

# 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	2019-08-13		
Re-audit due date	2020-08-12		

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

Head Office	No
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2. Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit type	Unannounced
Previous audit grade	AA+		Previous audit date	2018-07-18	
Certificate issue date	2019-09-23		Certificate expiry date	2020-09-23	

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	3

3. Company Details			
Address	Icknield Way Industrial Estate, Tring, Hertfordshire, HP23 4JZ		
Country	United Kingdom	Site Telephone Number	+ 44 1442822621
Commercial representative Name	Mr Huw Williams – Managing Director	Email	Huw.williams@stringerflavour.com
Technical representative Name	Katrina Barker – Technical Director	Email	Katrina.barker@stringerflavour.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 31-05-2020, Kosher Certificate number 34133 Expiry May 20209. 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 BRC audit	No significant change				

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 2,400m2. 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 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 Celery Nuts Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen			
Product claims made e.g. IP,		Organic, Kosher			

organic		
Product recalls in last 12 Months	No	
Products in production at the time of the audit	Flavourings – Banana, Onion, Bacon Powder, Vanilla and Natural Ginger Extract.	



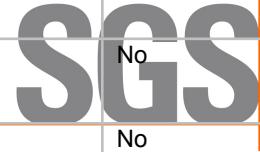
6. Audit Duration Details			
On-site duration	16 man hours	Duration of production facility inspection	<del>8 man hours</del>
Reasons for deviation from typical or expected audit duration	Requested to issue 8.		
Next audit type selected	Unannounced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-08-12	10.30	1800
2	2019-08-13	0800	1630

	Auditor (s) number	Name	Role
Auditor Number	176047	Philip Irwin	Lead Auditor
Second Auditor Number	176777	Louise Hill	Observer

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 – Operations Director	Yes	Yes	Yes	Yes
Katrina Barker – Technical Director	No	Yes (Part)	Yes	Yes	
Kevin McManus – Factory Compounder	Yes	Yes	Yes	Yes	
Andy Buckingham – Compounder	No	Yes(Part)	No	No	
Steve Gates – Compounder	No	Yes(Part)	No	No	
Chris Puddefoot – Compounder	No	Yes(Part)	No	No	

Adam Taylor – Compunder / Logistics	No	Yes(Part)	No	No
Daniel Harper – Laboratory Technician	No	Yes(Part)	No	No
Lorna Whiteley – Accounts Administrator	No	Yes(Part)	No	No
Terry Stilldan – External Consultant	No	Yes (Part)	Yes	Yes
Louise Hill – SGS Observer	Yes	Yes	Yes	Yes



## 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

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

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	4.7.3	Incomplete control of temporary repair ref. heat sealer with card and tape cover in place.	Replaced temporary fix with permanent hygienic solution.	Retrained Production and Internal GMP Audit Team to eliminate temporary unauthorised fixes, equipment validation and weekly Ops quality discussion.	<b>Photos before and after. Closed/signed NCR867/ CAR 226. Signed approved QST minutes to close NCR.</b>	2019-09-02	Philip Irwin
2	4.9.6.1	Incomplete SOP to prevent potential contamination of raw material ref. IBC lid ajar in racking number 3 under	Replaced lid. Reinforced in use IBC procedure with Operations Team. Fabricated plastic covers	Amended Audit Forms QF05 & QF26 with specific inspection	<b>Photos before and after. Reissued QF26 High Level Audit Form.</b>	2019-09-02	Philip Irwin



		wooden pallet.	for open IBCs.	instructions, reissued. Briefed Internal Audit Team with new standard.	<b>Reissued QMP07 storage of materials and packaging. Closed/signed NCR866/ CAR 225. Signed approved QST minutes to close NCR.</b>		
3	6.4.1	Calibration SOP QMP 18, version 2 incomplete ref. IR Gun and Fridge Thermometer not listed	Introduced weekly temperature record Swab Fridge using IR Gun.	Weekly record of all fridge/freezer Temps now in place. Redrafted QMP07 Handling & Storage Materials & Packaging to include consumables & fridge/freezer temperature inspections.	<b>Reissued QMP07 Storage of materials &amp; Packaging Closed/signed NCR868/CAR227 Signed approved QST minutes to close NCR/Doc Change</b>		2019-09-02

<b>Comments on non-conformities</b>

# Detailed Audit Report



## 1. Senior management commitment

### 1.1 Senior management commitment and continual improvement

There is a documented food safety policy – QP 1 signed by the Managing Director. The policy was reviewed during the management review dated 2019/07/09, there was an update in the policy as part of re-write of the QMS to address Food, issue 8 requirements, now dated 219/07/19. 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 6 monthly meetings. Monthly food safety, quality legality meetings were conducted. The minutes of the monthly meetings were sampled and verified 2019/05/14, 2018/12/13, 2018/10/31, 2018/06/20, 2018/02/26. The first Quality Conference was held in April – 2019/04/10 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.

The recent management review under SOP 27, issue 1 is 2 per year, approximately six monthly and the meeting was conducted on 2019/07/09. The directors and the QA team were present in the meeting. The minutes of the management meeting include last meeting minutes and actions, dated 2019/05/14, 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.

The food safety culture is implemented in the organisation by the senior management. Supported by the first Quality Conference was held in April – 2019/04/10 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 and the market move towards changes in extraction system methodologies.

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 year 2019 and last year. 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 production Director. Key impact is the market move towards changes in extraction system methodologies. The records for the week dated 2019/04/10, 2019/07/12 and 2019/06/13, were reviewed.

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 2019/04/10. Schedule 6 denoting contact details for the nominated independent person, in this case the External Food Safety Consultant.

BRC logo in use on website and limited stationery, in accordance with BRC conditions.

Quality Culture is driven by the Managing Director and Directors on site working with an external consultant with wide experience of improvement of food safety culture. The objectives and KPIs Key performance indicators are reviewed monthly and are part of the MRM.

The following Objectives and targets are in the KPIs;

- Justified Complaints under 30 per year and pro rata improvement on 2018. Achieved in 2018 at 30, retained as 2019 target and on target at 5 YTD.
- Internal Defects – Not Right First Time under 40 per year and pro rata improvement on 2018. Achieved in 2018 at 40, retained as 2019 target and on target at 30 YTD.
- Lead Time – order to despatch to be under 15 workig days, and pro rata improvement on 2018. Achieved in 2018 at 14, retained as 2019 target and on target at 11.5 YTD.

At monthly 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.

The site is kept informed of changes in legislation via BRC 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 BRC Position Statements – F8033 - Vulnerability, F837, 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 Flavouring Industry and Institute of Flavouring Industry Guidelines, Codex, FSA, BRC, 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 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.

## 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 Director, Quality under Technical Director, Commercial under Managing Director). An organogram is in place dated 2018/10/31. The key staff cover that is roles and responsibilities in the absence of key personnel were defined. Sampled responsibilities for the Managing Director as the BRC Representative, the Technical Director as the Deputy BRC Representative and the Operations Director as the support BRC Representative, the HACCP Team and the Internal Audit Team.

## 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 2018/12/13. The team consists of the Managing Director as the Team Leader who holds a BRC Intermediate HACCP certificate – ATP034 dated 2008/06/18, the Technical Director holds a Level 3 HACCP certificate by RSPH number 65221/1 dated 2014/11/18, the Operations Director holds a BRC HACCP certificate dated 2014/11/07 and the Purchasing Manager with a Level 2 HACCP certificate by CIEH number 3332 dated 2018/12/18.

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, BRC, 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.



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.

Site has been registered in UK. The registration number verified - GB154E0232. The company is also fulfils the requirements of local government.

Process Flow Diagram found verified by the food safety team on 2018.12.13.

- OP1 – open product liquid and powder,
- OP2 – liquid flavours – large vessel and open – CCP 1
- OP3 – WIP and re-pack (pack off)
- OP4 – interim,
- OP5 – powder flavours – CCP 2,

All took place on 2018/12/13. Supported by Allergen Risk Assessment Matrix dated 2019/04/10.

Powders CCP- 2 sieves – 1.25mm sieve for blending depending on product.

Liquids CCP 1 – filters - 530-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 check prior to use. Corrective Action of report if damaged sieve / filter or if debris in pack for CAPA report and remedial actions.

For food flavourings, colours and extract into small 1 lt plastic bottles, 5lt, 10lt plastic containers, 20Kg vented plastic sacks and 1 tonne IBC containers.

This study starts at goods receipt, decanting/mixing, 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.

A corrective action procedure is in place. Responsibilities for monitoring the critical limits and for corrective action are defined.

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, intended 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 (organic, kosher), vegetarian. Un-intended product use found defined for example any allergenic product used by allergy sufferers. The shelf life varies from 6-12 months. Products are packed in standard 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 a Soil Association Organic certificate Soil Association Certificate number MD0062895P4242 GB-ORG-05 Expiry 31-05-2020, Kosher Certificate number 34133 Expiry May 20209.

There are 5 flow process diagrams, Process Flow Diagram were verified by the food safety team on 2018.12.13.

- OP1 – open product liquid and powder,
- OP2 – liquid flavours – large vessel and open – CCP 1
- OP3 – WIP and re-pack (pack off)
- OP4 – interim,
- OP5 – powder flavours – CCP 2.

CCP Validation:  
 Powders CCP- 2 sieves – 1.25mm sieve for blending depending on product.  
 Liquids CCP 1 – filters - 530-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 check prior to use. Corrective Action of report if damaged sieve / filter or if debris in pack for CAPA report and remedial actions.  
 For food flavourings, colours and extract into small 1 lt plastic bottles, 5lt, 10lt plastic containers, 20Kg vented plastic sacks and 1 tonne IBC containers.

Physical, chemical, microbiological and allergen hazards have been considered within the study for every process step of the process. All work is in class L clean room production areas covering fill and sieve / filter stages with plastic slat doorways to central area holding WIP and finished stock. 2 class L clean room warehouse areas for raw materials and packaging, with plastic slat doorways to central production area.

This study starts at goods receipt, decanting/mixing, 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.

The risk assessment Matrix was developed based upon the severity and likelihood of risk. The level of risk defined for example 1-2 No risk, 3-4 Medium Risk, 6-9 high risk. Raw materials are ambient and arrive with C of C / C of A. Sampled C of A denoting Aldehyde, G.C. match, Refractive Index, Specific Gravity and flash point. Allergens handled on site are cereals containing gluten, milk, soya, fish, nuts (indirect) and celery.

Verification is carried out during internal audits the recent internal audit conducted on 2019/07/22 was verified, review of records for product non-conformance or deviation, review of complaints, review of incidents, recall and withdrawal and the daily verification checks performed. Verification reviews of paperwork are completed daily. The HACCP system was formally reviewed in 2018.12/13.

### 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 2019/07/12. 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. A list of all control documents indicate the latest version number and the identification and authorisation of controlled documents. This was sampled as art of the traceability exercise on the day.

#### 3.2 Document Control

Controlled documents are held in the computer system and hard copies as well and control is managed by a procedure covering control of documents, authorities found documented and communicated for the creation, authorisation, changes/amendments and replacement of existing documents. All necessary changes in the year 2019

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were found authorised. Key authorisation is by the BRC representative.

### 3.3 Record completion and maintenance

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, 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 in place under QM17, version 4. BRC 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 BRC are audited annually which is managed by the Managing Director, using an external consultant across the year and supplemented by the Managing Director and the Operations Director to ensure impartiality. Confirmed the risk assessment of all audits is conducted annually, as part of the MRM.

Internal audit reports sampled to issue 8 include;

Section 3.7 corrective and preventative action completed on 2019/05/08 – nil NCRs.

Section 4.8 Staff facilities completed on 2019/05/22 includes photos of facilities and nil NCRs.

A traceability test was conducted on 2018/12/18 on C.Bark extract batch number 7794-1-1-1 of 2018/12/11 production. 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. Specific gravity is calculated for point of fill during processing.

Positive release by in-house laboratory based upon density and refractive index. Tested on 2018/12/18 and nil NCRs.

Section 5.6 Product inspection and lab testing completed on 2019/07/09 – nil NCRs

Section 2.0 Food Safety Plan HACCP completed on 2019/07/22 with evidence of PRP's, procedures, flows, one NC raised and resolved.

Section 3 QMS dated 2019/05/08 – nil NCRs.

Test of product recall conducted on 2018/12/18 – Cinnamin Flavour – ET14232 from date of production 2018/12/12.

Trace test started 10:35 and finished at 11:15, under 1 hour. Product recall reason is product contamination. 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. Nil NCRs.

Section 4 – site – dated 2019/05/22 - nil NCRs.

Section 5 and 6 – Product and Process Control dated 2019/07/09 – 2 NCRs raised and resolved.

Section 7 – Training dated 2019/06/18 - 2 NCRs raised and resolved.

A traceability test was conducted on 2018/09/17 on NCR821 back to issue with Not Right First Time powder blend batch number 11407 - 96540 of 2018/08/16 production. 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 2018/08/16 and nil NCRs.

Section 3.6 Specification completed on 2019/05/08, objective evidence of two specifications included within report– nil NCRs..

Section 1.1 Senior management commitment completed on 2019/05/08, with evidence included of quality policy as displayed to staff and Quality Conference – Nil NCRs.

3 auditors onsite including;

Managing 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.

Operations Director with QF05 Training Record denoting in-house refresher training by External Food Safety Consultant dated 2014/03/12 and 2019/04/10.

External Food Safety Consultant holds a BRC 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.

Every Monday morning weekly production meeting held with cleaning, QA, finance, production to track outstanding actions.

Examples seen from 2019/04/10, 2019/07/12 and 2019/06/13.  
with Operations Director notes of progress being made on actions outstanding.

### 3.5 Supplier and raw material approval and performance monitoring

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

Suppliers are being inducted, monitored and approved as per the procedure Supplier Approval. A risk assessment based on suppliers and food fraud assessment is performed on raw material groups each individual raw material is risk assessed, with products assessed for allergens, allergens on site, 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 suppliers master list, assessment was carried out on 2019/07/09 at the MRM.

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 Sicilian Lemon.

The nominated supplier is either audited; self-audited and has been on trial assessment, based on risk related to the products, current accreditation BRC, GFSI etc. or Questionnaire. The suppliers have to fill the detailed questionnaire, details of their GFSI benchmarked certification, certification validity etc. There is no supplier which is approved on the basis of questionnaire only. Few examples of suppliers provenance and claims made;

Sicilian Lemon – with Lapua Certificate of Origin number 17238 by SGS with SINCERT accreditation number 1880 dated 2019/08/13.

Madagascar Vanilla – with Madagascar certificate of authenticity number 75853 issued by the Department of Agriculture. Supporting C – BRC Food certificate number 10648 expires 2019/10/17 and G – FSCC 2200 certificate by LRQA number 10110259 expires 2021/06/18.

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. Part of H E Stringer Flavours Soil Association Certificate number MD0062895P4242 GB-ORG-05 Expiry 31-05-2020, 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. Part of Kosher Certificate number 34133 Expiry May 20209. balance exercise as part of the external audit.

Vented plastic sack – supplier ISO 9001:2015 certificate number 442046 expires 2020/07/07 issued by ICC Ltd and supporting Declaration of Compliance to 10/2011/EC.

Plastic IBC - Mauser with TUV SUD ISO 9001:2015 certificate number expires 2020/08/13 and Declaration of Compliance to BfR dated 2011/07/08.

#### 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 is mandatory for the acceptance of raw and packaging materials.

The certificate of analysis for the following products were seen;

Sicilian Lemon – with Lapua Certificate of Origin number 17238 by SGS with SINCERT accreditation number 1880 dated 2019/08/13.

Madagascar Vanilla – with Madagascar 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.

### 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 14.11.2017.

The audit frequency is three years.

### 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 Director and are maintained for all raw materials and packaging. Manufacturing instructions/specifications are available at workstations and confirm compliance with finished goods specifications.

Specifications are agreed with customers. The following specifications were reviewed and found to be compliant.

The specifications were sampled;

Banana Flavour Powder – ET12046 – 6Kg

Onion Flavour Powder

Bacon Flavour Powder

Vanilla Flavour Liquid Extract

Natural Ginger Flavour Liquid Extract.

The customer communicates the changes of specification. Specifications are reviewed three yearly 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 Director.

### 3.7 Corrective and preventive actions

Corrective action procedures under SOP 15 are well implemented for non-conformances arising from a number of 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. Non-conformances raised during the internal audits were properly closed and corrective action found taken.

### 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. Due to warehouse facility, there is no designated quarantine area within 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 Director is overall responsible for deciding and management of NC products, if product should be reworked, released or disposed of, due to the foodstuffs nature of the product and its use in food production.

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



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

Examples of non-conformances seen during audit;

R005 – Raspberry Ketone (On QA Hold in Warehouse facility). Await disposition by the Technical Director as short shelf life left.

Non-conformances seen for internal audits and all resolved.

For last records of food destruction see waste section.

### 3.9 Traceability

A recording system is in place on the SAGE system with all raw materials, in process materials, packaging and finished product coded to allow for full traceability through the system. The following traceability exercise was conducted during the first day of the audit;

Banana Flavour Powder – ET12046 – 6Kg made 2019/04/11, tested and positive release by in-house laboratory dated 2019/04/12 to meet delivery promised date of 2019/04/29. In to 2 x 3Kg vented plastic sacks. CCP Monitor Record confirmed powder sieve used, COA and weight check and no issues. Used OP3060 3Kg vented plastic sacks to GRN057871 by operator C.P and training record verified. Supporting Batch inspection Sheet – QF01 denoting hygiene, line clearance, filter/sieve CCP, allergen pack check and line cleanliness. Positive release by in-house laboratory based upon COA and supporting QC Stamp on the despatch note. Under 2 hours and nil NCRs

Vanilla Flavour Liquid Extract code 13396. Made 2019/08/08, tested and positive release by in-house laboratory dated 2019/08/08 to meet delivery promised date. In to 1 x 5Kg plastic screw top container. CCP Monitor Record confirmed liquid filter 530 microns used. Operator training record verified. Supporting Batch inspection Sheet – QF01 denoting hygiene, line clearance, filter/sieve CCP, allergen pack check and line cleanliness. Positive release by in-house laboratory based upon COA, density and Refractive Index. And supporting QC Stamp on the despatch note. Under 2 hours and nil NCRs

Powder trace test conducted onsite from 2019/04/23 for product code ET.111.06 sale order of 80kgs recipe works order / weighing mixing / formulation sheet confirms 6 ingredients e.g. salt, oil, etc required to make product. Picking list confirms BOM reference, quality, location of each ingredient to be weighted to form the mix. Hazard control batch inspection confirms the compounder who conducts the formulation which includes PPE, Hygiene area, checked of CCP (filters), glass wear, allergen handling, check packaging. Post cleaning passed following inspection and effective cleaning.

Weight checks in place packed into vented sacks with sieve CCP checked and lot code of primary packaging recorded during packing. Analysis sheet for powders includes appearance, odour, taste and sign off from quality control team x 3 difference members.

Total dispatched 4 x 20kgs recorded on delivery note – Form QF47, issue 1 - DEL0023666 dispatched on 29.04.2019 a copy of product label is attached on back of confirmation order to ensure labelling matches product dispatched.

Mass balance;

Order for 80kgs (always plus 1% over total produced 80.08kg) any excess stock is disposed to ensure full qty within spec. Total time for trace test took 30mins. Nil NCRs.

Under 2 hours and nil NCRs

As part of internal Audit Schedule the site had completed the following traceability exercises;

A traceability test was conducted on 2018/12/18 on C.Bark extract batch number 7794-1-1-1 of 2018/12/11 production. 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. Specific gravity is calculated for point of fill during processing. Positive release by in-house laboratory based upon density and refractive index. Tested on 2018/12/18, under 2 hours and nil NCRs

Test of product recall conducted on 2018/12/18 – Cinnamin Flavour – ET14232 from date of production 2018/12/12. Trace test started 10:35 and finished at 11:15, under 1 hour. Product recall reason is product contamination. 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. Nil NCRs.

A traceability test was conducted on 2018/09/17 on NCR821 back to issue with Not Right First Time powder blend batch number 11407 - 96540 of 2018/08/16 production. 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 2018/08/16, under 2 hours and nil NCRs.

Detailed documented traceability procedures in place, includes traceability after rework. There is no rework for the majority of 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.

### 3.10 Complaint-handling

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. 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, 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 Director has overall responsibility for investigation of customer complaints.

Customer complaint trending in place, to support KPIs;

- Justified Complaints under 30 per year and pro rata improvement on 2018. Achieved in 2018 at 30, retained as 2019 target and on target at 5 YTD.
- Lead Time – order to despatch to be under 15 workig days, and pro rata improvement on 2018. Achieved in 2018 at 14, retained as 2019 target and on target at 11.5 YTD.

Complaints are trending against product categories e.g. faulty 5 litre bottle down to neck moulding dip and leakers – accounted for 7 issues. Part of mould improvement project with manufacturer. Rest black bits, flavour changes and balance awaited. Limited trends evident. Broken down into customers and feedback at customers meetings quarterly / monthly meetings. 17% product, 6% packaging and 44% delivery and 33% ingredient issues. Part of ongoing improvement project.

Communication to staff is at weekly 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.

### 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 Director and Operations Director. (recall committee) both office and mobile numbers with priority of contact details and customer list which is (managed through Managing Director).

The crisis management, food defence and BCP planning manual, dated 2019/07/09.

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 BRC (SGS) within three working days. Details of other regulatory bodies police, DEFRA, hospital, HSE, UK Retailers should be notified within 24 hours.

Test of product recall conducted on 2018/12/18 – Cinnamin Flavour – ET14232 from date of production 2018/12/12.

Trace test started 10:35 and finished at 11:15, under 1 hour. Product recall reason is product contamination. 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. Nil NCRs.

Testing of mock recall test is scheduled two a year due to retailer customer requirements and in additional mock recall testing out of hours.

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

## 4. Site standards

### 4.1 External standards

The site was built in 1966 and the building has under gone 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.

### 4.2 Site security and food defence

A security risk assessment has been carried out on 2019/07/09 and forms part of the contingency plan in year 2019. 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. The overall score of the site is 6 which means low risk. The site security is managed by: Cameras are 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. 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. The site is visited by the local Council - number GB154E0232.

### 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 2018/12/13, which 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. Sampled as part of the traceability exercise on the day. 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. 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 store rooms – 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 is 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 noted in the lay out. Sampled as part of the traceability exercise on the day.

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

The buildings were suitable for their purpose. 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 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. Under QMP21, issue 1, cleaning records were recorded; Weekly hygiene/housekeeping audit checklist dated 2019/04/10, 2019/07/12 and 2019/06/13 verified. Daily hygiene/housekeeping audit checklist dated 2019/04/10 verified.

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

The water distribution plan or taps plan for the distribution into the site dated 2019/04/23 was verified. Water used on site is potable and mains supplied. Water is ambient or on demand heated by process equipment. Mains water is supplied by Thames Water, with potable water data from 2017/12/31 to 2019/03/04. There is a water diagram and sampling plan in place dated

2018/10/12. Taps are flushed for 2 minutes at key points, determined by risk assessment, on a weekly 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. 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 report number 2860-1 dated 2019/07/03 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and molds, staphylococcus, salmonella, E.Coli, Enterobacteriaceae and gamma negative verified. Gases not used. Supporting Legionella SHEQ Survey dated 2019/06/18 – all within specifications.

#### 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. There is a line clearance after each job, as part of job completion. This is confirmed on the Batch Inspection Record. 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. Cleaning is completed by production staff. The method, responsible person, cleaning equipment and any chemicals is detailed on the work instruction. 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. Work instructions were viewed for allergen cleaning, dry blenders, reflux vessels, small items and utensils and floor. Cleaning equipment is colour coded: blue – food contact, red non-food contact. A list of approved cleaning chemicals with details of where they can be used is maintained. Data sheets were viewed for; Cafflon Soap, Hypochlorite, Combat Cleaner, IPS and IPA. Swabbing is carried out after cleaning for validation. The records are trended for July 2019 verified and found satisfactory.

#### 4.7 Maintenance

A preventative maintenance schedule found developed for year 2019. 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 2019/03/25, no issues.

There is no Engineering workshop on site.

The third party maintenance records sampled;  
FLT – Fourway Group report number 125737 – 72245 dated 2019/07/10.

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 Deep clean down by the production team at post maintenance hand back.

**However, Incomplete control of temporary repair ref. heat sealer with card and tape cover in place. Minor CAR 1 of 3 raised.**

#### 4.8 Staff facilities

Staff facilities were found to be satisfactory 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 no nuts allowed into the factory.

Working clothing is controlled with hooks in use for “production clothing” and all personal items kept in lockers within toilet facilities. 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 stored in a designated storage area with restricted access outside the production area. Non-food contact chemicals are approved by review of the MSDS. Strongly scented/taint-forming materials are not used. MSDS sheets found at storage and usage point. No strong scented products allowed on site, 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. 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. Sampled as part of the traceability exercise on the day.

##### 4.9.2 Metal control

There is a documented metal control policy in place. 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 2019/08/05 and 2019/07/29, no issues found on weekly walk around conducted by the Operations Manager. One pair of scissors in production, 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 is controlled by the use of sieves which is a CCP.

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

Glass breakage procedure. 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. Glass check records for 2019/04/10 sampled. The site has a breakage procedure which requires any breakages to be reported to a director. 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 is checked for contamination. Supported by monthly external audit on QF26 dated 2019/04/10.

##### 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. Sampled as part of the traceability exercise on the day.
<b>4.9.5 Wood</b>
No wood is permitted in the production area. Plastic pallets or metal trolleys are used. Wood is allowed in the warehouse.
<b>4.9.6 Other physical contaminants</b>
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.  <b>However, Incomplete SOP to prevent potential contamination of raw material ref. IBC lid ajar in racking number 3 under wooden pallet. Minor CAR 2 of 3 raised.</b>
<b>4.10 Foreign-body detection and removal equipment</b>
<b>4.10.1 Selection and operation of foreign-body detection and removal equipment</b>
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.
<b>4.10.2 Filters and sieves</b>
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 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. 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. The sieve assessment checked were Certificate of conformity - dated 2016/01/26 - stainless steel, food grade and 1.25mm woven warp/weft mesh, with 5 % tolerance to C21FDA. Filters used on liquids; Filter – 530 microns - Certificate of conformity - dated 2015/09/03 - stainless steel, food grade and 530 microns mesh, to 5% tolerance. Staff working on the CCP have demonstrated the required level of competency.
<b>4.10.3 Metal detectors and X-ray equipment</b>
Not applicable as sieves are present.
<b>4.10.4 Magnets</b>
Not applicable. No magnet in the system as sieves are installed.
<b>4.10.5 optical sorting equipment</b>
Not applicable. No optical sorting in the system as sieves are installed.
<b>4.10.6 Container cleanliness – glass jars, cans and other rigid containers</b>
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.

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. It includes daily cleaning procedure using Caflon soap – yellow neck container and IPS/IPA – green neck container.

Cleaning chemicals Saflon soap, IPA were approved for the use on site. Swabbing is carried out after cleaning periodically for validation. The swab results as part of ALS laboratory report number 2860-1 dated 2019/07/03 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and molds, staphylococcus, salmonella, E.Coli, Enterobacteriaceae and gamma negative verified, and found satisfactory. Environmental swabbing schedule location type of sample frequency monthly number of samples – every 3m. Viewed surface swabs expiry date of February 2020 and water test swabs expiry date of 2019/12/07. 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. Supporting ATP machine for background cleanliness / ATP bioluminescence verification. Sampled ALS report 1784858-1 dated 2019/06/23 and number TCHT/1717421-1 dated 2019/03/19.

Ribbon blended was inspected for cleanliness during the traceability audit process, with supporting sieves in wash room.

##### 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.

#### 4.12 Waste / Waste Disposal

Waste bins are clearly identified and emptied by a third party contractor – all streams Grundon with licence number CBDU 19821.

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

Not applicable due to limited potential surplus due to mass balance based formulaes, customised production to individual orders and monitored as a KPI on production efficiency by the Operations Director. 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, 2 EFK services, 2 field biologists visits and 1 annual review trend meeting held. BPCA certificate number M15/246 expires 2020/02/29. 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. Data sheets held on file for Conrac Blox – 91340 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.

Last Biologist visit dated 2019/05/08 (actions still pending on small proofing issues). Next visit due October 2019. Last

technical visits dated 2019/07/12 and 2019/06/13 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, 2019 e.g. rodents, insects, birds, with monthly trending no issues reported to date for 2019. Annual review meeting held between contractor and site and minuted notes reviewed from October 2018, next scheduled review set for October 2019.

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.

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

#### 4.15 Storage facilities

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. Some volatile ingredients are stored at chill to maintain shelf life and prevent loss of material. Temperatures are monitored and recorded. Raw materials are used on a FIFO basis. Where product is approaching its expiry date, the Technical Director 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. This was verified as part of the traceability audit on the day of audit.

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.

#### 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 Agility – code WU1110TK and supporting QF42 report dated 2019/07/09. Supporting pre-despatch hygiene check based upon COA, as part of despatch note, stamped and signed by the warehouse manager. Witnessed delivery of raw materials on day 1, with supporting use of daily quarantine hold area and witnessed despatch on day 2, with supporting use of marshalling area.

### 5. Product control

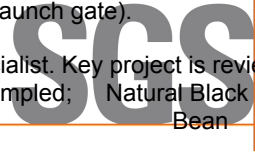
#### 5.1 Product design/development

QMP14 New product and process development covers both product 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. 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 Director. 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. Specifications found updated, signed off by the Technical Director. Minimum reviewed after three years and reviewed whenever any requirement is changed.



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

Full organoleptic test kitchen on site under the Technical Director as an organoleptic specialist. Key project is review of extraction solvent systems in recipes, to offer customer a wider selection of options. Sampled; Natural Black Bean  
 Current Flavour – ET10216  
 Extract – steam / ethanol code V025 – X1239  
 Madagascar Vanilla – ET13372  
 Sicilian Lemon Oil - XP181.



## 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. 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. Nutritional claims do not tend to be made at this stage, but can be verified by the Technical Director and off-site testing, if requested, with none made to date.

The following claims are made:

Organic and Kosher. Sicilian Lemon and Madagascar Vanilla.

## 5.3 Management of allergens

Allergens on site are cereals containing gluten, fish, soy, milk, cheese, lactose, 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 allergen found maintained and also 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. Nuts cannot be brought on site. 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 Elisa 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.

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. 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 is in place. All raw materials, products and the process have been risk assessed dated 2019/04/10.

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 vulnerability 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. The site obtains information on raw materials by monitoring of websites, alerts and legislation. A food fraud assessment is performed on ingredient groups (oils, Sugar syrups, Dry Sugar, flavours etc.) and Provenance (Sicilian Lemon, Madagascan Vanilla, Kosher 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.

Recent 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 Director.

As per the risk assessment, various products are included and are high and low risk as well. The vulnerability risk assessment, issue 2 dated 2016/08/23 was reviewed in 2019/07/09, no changes.

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. Part of H E Stringer Flavours Soil Association Certificate number MD0062895P4242 GB-ORG-05 Expiry 31-05-2020, 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. Part of Kosher Certificate number 34133 Expiry May 2020. balance exercise as part of the external audit.

Sicilian Lemon – code L015, with Lapua Certificate of Origin number 17238 by SGS with SINCERT accreditation number 1880 dated 2019/08/13.

Madagascan Vanilla – with Madagascan certificate of authenticity number 75853 issued by the Department of Agriculture.

The following claims are made:

Organic and Kosher. Sicilian Lemon and Madagascan Vanilla.

#### 5.5 Product packaging

Primary packaging is plastic containers - 1 lt 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 Director. 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.

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.

Off line 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.

#### 5.6 Product inspection and laboratory testing

##### 5.6.1 Product inspection and testing

Positive release by in-house laboratory based upon COA, density and Refractive Index. And supporting QC Stamp on the despatch note.

All new products are tested for RI 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. Samples are retained from each batch and colour coded white, yellow, orange and red to indicate the number of batches. All end product is tested and positive released based upon COA – Colour, Odour and Appearance to retained samples. This is via the technical team of trained flavourists, supported and lead by the Technical Director who is the sign off at any disputed results. Confirmation of shelf life testing is at NPD. Raw materials are used on a FIFO basis. Where product is approaching its expiry date, the Technical Director 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 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.

The test report from a third-party Laboratories. ALS laboratory report number 2860-1 dated 2019/07/03 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and molds, staphylococcus, salmonella, E.Coli, Enterobacteriaceae and gamma negative verified.

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. Written instructions are available in the laboratory for all tests and were viewed for the Density Meter, and refractometer. Test pieces or distilled water are used for calibrating the equipment. Samples from compounding are tested for RI, flashpoint and SG. QC personnel to retrain every 3 months, evaluated against UKAS third party analysis.

Test pieces or distilled water are used for calibrating the equipment. Samples from compounding are tested for RI, flashpoint and SG.

Microbiological product analysis is sub contracted to ALS (UKAS Accredited) which is carried out to customer requirements (frequency and test suite). ALS UKAS accredited number 1282.

Sampled ALS laboratory report number 2860-1 dated 2019/07/03 covering Karl Fisher moisture assay and bioburden based upon TVC, yeast and molds, staphylococcus, salmonella, E.Coli, Enterobacteriaceae and gamma negative verified to ISO/IEC 17025 principles.

Sampled ALS report 1784858-1 dated 2019/06/23 and number TCHT/1717421-1 dated 2019/03/19.

### 5.7 Product release

There is positive release in this site. Sampled;

Banana Flavour Powder – ET12046 – 6Kg made 2019/04/11, tested and positive release by in-house laboratory dated 2019/04/12 to meet delivery promised date of 2019/04/29. In to 2 x 3Kg vented plastic sacks. CCP Monitor Record confirmed powder sieve used, COA and weight check and no issues. Used OP3060 3Kg vented plastic sacks to GRN057871 by operator C.P and training record verified. Supporting Batch inspection Sheet – QF01 denoting hygiene, line clearance, filter/sieve CCP, allergen pack check and line cleanliness. Positive release by in-house laboratory based upon COA and supporting QC Stamp on the despatch note.

Vanilla Flavour Liquid Extract code 13396. Made 2019/08/08, tested and positive release by in-house laboratory dated 2019/08/08 to meet delivery promised date. In to 1 x 5Kg plastic screw top container. CCP Monitor Record confirmed liquid filter 530 microns used. Operator training record verified. Supporting Batch inspection Sheet – QF01 denoting hygiene, line clearance, filter/sieve CCP, allergen pack check and line cleanliness. Positive release by in-house laboratory based upon COA, density and Refractive Index. And supporting QC Stamp on the despatch note.

A traceability test was conducted on 2018/12/18 on C.Bark extract batch number 7794-1-1-1 of 2018/12/11 production. 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. Specific gravity is calculated for point of fill during processing. Positive release by in-house laboratory based upon density and refractive index. Tested on 2018/12/18 and nil NCRs.

A traceability test was conducted on 2018/09/17 on NCR821 back to issue with Not Right First Time powder blend batch number 11407 - 96540 of 2018/08/16 production. 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 2018/08/16 and nil NCRs.

### 5.8 Pet Food

No Pet food is made in this site.

## 6. Process control

### 6.1 Control of operations

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.

Sampled lines;

Banana Flavour Powder – ET12046 – 6Kg made 2019/04/11, tested and positive release by in-house laboratory dated 2019/04/12 to meet delivery promised date of 2019/04/29. In to 2 x 3Kg vented plastic sacks. CCP Monitor Record confirmed powder sieve used, COA and weight check and no issues. Used OP3060 3Kg vented plastic sacks to GRN057871 by operator C.P and training record verified. Supporting Batch inspection Sheet – QF01 denoting hygiene, line clearance, filter/sieve CCP, allergen pack check and line cleanliness. Positive release by in-house laboratory based upon COA and supporting QC Stamp on the despatch note.

Onion Flavour Powder

Bacon Flavour Powder

Vanilla Flavour Liquid Extract code 13396. Made 2019/08/08, tested and positive release by in-house laboratory dated 2019/08/08 to meet delivery promised date. In to 1 x 5Kg plastic screw top container. CCP Monitor Record confirmed liquid filter 530 microns used. Operator training record verified. Supporting Batch inspection Sheet – QF01 denoting hygiene, line clearance, filter/sieve CCP, allergen pack check and line cleanliness. Positive release by in-house laboratory based upon COA, density and Refractive Index. And supporting QC Stamp on the despatch note.

Natural Ginger Flavour Liquid Extract.

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 Director and supporting CAPA report for recipe improvement or pre-make steps.

### 6.2 Labelling and pack control

Labels are printed for each batch of product. 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 and detailed on the job bag documentation.

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, as part of the traceability exercise on the day.

### 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;

Banana Flavour Powder – ET12046 – 6Kg

Onion Flavour Powder

Bacon Flavour Powder

Vanilla Flavour Liquid Extract

Natural Ginger Flavour Liquid Extract.

## 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 2019 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. Thermometers back to empirical standards based upon boiling water and iced water.

Examples of certificates checked for;

Scales and test weights – 5g, 10g and 50g - BRASH certificate number 270626 2019/07/02

Scales – Daily balance checks in place prior to production taking place conducted by QA.

CCP – Filter – Certificate of conformity 16.01.2019 2 “clamp 90 fine screen filter 1.25mm screen mesh sieve certificate of conformity 16.01.2019. cert number 27535.

certificate of conformity 30.11.2018 Clamp pure screen inline filter 530 cert number 27266.

Inspection by production / QA countersigned and production supervisor checked as part of cleaning schedule to ensure no issues on product changeovers.

**However, Calibration SOP QMP 18, version 2 incomplete ref. IR Gun and Fridge Thermometer not listed. Minor CAR 3 of 3 raised.**

## 7. Personnel

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

Training has been changed to new online HR system Breathe.

Sampled key team training records including BRC Representative – Managing Director, deputy BRC Representative – Technical Director and support BRC Representative – Operations Director.

Sampled HACCP team;

The team consists of the Managing Director as the Team Leader who holds a BRC Intermediate HACCP certificate – ATP034 dated 2008/06/18, the Technical Director holds a Level 3 HACCP certificate by RSPH number 65221/1 dated 2014/11/18, the Operations Director holds a BRC HACCP certificate dated 2014/11/07 and the Purchasing Manager with a Level 2 HACCP certificate by CIEH number 3332 dated 2018/12/18.

Audit Team;

3 auditors onsite including.

Managing 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.

Operations Director with QF05 Training Record denoting in-house refresher training by External Food Safety Consultant dated 2014/03/12 and 2019/04/10.

External Food Safety Consultant holds a BRC Internal Auditor Certificate number 0149 dated 2003/10/09.

Sampled CCP Operator training records;

AB- Compounder – Food Safety level 2 certificate by Highfields number 03517 dated 2019/04/11.

SG- Compounder – Food Safety level 2 certificate by Highfields number 06264 dated 2019/04/11.

CP- Compounder – Food Safety level 2 certificate by Highfields number 06267 dated 2019/04/11.

The company has a training programme for staff on induction and production roles. 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 standards have been established and documented. Personnel hygiene is a part of induction training and basic food hygiene training.

Company Hygiene Health and Safety Policy dated 2018/05/25, 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.

Hand washing facilities on entry to production areas which were hands free with soap, paper towel available.

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

Blue Plaster register in place last logged on 2019/05/30 and 2019/05/28 issued 'to' and 'disposition record' signed and recorded on record of plaster control issue dated 2017/07/19, issue 1. No metal detection onsite.

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.

QF32 Return to work medical questionnaire for food handlers issue 1 dated 2012/07/19 checked for two employees (compounder & Operations Manager) on 2018/03/20 & 2019/06/24 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. Visitor questionnaire in place QF35 Factory visitors Form Issue 3 dated 12.06.2018. Questionnaire confirm visitors are fit and healthy before entering production areas. Visitor PPE consisting of white coat for visitors, hat, beard snoods and safety shoes.

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

Protective clothing is laundered by Johnsons collected each Tuesday. Signed contract in place 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 Ait Filter Kits for employees within the mixing / compound areas).

White gloves are used in production area which are disposable and replaced when required.

No Aprons are used onsite.

No PPE used onsite which is not disposable or laundered 7.4.6 NA



**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

N/A

8.2 Building fabric in high-risk and high-care zones

N/A

8.3 Maintenance in high-risk and high-care zones

N/A

8.4 Staff facilities for high-risk and high-care zones

N/A

8.5 Housekeeping and hygiene in the high-risk high-care zones

N/A

8.6 Waste/Waste disposal in high risk, high care zones

N/A

8.7 Protective clothing in the high-risk high-care zones

N/A

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

Clause/section reference	Justification
3.5.2.3	No live animals in the process

3.5.4	No outsourced processing
3.9.4	No rework in the system.
4.4.5	No suspended ceilings or roof void.
4.3.5	No temporary structures.
4.10.3	No X-ray equipment
4.10.4	No magnet in the system as sieves are installed
4.10.5	No optical sorting equipment utilised
4.11.7	The whole equipment is simple design, fully taken apart out and washed.
4.13	Use of mass balance based formulaes and customised production to individual orders.
4.14.3	Pest control is outsourced.
4.15.5	No storage outside
4.16.3	No temperature controlled distribution required.
5.8	No pet food is made on site
6.2.4	No on-line vision equipment utilised
7.2.4	No metal detection onsite.
7.4.6	No such items on site which cannot be laundered
8.0	No high risk, high care and ambient high care area.



9.0	No traded products on site.
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<b>9 - Traded Products</b>
<b>9.1 Approval and performance monitoring of manufacturers/packers of traded food products</b>
N/A
<b>9.2 Specifications</b>
N/A
<b>9.3 Product inspection and laboratory testing</b>
N/A
<b>9.4 Product legality</b>
N/A
<b>9.5 Traceability</b>
N/A