audit dated 2020-05-29, with Soil Association Certificate number MD0062895P4242 GB-ORG-05 Expiry 2021-05-30, with full traceability balance conducted.
Kosher Certificate with on site audit dated 2020-09-08, with full traceability balance conducted, number 34133 Expiry 2021-05-30.
Halal Agreement dated 2018-10-30 based upon full traceability balance conducted. Not Halal certified to date.
Sampled; Mixed Fruit – 16452 – version 2 - special address requirement agreed.
Natural Cherry – 12241 – version 2 - special address requirement agreed
Nutritional claims do not tend to be made at this stage but can be verified by the Technical Manager and off-site testing, if requested, with none made to date.

5.5 Product packaging

Primary packaging is plastic containers - 1 litre plastic bottles, 5lt, 10lt plastic containers, 20Kg vented plastic sacks and 1 tonne IBC containers.
Packaging is composed of plastic and specifications and migration certificates are available to ensure compliance with 10/2011/EC or other customer / country requirements, particularly in relation to food contact surfaces, denoted by the Technical Manager.
Food contact information and suitability for the intended product has been provided by suppliers of all food contact packaging. Product liners are not used. It is not common to return unused packaging. Packaging is stored on site in a segregated area.
Some generic secondary and tertiary packaging materials such as hot melt glue, tape and cartons may be purchased by the site.
Part used packaging is stored suitably and fit for purpose if it is to be used in production.

Traceability for all packaging used is recorded and maintained. The packaging materials required for the production process is issued and entered into the production report for traceability purposes. Packaging is checked at start and end of run, hourly as well.
Offline printed labels are supplied as part of the documentation and are printed to recipe for each job, any over label is a CAPA.

Obsolete packing is limited due to the generic nature of the packaging specification, not overprinted brands. It would be held in the dedicated packing warehouse area and disposed of in the normal waste stream.
The site holds external certification. Soil Association Organic certificate, last on site audit dated 2020-05-29, with Soil Association Certificate number MD0062895P4242 GB-ORG-05 Expiry 2021-05-30, with full traceability balance conducted.
Kosher Certificate with on site audit dated 2020-09-08, with full traceability balance conducted, number 34133 Expiry 2021-05-30.
Halal Agreement dated 2018-10-30 based upon full traceability balance conducted. Not Halal certified to date.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Positive release by in-house laboratory based upon COT- Colour, Odour and Taste, densityand Refractive Index - RI. And supporting QC Stamp on the despatch note.

All products, including new, are tested for RI – Refractive Index and density for the first four batches and thereafter, every fourth batch is tested.

Shelf life has been determined for various types of product and raw material; 06 months to 01 year, some 24 months. Samples are retained from each batch and colour coded white, yellow, orange and red to indicate the number of batches.
All product is tested and positive released based upon COT – Colour, Odour and Appearance/ Taste to retained samples. This is via the technical team of trained flavourists, supported and lead by the Technical Manager who is the reviewer and sign off at any disputed results.
Confirmation of shelf life testing is at NPD – New Product Development. Raw materials are used on a FIFO basis. Where product is approaching its expiry date, the Technical Manager is responsible for assessing the material and extending life or authorising disposal. This was sampled as part of the traceability audit on the day.

In-house flavour testing is to ISO 17025 principles with set procedures, calibrated equipment and trained personnel, supported by periodic round robin testing, last being dated 2020-03-16 across 4 operatives, all within specification.

In addition, to in-house testing. The site has acquired the services of third party laboratory. Third party lab is UKAS accredited ALS UKAS accredited number 1282 . The third party testing schedule for raw materials, finished products were developed, and is in place at a sample frequency 3 monthly.

The test report from a third-party Laboratories. ALS Laboratory report number 3636-1 dated 2020-07-29 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and moulds, staphylococcus, salmonella, E. coli, Enterobacteriaceae and gamma negative verified and found satisfactory.
Trend analysis and reviews of all test results are carried out and any out of specification results are risk assessed and the customer consulted.

5.6.2 Laboratory testing

Limited chemical testing is completed on site. It is a dedicated area, in the office block, away from manufacturing and storage areas.
Written instructions are available in the laboratory for all tests and were viewed for the Density Meter, and refractometer (Refractive Index) by Mettler Toledo. Test pieces / Merck Index solutions or distilled water are used for calibrating the equipment. Samples from compounding are tested for RI, flashpoint and SG/density. Sampled weekly check using Merck Index linked Ethanol, De-ionised water and Glycerine on Form QF49 dated 2020-08-19.
Supporting flash point closed cup work instruction using mainly pictures.
QC personnel to retrain every 3 months, evaluated against UKAS third party analysis.
Microbiological product analysis is subcontracted to ALS (UKAS Accredited) which is carried out to customer requirements (frequency and test suite). ALS UKAS accredited number 1282.
Sampled supporting ALS laboratory report number 3636-1 dated 2020-07-29 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and moulds, staphylococcus, salmonella, E. coli, Enterobacteriaceae and gamma negative verified, to ISO/IEC 17025 principles and found satisfactory.

Freeston report – water softener covering alkalinity, total dissolved and total iron dated 2020-04-20.
In-house flavour testing is to ISO 17025 principles with set procedures, calibrated equipment and trained personnel, supported by periodic round robin testing, last being dated 2020-03-16 across 4 operatives, all within specification.
Laboratory is of suitable design, with appropriate operation of drainage to outside walls, suitable ventilation systems, limited access and security of the facility. Control of movement of laboratory personnel with supporting protective clothing arrangements, normally laboratory coats and supporting processes for obtaining product samples and disposal of laboratory waste to ISO 17025 principles.

5.7 Product release

There is positive release authorised release by the Technical Manager. Sampled on the days of manufacture;

Weak Vanilla Extract code ET16451 (dilution from Vanilla Ethanol extract intermediate).
To BOM batch number into food grade metal holding barrel for excess and despatched in PP plastic kegs. BOM – Bill of Materials with weights confirmed, MOM – Method of Manufacture, Form QF06 - Line before and after checks for clearance, no allergens or suitable allergen deep clean controls in place cleanliness, hygiene, contamination, tape engineering and packaging. Supporting QF01 – cleaning record form. CCP check by L.B. confirmation of 560 microns metal filter in use, no damage and no issues in manufacturing Booth 2. Ethanol from bonded cage storage area and supporting cage book denoted E048 stock and weight removed. Use of potable mains water in the still via the steam generator and hard pipe system. Vanilla beans shredded in dedicated equipment to increase surface area for extraction. To 1 customer denoted on the SAGE Manufacturing database. Retained white powder sample was available and viewed.
Certificate of Analysis and Quality Report issued based upon COT, RI, density and weight check. Halal compliant – no – contains Ethanol. Pass stamped.

No product held off site. Some product is made for interim stock, majority is made to order.

5.8 Pet Food

No Pet food is made in this site.

Details of non-applicable clauses with justification

Clause/section reference	Justification
5.2.3	Not Applicable
5.2.5	Not Applicable
5.8.	No pet food.

6. Process control

6.1 Control of operations

No further CCP steps beyond filter / sieve. Key QC step is current specification with latest special notes is issued with each job. Positive release by QC on all product.
Pre-requisite programs such as cleaning and sanitisation, pest control, Allergens and their handling methods, Equipment calibration and maintenance were communicated to the line personnel.
Packaging is checked at the start of all production runs to ensure correct. A record of product changeover, time and packaging batch codes is maintained. Product is checked for quality and food safety aspects based upon Colour, Odour and Appearance. Before production can begin. The Compounder is responsible for clearing previous packaging. In line equipment is used for metal, weight and code reading. The CCP monitoring is also filled by the competent staff. Sampled training records.
In the case of equipment failure or deviation of the process from specification, CAPA procedures are in place to establish the safety status and quality of the product to determine the action to be taken.

Settings relating to product safety, based upon risk assessment tend to be down to the CCP covering filters / sieves and record with supporting supervisor signature on the Production Batch Sheet. Sampled as part of the traceability exercise on the day. Process irregularities are part of reporting to supervisor, Operations Manager and supporting CAPA report for recipe improvement or pre-make steps.
The following were witnessed on the day;
Weak Vanilla Extract code ET16451 (dilution from Vanilla Ethanol extract intermediate).
Natural Lemon 13449 – booth 1 – liquid blend
Condensed Milk Concentrate – 14312 - booth 2 – liquid blend
Natural Coffee Flavour – 13380 – booth 5 – powder blend.

6.2 Labelling and pack control

Latest labels with all changes, are printed for each batch of product, with bar code verification at this point. Customers generally receive product with the HE Stringer brand on the label but may opt for plain labels if required. Label checks and sign off are recorded on the works order. A sample label is attached to the order confirmation. Most product is positive release as finished. Some is placed back into stores to be used as an ingredient in another formulation.
Labelling and pack control are checked throughout the run, at start up change and line clearance and detailed on the job bag documentation. Viewed change over;
Natural Lemon 13449 – booth 1 – liquid blend, replaced by
Lime Oil lot code 108544 – booth 1 – liquid blend .

There is a line clearance after each job, as part of job completion. This is confirmed on the Batch Inspection Record. Sampled as part of the traceability exercise on the day, with sampling of start-up checks and positive release.
Over labels, as they are job specific and recipe calculated, would be a CAPA. After the line changeover, it is ensured that no previous packaging is left on the line. During the audit the line changeover was verified;
Natural Lemon 13449 – booth 1 – liquid blend, replaced by
Lime Oil lot code 108544 – booth 1 – liquid blend.

Bar code verification is not used online, as single batch manufacture.
Bar code scanning is only used at despatch, to verify despatch label quality of code and pack details, as a despatch process aid. The following labelling and pack control were witnessed on the day;
Weak Vanilla Extract code ET16451(dilution from Vanilla Ethanol extract intermediate).
Natural Lemon 13449 – booth 1 – liquid blend
Condensed Milk Concentrate – 14312 - booth 2 – liquid blend
Natural Coffee Flavour – 13380 – booth 5 – powder blend.

6.3 Quantity, weight, volume and number control

HE Stringer Flavours is complying with legislative requirements in line with the type of weight declared (gross weight, Net weight) and the in UK regulations. Product is hand packed to minimum weight. Weight checks are recorded on the works order. Any surplus product is added to the pack as overfill, no re-work takes place.

Procedures are in place to calculate and verify packaging tares used at a suitable frequency to ensure the actual product net weight is measured accurately. This conforms to legal requirements and additional industry sector codes for example Net content, target weight etc. Quantity control based on weight of finished product comprises of net

weight, Target, tare and actual weight, excessive and less products. The scales are calibrated by the third party accredited by ISO/IEC17025. In case of less weight of pack, it will be rejected. Daily scale verifications by Standard dead weights is also carried out. During the audit, a number of products were checked;
Weak Vanilla Extract code ET16451 (dilution from Vanilla Ethanol extract intermediate).
Natural Lemon 13449 – booth 1 – liquid blend
Condensed Milk Concentrate – 14312 - booth 2 – liquid blend
Natural Coffee Flavour – 13380 – booth 5 – powder blend
Natural Almond Flavour – 13641 – ethanol extraction
Juniper Flavour – 198546 lot 17041 – powder blend
Vanilla Flavour liquid – 12518 lot 108609 - ethanol extraction
Lime Oil lot code 108544.
No automatic weight systems

6.4 Calibration and control of measuring and monitoring devices

The company maintains calibration records of all measuring and monitoring devices. A register of all equipment on site requiring calibration is available. The only production equipment requiring calibration are the balances. Laboratory equipment is also calibrated. The calibration certificates from external third-party calibration services for year 2020 YTD were verified.

The procedure QMP18, version 2 outlines schedule of calibration with provider of calibration and frequency of scheduling. Procedure Includes corrective action in event of any product safety issue and corrective action to inform QA staff; product is placed on immediate QA HOLD for investigation to ensure product safety is within parameters and customer specifications.

Equipment schedule and calibration list includes model, internal reference number, serial number, capacity, calibration frequency, date checked, due date, in house calibration and frequency.

Examples of certificates checked for;
Scales – BRASH certificate number 270665 dated 2020-07-10.
Test weights – 5g, 10g and 50g - BRASH certificate number 270626 dated 2019-07-02 and calibrated in-house dated 2020-07-10. Scales – Daily balance checks in place prior to production taking place conducted by QA.
Refractometer – Mettler Toledo certificate and service report number 2679 dated 2020-01-28, to national standards.
Densitometer – Mettler Toledo certificate and service report number 919 dated 2020-01-28, to national standards.
Torque Gauge for tightening caps on plastic jerry cans – Britool certificate number 014406 dated 2019-05-02, to national standards, on full re-calibration frequency of 5 years based upon use and risk assessment.
Samples from compounding are tested for RI, flashpoint and SG/density. Sampled weekly check using Merck Index linked Ethanol, De-ionised water and Glycerine on Form QF49 dated 2020-08-19.

CCP – Filter – Certificate of conformity 2019-01-16 “clamp 90 fine screen filter 1.25mm screen mesh sieve certificate number 27535. To national standards, on full re-calibration frequency of 5 years based upon use and risk assessment. certificate of conformity dated 2018-11-30 Clamp pure screen inline filter 560 microns certificate number 27266. Inspection by production / QA countersigned, and production supervisor checked as part of cleaning schedule to ensure no issues on product changeovers, on Form QF01.

Recently Calibration SOP QMP 18, version 3 updated and listed IR Gun and Fridge Thermometer. Introduced weekly temperature record Swab Fridge using IR Gun. With updated procedure QMP07 Handling &
Storage Materials & Packaging to include consumables & fridge/freezer temperature inspections. IR Gun – ATP Instruments certificate number 60684-9820 dated 2017-04-21 to national standards, on full re-calibration frequency of 5 years based upon use and risk assessment.
Thermometers back to empirical standards based upon boiling water and iced water. Sampled weekly in-house calibration record dated 2020-08-24.

Details of non-applicable clauses with justification

Clause/section reference	Justification
6.2.4	Bar code scanning is only used at despatch

7. Personnel

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

Managing Director, new Operations Manager, both promoted internally. New Technical Manager recruited. Site working to Covid 19 rules.
Training has been changed to new online HR system Breathe, which after 18 months is bedding in, with annual competence review of all staff and would include temporary staff, nil to date.
Sampled key team training records including;
BRCGS Representative – Managing Director, deputy BRCGS Representative – Operations Manager and support BRCGS Representative – Technical Manager.

CCP competency assessments are in place.
Sampled CCP Operator training records;
CCP check by A.B. – Compounder – Food Safety level 2 certificate by Highfields number 262 dated 2019-04-02.
SG– Compounder – Food Safety level 2 certificate by Highfields number 06264 dated 2019-04-11.
C.P.– Compounder – Food Safety level 2 certificate by Highfields number 267 dated 2019-04-11.
Good level of understanding of operating procedures by the operators sampled.

Water softener and steam generator training, intruding water hardness daily test by Curtess Ltd – L.B. and K.M. dated 2016-08-10.

The company has a training programme for staff on induction and production roles, all in English. Induction training covers GMP, personal hygiene, jewellery, smoking, eating and drinking, allergen awareness, Site Security and SOPs. All staff have been trained in label control.

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

Personal hygiene policy and standards have been established and documented. Personnel hygiene is a part of induction training and basic food hygiene training, including agency staff.
Company Hygiene Health and Safety Policy, issue 3. The topics includes clothing, smoking, personal hygiene, jewellery, false nails, perfumes, gloves, food and drink, safety at work, accidents onsite, glass contamination. Plain wedding band only permitted, including;

- watches shall not be worn
- jewellery shall not be worn, with the exception of a plain wedding ring, wedding wristband or medical alert jewellery
- rings and studs in exposed parts of the body, such as ears, noses and eyebrows, shall not be worn
- fingernails shall be kept short, clean and unvarnished
- false fingernails and nail art shall not be permitted
- excessive perfume or aftershave shall not be worn.

Hand washing facilities on entry to production areas which were hands free with soap, paper towel available. Increased under Covid 19 rules and signed off on first entry to site as a visitor /contractor to ensure in compliance with WHO and 20 second rules.

Storage of personal medicines is controlled within lockers for personal items away from production areas.

Blue Plaster register in place last logged on 2020-07-03 issued 'to' and 'disposition record' signed and recorded on record of plaster control issue 1. No metal detection onsite. Procedures are all in place and being effectively controlled.

As part of induction to the site the process consists of 3 months period; which consists of Health & Safety, HACCP, Quality Culture, process, lab, first aid and time with all depts onsite. No nuts onsite is permitted which is part of induction training.

7.3 Medical screening

There is a requirement to report infectious diseases from which an individual may be suffering or have been in contact and requires a return to work interview and assessment is carried out on site. Visitors are required to complete a health screening questionnaire, reminding of responsibilities regarding notification of illness/risks of food borne disease in line with UK requirements.

QF32 Return to work medical questionnaire for food handlers issue 2 dated 2020-07-01, with Covid 19 update, with details of dates away and ensure fit to return to work. Signature shows compliance and forms held by HR.

Visitors book in reception area to confirm if contractor / visitors to site who visiting and time in and out and verified by host onsite. Covid 19 Visitor questionnaire in place QF35 Factory visitors Form Issue 4 – sampled Steam Generator – Certuss engineer dated 2020-06-03, including Covid 19 questions and temperature taken at reception using IR gun under site Covid 19 rules. Questionnaire confirm visitors are fit and healthy before entering production areas. Visitor PPE consisting of white coat for visitors, hair net, beard snoods and safety shoes.

7.4 Protective clothing: employees or visitors to production areas

Protective clothing is laundered by Johnsons Apparel Master collected each Tuesday. Signed contract in place dated 2017-08-17 in place. All clothing is changed daily.

Protective clothing for employees consisted of hairnets, snoods, safety boots, safety glasses and (3M Juniper RTU Air Filter Kits for employees within the mixing / compound areas) and is changed on a regular basis according to risk assessment. Verification of cleanliness is visual by the line supervisor.
Visitors / temporary workers are provided with disposable laboratory coats.
No PPE are used in production area which are not disposable, including food grade blue gloves and replaced at change of product, return to production at wash station or sooner when required.
No Aprons are used onsite.

Details of non-applicable clauses with justification

Clause/section reference	Justification
7.2.4	No metal detector on site.
7.4.6	No PPE used onsite which is not disposable or laundered.

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Low Risk – Section 8 is Not Applicable
8.2 Building fabric in high-risk and high-care zones
8.3 Maintenance in high-risk and high-care zones
8.4 Staff facilities for high-risk and high-care zones
8.5 Housekeeping and hygiene in the high-risk high-care zones
8.6 Waste/Waste disposal in high risk, high care zones
8.7 Protective clothing in the high-risk high-care zones

Details of non-applicable clauses with justification

Clause/section reference	Justification
8.1 – 8.7	Low risk