# Audit Report

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

| 1.Audit Summary | | | |
|---|---|---|---|
| Company name | Alara Wholefoods Ltd. | BRC Site Code | 1298291 |
| Site name | | | |
| Scope of audit | The milling, blending and packing of breakfast cereals, including muesli, nuts, dried fruit and seeds in heat sealed bags, sachets, pots and stitched paper or multi-ply sacks. The mixing and roasting of granola as a raw material for inclusion in breakfast cereals. The filling of syrups into PET squeeze bottles and tubs. | | |
| Exclusions from scope | None. | | |
| Justification for exclusion | Justification for exclusion | | |
| Audit Finish Date | 2018-07-12 | | |
| Re-audit due date | 2019-07-22 | | |

| Voluntary modules included | | |
|---|---|---|
| Modules | Result | Details |
| AOECS Gluten-Free Foods | Passed | Gluten-free breakfast cereals including granola and muesli. |
| Choose a module | Choose an item | |
| Choose a module | Choose an item | |

| 2. Audit Results | | | | | |
|---|---|---|---|---|---|
| Audit result | Certificated | Audit grade | AA | Audit type | Announced |
| Previous audit grade | B | Previous audit date | 2017-07-03 | | |

| | | |
|---|---|---|
| Number of non-conformities | Fundamental | 0 |
| | Critical | 0 |
| | Major | 0 |
| | Minor | 4 |

## 3.Company Details

| | | | |
|---|---|---|---|
| Address | 108-112 Camley Street<br>London<br>NC1 4PF | | |
| Country | UK | Site Telephone Number | 02073 879303 |
| Commercial representative Name | Alex Smith | Email | alexsmith@alara.co.uk |
| Technical representative Name | Georgios Margaritis | Email | technical.manager@alara.co.uk |

## 4.Company Profile

| | | | | | |
|---|---|---|---|---|---|
| Plant size (metres square) | <10K sq.m | No. of employees | 51-500 | No. of HACCP plans | 1-3 |

| | |
|---|---|
| Subcontracted processes | No |
| Other certificates held | Organic exp. 30/6/19, Fairtrade exp. 20/11/18, ISO14001:2015 exp. 29/1/2020, AOECS certification exp. 19/12/18. |
| Regions exported to | Europe<br>Asia<br>Africa<br>Oceania<br>Choose a region<br>Choose a region |
| Company registration number | None |
| Major changes since last BRC audit | There is a new Technical Manager since Jan 2018. |

Company Description

Alara Wholefoods Ltd is a privately-owned company, which was established in 1975 and moved to its current site in 1985 (Unit 1). Growth led to the acquisition of an additional premises (Unit 2) in 2004. The units are around 35 years old and have been adapted to meet food handling and storage requirements. The business has an organic product range amounting to around 50% of output and has been organically certified since 1986. Most products are retail packed and sold under Alara or customer own label branding. There is a site owned OTE brand which includes syrups sold in squeezy bottles and tubs. Weekly output is about 100 tonnes and there is a single production shift. Customers include major retailers, independent retailers, wholesalers and food service groups.

| 5.Product Characteristics | | | | | |
|---|---|---|---|---|---|
| Product categories | 15 - Dried food and ingredients<br>17 - Cereals and snacks<br>VM AOECS Gluten-Free Foods<br>Category<br>Category<br>Category | | | | |
| Finished product safety rationale | Ambient stable dry foods (aw <0.6). Long shelf life. | | | | |
| High care | No | High risk | No | Ambient high care | No |
| Justification for area | The production zones have been concluded using the BRC Zonal Decision Tree. Ambient stable , low water activity product. | | | | |
| Allergens handled on site | Cereals containing gluten<br>Milk<br>Soya<br>Peanuts<br>Soya<br>Sesame<br>Sulphur dioxide and Sulphites<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen | | | | |
| Product claims made e.g. IP, organic | Organic, Fairtrade, Gluten/Wheat Free, Scottish Oats, Vegetarian and Vegan. | | | | |
| Product recalls in last 12 Months | No | | | | |
| Products in production at the time of the audit | Granola base honey org GF sample; FT muesli exotic fruit 750g BB 10/7/19; Irish muesli 750g; Trail mix 10kg; Raisin granola and golden syrup BB 10/7/19. | | | | |

## 6.Audit Duration Details

| | | | |
|---|---|---|---|
| On-site duration | 17 man hours | Duration of production facility inspection | 6 man hours |
| Reasons for deviation from typical or expected audit duration | The on-site duration includes AVM12. The overall duration was slightly shorter than calculated, and the duration of the production facility inspection was less than 50% of the duration of the audit as the milling plant was not in operation, and some of the lines ran for only a very short period. | | |
| Next audit type selected | Announced | | |

## Audit Duration per day

| Audit Days | Audit Dates | Audit Start Time | Audit Finish Time |
|---|---|---|---|
| 1 | 2018-07-11 | 10:00 | 17:15 |
| 2 | 2018-07-12 | 08:15 | 18:15 |
| | | | |

| | Auditor (s) number(s) | Names and roles of others |
|---|---|---|
| Auditor Number | 135055 | Catherine Gladwin: Lead Auditor |
| Second Auditor Number | N/A | N/A |

## Present at audit

| Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9)<br>Name / Job Title | Opening Meeting | Site Inspection | Procedure Review | Closing Meeting |
|---|---|---|---|---|
| Alex Smith, Founding Director | X | | | X |
| Georgios Margaritis, Technical Manager | X | X | X | X |
| David Effa, Production Manager | X | X (part) | X (part) | X |
| Tom Furga, Warehouse Manager | X | X (part) | | |
| Katrina Smith, MD | X | | | |

# Non-Conformity Summary Sheet

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

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

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

| Minor | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| 1 | 4.4.9 | The door to unit 2 is not close fitting. | The site maintenance operative was informed for the non-compliance and the door was fixed. | The QA Technicians were re-trained on the importance of and the requirements of Fabrication audit. | Photos of the door. Training records.<br><br>Maintenance Issue records. | 2018-08-09 | C Gladwin |
| 2 | 4.9.5.1 | There is wood flooring on the upper mezzanine level which is exposed as the ceiling in the baking line. | The site maintenance operative informed for the non-compliance and a plastic cover was installed. | The glass and hard plastic audit amended.<br>The QA Technicians were re-trained on the importance of and the requirements of Fabrication audit as well as the Glass and Hard Plastic | Photos of the area before and after the installation of the plastic cover.<br><br>Glass and hard plastic audit V39. | 2018-08-09 | C Gladwin |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | Audit. | Training Records dated 1 and 2 Aug 18. | | |
| 3 | 4.11.1 | The overall state of the open product areas was not seen to be clean and hygienic (though there was no perceived risk of product contamination that would compromise the low risk nature of the product). | A deep cleaning carried out. | The monthly cleaning schedule amended. More areas were included and the time between the cleaning was reduced.<br>The hygiene operatives, the Team Leaders and the production operatives re-trained on the importance of and the requirements of Cleaning.<br>The QA Technicians re-trained on the importance of and the requirements of Cleaning Audit. | Photos of the company before and after deep cleaning.<br><br>Amended cleaning schedule V9.<br><br>Training Records dated 2018-08-02. | 2018-08-09 | C Gladwin |
| 4 | 6.3.1 | An operator recorded pass for several check-weigher challenges when the reject mechanism was not working. The actual weights were not of concern as sample-based checks were carried out. | Engineer called and adjusted the check-weigher. | The Team Leaders were re-trained on the importance of and the requirements of Finished Product Weight Checks. | Engineer invoice dated 2018-07-31.<br><br>Training Records dated 2018-08-02. | 2018-08-09 | C Gladwin |

| Comments on non-conformities |
| --- |
| A minor NC was raised at the previous audit against clause 4.9.5 and again at this audit however, the two issues are different (previously related to condition of a pallet and this time to the fabrication/ceiling) and therefore an NC has not been raised against clause 1.1.10. |

# Voluntary Modules Non-Conformity Summary Sheet

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

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

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

# FSMA Module Non-Conformity Summary Sheet

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

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

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

# Detailed Audit Report

## 1. Senior management commitment

### 1.1 Senior management commitment and continual improvement

There is a documented food safety policy signed V11 by and dated 7/11/17 which is displayed on the staff notice board. It is also included in the induction information given to all new employees.

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

Clear objectives/targets are established by the company ref. the Quality Objectives document V13 dated 17/5/18 (which includes pass/fail criteria for microbial tests), which are specific, measurable and achievable and these are:

| Objective | Target | Achieving (at Jun 18) |
|---|---|---|
| Complaints | Stones <4 CPMU<br>Total complaints <30CPMU | 2 stone complaints (5.7 YTD)<br>12 complaints total (33 YTD) |
| Site hygiene audits | Min score 90% | Unit 1 95.75% Unit 2 97.25% |
| Gluten swab results | <20ppm | No failures in Jun. |
| Micro results within specification | Finished products 100%<br>Food contact swab 100%<br>Hand swabs 100% | 100%<br>100%<br>100% |

These are reported on, and reviewed at the Management Review meetings held monthly, with minutes viewed dated Jun 18.

Management Review meeting agendas include all elements of 1.1.3, last annual meeting held 21/5/18, with minutes viewed. Other meetings held include monthly meetings covering Technical, NPD, production issues and other current issues.

The site is kept informed of the points listed in 1.1.6 by subscription of Campden BRI (membership number 884892), the Soil Association, Coeliac Society and the Food and Drink Federation and official websites and industry alerts the from FSA and Food Fraud site. These are reviewed by horizon scanning by the Technical Manager as necessary, via alerts.

The 9 non-conformities raised at last year's audit (against clauses 2.3.2, 3.5.1.2, 3.5.1.2, 3.9.3, 4.9.5, 4.11.1, 5.3.8, 5.4.4 and 6.1.1) have been resolved and there was evidence that root cause has been identified and actions instigated to prevent recurrence.

## 1.2 Organisational structure, responsibilities and management authority

There is an established and experienced team of managers based on site with the Managing Director being in overall charge. The day to day operations of the site are shared between the Production, Technical and Warehouse Managers. An organogram is in place, dated 10/7/18.

Deputies for key staff are defined in the Organisational Structure, Responsibility and Management Authority document ref: AWQM1.2 V11 dated 18/5/18.

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

A number of work instructions for were challenged during the audit and found to be operational and relevant, including:

- Metal Detection Procedure V12 dated 7/3/18
- Rework Procedure V4 dated 19/6/18

Job descriptions were challenged for the following roles:

- QA Controller signed by RD on 22/7/16
- Production Operative signed by LS on 10/1/17

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

| Clause reference | Justification |
|---|---|
| N/A | N/A |

## 2 The Food Safety Plan – HACCP

The company's food safety plan is based on Codex Alimentarius HACCP principles. There is 1 HACCP study, currently at revision 12 and dated 27/4/18.

The HACCP team is led by the Technical Manager GM, who is competent in HACCP, through L2 HACCP on 24/10/17 and L3 Food Safety on 14/4/18, both through CIEH and a Master of Science degree through University of Reading on 10/12/15.

The HACCP team includes representatives from technical, production and warehouse areas and are competent through industry experience and training through, as a minimum, internal training.

The scope of the study includes microbiological, physical, chemical and allergenic hazards and covers all the products produced at the site. It is systematic, comprehensive and fully implemented and maintained.

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

hygiene and housekeeping, glass and hard plastic control, maintenance, traceability, raw material handling, training, calibration and storage.

Pre-requisites used to manage specific hazards such as allergen cleaning have been validated via testing at an external third-party laboratory (FAC UKAS 4400), and weekly verification through allergen swabs with records kept.

Product descriptions are defined as:

Varieties of multiple ingredient MUESLI products (including granola base products processed on site), 'Gluten Free' products, Breakfast Snack Pots (ready to eat), Single ingredient cereal based products and other single ingredient products.

Products are packed into polyethylene clear film bags, Kraft paper bags with internal laminate and tin tie closure, 3 ply Kraft paper sacks, various films (PE, PP, biodegradable PP, co-ex), pouches, plastic pot & lid and paper pot & lid, Inner and outer cardboard boxes and plastic jars with metal lids.

References to legislation have been made within the study including:

- The Materials and Articles in Contact with Food (England) Regulations 2012
- (EC) No. 828/ 2014 and the AOECS standard for gluten free foods.

Legislation, standards and COPs for other countries where the product is sold are covered via the product specification, which details the requirements and is signed by the customer as correct.

Intended use is documented as suitable for all consumers including vulnerable groups like children, pregnant women and elderly people, as well as other specialist groups:

- Allergy Sufferers - Gluten Free Muesli
- Health Conscious - Organic, Vegetarian, Vegan and products with added protein
- Welfare Conscious – Fairtrade Muesli

The products may not be suitable for people with allergies to particular foods, including but not limited to, Coeliacs.

The HACCP study has concluded that there are no known alternative uses for the products which will affect the level of risk.

There is one generic flow chart V12 (dated and verified on 1/3/18) and 9 line specific diagrams, each verified on the date of issue:

- Cold Milling V3 dated 1/3/18
- Flow Wrap V2 dated 6/3/18
- Roasting V4 dated 2/3/18
- Bagging V8 dated 1/3/18
- Boxing V7 dated 7/3/18
- Portion Packing V7 dated 7/3/18
- Ton Mixing V6 dated 1/3/18
- Hand Packing V7 dated 1/3/18
- Manual Packing V6 dated 27/3/18

The process flow diagrams cover the process steps, which typically include: Purchase, delivery to external store, receipt on site, allocation of pallet codes, QA inspection of ingredients and inspection of packaging items, allocation to storage areas, picking of stock to order, machine cleaning prior to use, ingredient addition (scaling to recipe quantity), mixing, roasting, cooling and bagging of granola as WIP, finished product assembly, mixing, gravity transfer to bagging/boxing portion packs or ton mix/bagging, packing to form filled films or paper sacks, hand/manual filling to pouches, pots, closure, metal detection, check-weighing, case packing palletising warehouse storage as stock or direct delivery to customer.

Physical, chemical, microbiological and allergen hazards have been considered within the study, for example:

- Biological Hazards: e.g. microbiological controls covering the following pathogenic and indicator organisms;TVC, Salmonella, E.coli, Staphylococcus aureus, Bacillus cereus, Enterobacteriaceae, Yeasts and Moulds
- Physical Hazards: e.g. Glass, metal, paper, plastics, stones, nut shell, pit fragments, wood, stalks, cap, stems, indian meal moth, red flour beetle
- Chemical Hazards: e.g.Cleaning chemicals, pesticides residue,mycotoxins
- Allergen hazards: Including supply chain risks, handled on site and via visitors/workers raw materials, and also include 'Gluten Free' and 'Free From' products.

Hazard analysis and CCP identification, ref. HA AWQM 2.5 V24 dated 20/4/18, 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:

| CCP | Hazard | Critical Limit | Monitoring Method | Monitoring Frequency | Recorded On |
|---|---|---|---|---|---|
| 1 | Goods-in | As per raw material specification | Inspection of raw materials against specification and packaging integrity. | Every delivery of nuts, fruits, seeds and some cereals | System database QC Sheet |
| 2 | Machine cleaning | Machine cleaned, Negative gluten swab test | As per end of the week cleaning and swab test results | Weekly, as required | CCP2 Gluten Swab form |
| 3 | Metal detection | No metal Phantom Fortress 2mm FE, 2mm N-FE 2,5mm SS. Tek II & Stealth Fortress 3mm FE, 3mm N-FE 3,5mm SS | As per Metal Detection Procedure | Start & end of production run, hourly checks, after Machine breakdown | M Metal Detector Check Record CCP 3 |

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

Validation of the critical limits has been based on industry standards (CCP3), allergen validation (CCP2 with validation detailed in section 5.3) and visual inspection (CCP1).

Verification is carried out during internal audits and the daily verification checks performed. Verification reviews are carried out quarterly audits and are based on a review of the system documentation, records, internal audits, deviations and corrective actions, complaints and incidents.
The HACCP plan is reviewed at least annually (last reviewed on 27/4/18), when relevant changes or if a

recall occurs.

| Details of non-applicable clauses with justification | |
|---|---|
| **Clause reference** | **Justification** |
| N/A | N/A |

## 3. Food safety and quality management system

### 3.1 Food safety and quality manual

The Quality Manual is a collection of individually controlled documents. It has been written to meet the requirements of the Standard and contains policies, procedures, work instructions and record forms. It is controlled electronically by the Technical Manager.

Department specific work instructions are available at key locations and all documents are in English, with no requirement for other languages.

### 3.2 Documentation control

Controlled documents are listed on register, ref: Food Safety and Quality Management System – Document Control System and control is managed by the Documentation Control procedure, ref: AWQM3.2 V10 with the Technical Manager responsible for authorisation, changes/amendments and replacement of existing documents.

### 3.3 Record completion and maintenance

Records are completed manually and electronically and are stored as hard copy and electronically (off-site) and backed up daily, weekly and annually.

Records reviewed during the facility inspections were seen to be legible and genuine and in addition, the following records were viewed as part of the trace test:

- Picking sheet for Hi Protein Muesli L8101 and mixing sheet and weight check sheet.
- Metal detector check record V11 dated 7/7/16 completed 11/4/18.
- Sales order collating sheet and delivery note on 12/4/18.

Records are retained for 36 months (longest shelf life of product is 24 months).

### 3.4 Internal audit

There are 6 trained internal auditors based on site who are responsible for the site internal audits, who have been trained by the Technical Manager in-house. The last training was carried out by the previous Technical Manager OO who trained the new Technical Manager GM on 8/11/17. The auditors on site

cross audit departments to ensure independence from direct responsibility.

The internal audit schedule for 2018 is documented and covers all the documentation and processing systems on site. Each area is audited at least annually, based on the 7 sections of the BRC standard. Internal audits are carried out throughout the year with the frequency determined by risk assessment.

Internal audit records reviewed included:

- Site standards by GM Technical Manager on 30/3/18 with no issues raised.
- HACCP by DE on 30/4/18 with no issues raised.

The audits were a comprehensive recording evidence of both conformity and non-conformity.

Corrective actions and their timescales are not relevant as no NC's have been raised (although the audits were comprehensive).

Monthly hygiene/fabrication and daily GMP inspections are carried out, based on risk assessment. Reports reviewed included:

- Daily GMP audits conducted by MV for both units 1 and 2 with completed records seen for June and July 18. In some cases, concessions are raised for non-allergen products (fully packaged) stored in allergen dedicated warehouse bays due to space shortages.
- Monthly fabrication audit viewed for 2018 by MV (N/Cs managed by Maintenance).
- Weekly cleaning audits are carried out by MV, with reports viewed for Jun & Jul 18.

## 3.5 Supplier and raw material approval and performance monitoring

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

A risk assessment of raw materials has been carried out V5 dated 8/5/18, with products assessed for allergen, foreign body, chemical, microbiological and substitution/fraud risks.

All suppliers have been assessed as low risk however the supplier monitoring which is scored on the approved supplier list 3.5.1.1 V4 dated 26/6/18 takes into account complaints made to suppliers and as a result of this monitoring, there is one supplier WS which has had their rating escalated to Medium risk. The supplier complaints (related to mouldy bags) have been monitored appropriately and an increased level of sampling and inspection implemented.

Suppliers of products are approved and monitored by the Technical Manager, in line with the Supplier and Raw Material Approval and Performance Monitoring procedure, ref: AWQM3.5 V11 dated 9/8/17 and assessment of suppliers is based on risk, quality and historical compliance.

Supplier questionnaires are issued at a frequency based on risk and suppliers are required to notify the site of any significant changes in the meantime, every 3 years as a minimum.

Agents and Brokers are used and the identify of the manufacturer is known.

Exceptions are covered under the Supplier Approval procedure AWQM3.5 V11, with Technical authorisation required where a supplier is not approved.

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

Raw materials are checked on intake for compliance with purchase orders and certificates of analysis/compliance are received. This involves a detailed inspection process which is specifically CCP1.

A Goods In Procedure V8 dated 6/6/18 is in place and covers: intake checking requirements, including vehicle hygiene, pallet condition, and product / documentation review – undertaken by forklift drivers. An Expected Deliveries Sheet is issued weekly to identify the goods expected (by day and item) and includes a verification record for organic / Fairtrade status and other provenance claims. This was viewed completed as part of the trace test for Expected delivery sheets dated 12/12/17 for

- peanuts blanched 25kg x40 lot B-03-169.
- Sesame organic seed lot 2017220264-01.
- Sunflower seed kernels lot 28695.

The Raw Material Control document V10 dated 5/4/16 identifies materials for which a Certificate of Analysis/conformance is required for every batch and the specific test results required, with the acceptance limits for these tests:

- nuts and peanuts – aflatoxins
- vine fruits – ochratoxin
- tropical fruits – SO2 levels
- gluten free products – ppm gluten
- sunflower seeds – micro
- goji berries and strawberries – micro, pesticides and SO2
- coconut - micro

Items are assigned colour coded pallet labels with product description and date of receipt and then further assigned to specified storage areas, according to status. Blue = gluten free, red = organic etc. Materials are placed ‘On Hold’ and then sampled by QA in a separate area of the Unit 1 warehouse. Specific inspection criteria are preloaded to the Alara database by ingredient description. The QA inspection checklist covers organoleptic, foreign bodies, infestation and for packaging, artwork checks and checks of the COA which must include the specific tests related to the product, as detailed above.

### 3.5.3 Management of suppliers of services

Service suppliers are approved and monitored by using the Contractors Approval Procedure, with appropriate contracts in place.

These were reviewed for suppliers of External Storage PW Gates BRC S&D exp. 28/11/18 and Pest Control Check Services, signed 5/2/18.

### 3.5.4 Management of outsourced processing and packing

N/A

## 3.6 Specifications

Manufacturing instructions/specifications are produced on the daily recipe sheets, which are available at workstations and confirm compliance with finished goods specifications. These were reviewed for a number of products e.g. Alara ITG GF with Goji & Cranberries Organic manufacturing specification for the production date 14/5/18, which when completed, forms part of the batch records (viewed as part of the 6 monthly mass balance for claims).

Finished product specifications are generated by the company and are supplied to customers on either the site or customer format.

Specifications are agreed with customers through order placement.

The following specifications were reviewed and found to be compliant:

- Finished product: Alara Organic Gluten Free Scottish Oats Granola V6 dated 26/9/16.
- Finished product: Alara Into the Garden Organic Muesli Active Gluten Free V6 dated 26/9/16.
- Manufacturing spec (recipe): Granola base honey organic GF dated 27/6/18 (NPD sample).

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

## 3.7 Corrective and preventive actions

Corrective action procedure AWQM3.7 V7 dated 3/1/18 is in place. Non-conformities that result in a risk to product safety, legality or quality are investigated and recorded in line with clause requirements. This includes the assessment of the consequences of the non-conformity by the owner of the non-conformance and verification of corrective action by Technical department.

Root cause analysis and the implementation of further corrective action to address the root cause, are carried out, where this is necessary. Corrective actions were reviewed for the complaints viewed.

Corrective actions taken are recorded and discussed during the management reviews held monthly.

## 3.8 Control of non-conforming product

Non-conforming products are identified by ‘QC Hold’ or ‘QC Rejected’ tape and held in the appropriate area and held via the electronic database system. The Technical department is informed and are responsible for the holding and release of products. All incidents of non-conforming product are recorded on either the Suppliers Non-Conformance Report, or the Raw Material Non-Conformance document.

Records are in place to demonstrate the investigation, analysis and cause of any non-conforming product. Defined responsibility and actions/timescales are documented, in line with the Control of Non-conforming Product Procedure, ref: AWQM3.8, V9 dated 13/11/17.

A monthly trend analysis is undertaken for N/C products, with no specific trends identified.

## 3.9 Traceability

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

The traceability system is mainly manual being paper based and operates on a date based system, with finished product assigned a best before date and a batch code and raw materials being assigned a receipt date. The receipt date is recorded on a mix/ packing record which includes the finished product best before date and the batch code.

Traceability systems of suppliers approved via questionnaire only are verified by trace audit data supplied.

The Rework Procedure V4 dated 19/6/18, specifies rework types and details that all 'over' products are packaging into their finished product boxes and these are picked first when the next consignment is ordered. This was seen for a small number of finished packs stored in Unit 2, stored on racking for use in the next production run of the same product, however Technical approval is required. Rework record 3.9.3a is used to ensure traceability.

The company carrys out several traceability challenges through the year including mass balance. For example, a trace and mass balance was carried out on Alara Gluten Free Organic Scottish Oats Granola, batch 157944 on 9/5/18

A traceability challenge and mass balance was undertaken during the audit on Hi Protein Muesli L8101, 1476 bags produced on 11/4/18. Further to the exercise, three of the ingredients (peanuts, sunflowers and sesame seeds) were traced as full mass balances forwards into all other products produced with the selected ingredients. The exercise was completed within the 4 hours.

## 3.10 Complaint handling

A system of complaint handling is implemented via complaint procedure V7 dated 3/1/18. All complaints are logged and investigated by the Technical Manager, with full details kept of all actions taken.

Complaint target is set at: Stones <4 CPMU and Total complaints <30CPMU.
Current performance for Jun 18: 2 stone complaints (5.7 YTD) and 12 complaints total (33 YTD).
Complaints are trended by type of complaint and by customer

Complaint types are mainly due to foreign bodies and these are discussed monthly.

- Complaint no. 4118 received 8/3/18 was viewed relating to a small plastic/metal ball found by the customer in granola. The customer did not respond to a request for a BB date or to return the FB. The site investigated the ingredients and no further action could be taken.
- Complaint no. 4162 received 3/7/18 for hair in granola. The customer again did not respond to a request for further information however as a preventive action the technical department carried out a staff briefing regarding controls.

Analysis of complaints viewed for the past 12 months indicate that the level has increased, however a number of the complaints viewed and discussed were deemed unjustified.

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

The company has comprehensive procedures, including the product recall and withdrawal procedure V18 dated 11/5/18 and an out of hours contact list for all key members of staff, customers and organisations including the Certification Body. The requirement to notify the Certification Body within three days of the decision to issue a recall is included.

There have been no live recalls

A recall challenge is undertaken by the company with the product traced to the customer. The last challenge was undertaken on DT Gluten Free Muesli 1kg BB Mar 19, lot 210810 produced13/3/18. Following the exercise, a meeting was held to confirm success.

## 3.12 Customer focus and communication

Specific customer requirements are determined through codes of practice, product development and through electronic databased specification systems.
Customers are able to pick an individual recipe for their chosen Muesli.

The site ensures these are kept up to date and communicated via management meetings and staff briefings. Product specific recipes/working methods etc. are amended to meet requirements. Specifications would be amended and agreed with suppliers, as needed to meet particular customer requirements.

### Details of non-applicable clauses with justification

| Clause reference | Justification |
|---|---|
| 3.5.4 | No outsourced processes or packing. |

# 4. Site standards

## 4.1 External standards

The site occupies approximately 1400 $m^2$ and production and storage buildings occupy most of this at approx. 1200 $m^2$. The site is located on a small trading estate on Camley Street, in an area to the north of Kings Cross Station and major developments to site have taken place over recent years. The premises comprise two units across a secure yard that is shared with one other business, a stationary wholesaler.

The main premises were constructed about 40 years ago and have been updated and adapted to current use and appear externally sound and well proofed against potential pest ingression.

The grounds are maintained in good order and the yard / roadways suitably surfaced. The only other adjoining business, on the opposite side of the short service road is a cash and carry.

## 4.2 Security

There is a legal requirement for the site to be registered with Camden Council.

The site security is managed by a fenced yard which is secured out of operating hours, in addition to a CCTV provision externally and internally.

Access to Unit 1 is via a reception area, with a clocking in point for staff and screening for visitors and contractors. There is no unaccompanied access to Unit 2, as the unit has key pad entry.

There are no external storage tanks, silos, intake pipes etc.
Training is in place to remind staff to identify and report any unauthorised personnel.

A documented security assessment has been carried out, reviewed and up issued to V6 on 19/2/18 and the necessary controls are implemented with reporting to site for all visitors and contractors.

## 4.3 Layout, product flow and segregation

The site is classified as low risk and a plan dated 23/2/18 and verifed 1/3/18, identifies specific areas including enclosed product and non-production areas.

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

There are no high risk/high care areas. There were no temporary structures noted.

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

Internal fabrication is generally well maintained. The units are steel framed and metal clad, with blockwork walling to around 2.5m. Wall finishes vary according to area and include painted, panelled and tiled. Floors are sealed concrete and are maintained in good repair.

There are no suspended ceilings or roof voids. Overheads are accessible for inspection and cleaning. There are some external facing windows within the production area, for example in the Granola room, which are screened against insects. Internal glazing is plastic, and all lights are fluorescent tubes protected by diffusers.

Separate pedestrian and vehicular access doors. Units 1 and 2 have high speed roller doors for movement of raw materials, packaging and finished products. Other doors, including fire escapes are close fitting.

Extraction systems are used near the Granola oven and no evidence of excessive dust was noted.

There are no high risk/care areas.

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

**Minor NC1**: 4.4.9 The door to unit 2 is not close fitting.

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

Water used on site is potable and mains supplied from Thames Water Utilities Ltd. Annual microbiological and chemical analysis is obtained from the supplier (last report 1/1/16 to 31/12/16) and additional surveillance testing is carried out by an external laboratory in accordance with the 2018 water sample schedule. There are 11 sample points which are primarily hand and utensil was stations. Testing results reviewed included:

- ALS report dated 1/6/18 for the Utensil wash area with a colony count of 1 cfu/ml found and no coliforms or e. coli detected.

Ice/steam are not used.

No gas is used

Compressed air is used for machinery operation and dry cleaning of production lines only.

## 4.6 Equipment

Equipment on site consists of industry standard mixing and blending items. Ingredients are added to mixers at high level, blended and deposited into the packing lines. The packing lines are specific to final pack formats and include VFFS bagging, VFFS bags into cartons, filling of pots, pouches etc. via easi-weigh type dispensers.

Granola ingredients are blended on Hobart type mixers, spread to baking trays, racked and baked off in two rack ovens, prior to cooling and manual crumbing. Product is packed to 3 ply sacks as WIP for inclusion in finished product recipes.

Most of the equipment is constructed of food grade stainless steel, either 316, or 304 (as appropriate).

Other food contact equipment and utensils include conveyor belts, valves, bins/trays.

Equipment is designed and placed for effective cleaning and maintenance.

The following certificates/evidence was seen to confirm suitability for food use: Detectamet compliance statement dated 27/2/13 for scoops recently purchased.

## 4.7 Maintenance

The on-site engineering team are responsible for day to day servicing and maintenance of equipment and plant. Specialised equipment is subcontracted to specialist servicing: 4 x Metal detector validation and 3 x check-weigher calibration reports from Sparc Systems dated 7/6/18.

The schedule is defined within the forms used to document maintenance activities and these are based on risk, historical information and manufacturers' recommendations.

There are individual pre-planned maintenance records for each piece of equipment which record all repairs and scheduled maintenance.

There is a daily hygiene/integrity check of all equipment.

Maintenance checks are completed following intrusive maintenance which includes sign off by engineering and production, and the following completed records were viewed:

- Weekly maintenance checklist 4.7.1 V6 dated 9/2/16, seen completed 6/7/18.
- Maintenance issue form V5 dated 24/6/16, seen completed for recent months as an action list of fabrication tasks.
- Breakdown report V4 dated 2/5/16 seen completed 30/1/18 for a broken transformer, with a hygiene sign off by production and technical.
- Safety equipment checklist, completed Mondays and viewed completed 9/7/18.

There are no high risk/care facilities.

Contractors are supervised on site and have separate signing in procedures which include references to prevention of foreign body contamination.

The engineering workshop is located next to Unit 2 Production area and potential contaminants from workshops are controlled by swarf matting.

Chemicals/lubricants used are suitable for food contact (where applicable) and details of allergen status has been obtained, ref. CRC statement dated 18/5/18. Two lubricants are used on site (and two solvent based cleaners) ref. the 2018 lubricant list dated 26/6/18:

- Ambersill Machine Oil, H1 registered 137999
- Ambersill Ambergrease FG3, H1 registered 14248.

No temporary repairs were noted. Temporary repairs are subject to recording on maintenance request logs.

## 4.8 Staff facilities

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

There are no high risk/high care facilities.

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

There is no catered canteen facility. Staff are provided with vending machines, microwaves and refrigerators which are cleaned and the temperature is monitored weekly.

No smoking is permitted on site.

## 4.9 Chemical and physical product contamination control
## Raw material handling, preparation, processing, packing and storage areas

The business has in place suitable measures for the control of foreign body and chemicals based on risk-assessment and include controls in relation to: knives / glass / plastic / wood / pens / paper clips & staples / chemicals and cardboard.

### 4.9.1 Chemical control

Non-food chemicals are risk assessed and managed. Chemicals are stored in a designated storage area with restricted access. The main chemicals used on site are Jangro supplied: heavy duty cleaner for floors and kitchen cleaner sanitiser. Cleaning Operator MS was interviewed and could demonstrate correct dilution and usage.

Strongly scented/taint-forming materials are not used.

### 4.9.2 Metal control

There is a documented metal control policy in place with a registration system for sharp utensils and equipment, which includes needle checks (used for sack stitching), ref: Knife register V3 dated 7/7/16, seen completed 9 to 12/7/18.

Daily start up checks are performed and recorded on the Daily start-up and changeover check sheet which is printed from the database specific to the products due to be produced.

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

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

Weekly glass and brittle plastic audits are carried out by the QAs. Completed audits were viewed for May to Jul 18.

An appropriate Glass and Hard Plastic breakage procedure is in place V6 dated 8/1/18 which includes isolation, cleaning and authorised clearance inspection procedures. No breakage incidents have been recorded for the last 12 months.

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

N/A

### 4.9.5 Wood

Wood is restricted to the use of only intact pallets in good condition, with checking systems in place. There is some office fabrication using wood.

**Minor NC2**: 4.9.5.1 There is wood flooring on the upper mezzanine level which is exposed as the ceiling in the baking line.

## 4.10 Foreign-body detection and removal equipment

### 4.10.1 Foreign-body detection and removal equipment

Following a documented assessment as part of the HACCP study, the following types of foreign object detection/removal equipment are used: Hand sieve (for spices) and metal detection.

The use of the sieves is a customer specific requirement. Integrity checking criteria for the sieve device is detailed.

Additionally, coarse stainless grids are available for use to break up lumps of vine and dried fruits, chopped dates etc. that might otherwise clump and cause quality/mixing issues with ingredient dispersion in finished products. The use of the grids is specified on recipe instructions.

### 4.10.2 Filters and sieves

Sieves are used; these general catering sieves as well as the large grids used in hoppers. They are checked/inspected for integrity on a per use basis.

The mesh size on the grids are 20mm and material retained by the grids is inspected and recorded to identify contamination risks.

### 4.10.3 Metal detectors and X-ray equipment

All products are metal detected post packing. The method of rejections are:

- 10kg bags and 25kg sacks, hand pack lines 1 and 2 and the milling lines, are belt stop/alarm systems. Test piece sizes are: Fe. 3.0mm, non Fe 3.0mm and SS 3.5mm.
- Portion and bagging lines are mechnical rejection into a locked box. Test piece sizes are: Fe. 2.0mm, non Fe 2.0mm and SS 2.5mm.

The Metal Detection Procedure V12 dated 7/3/18 ensures the effective removal and isolation of products identified as potentially containing metal.

Products are inspected to identify the source of the metal. The line is restarted by designated staff (Team Leader or QA Technician) using a key.

The effective removal of contaminated product has been validated. The equipment is tested at start up, at hourly intervals, after breakdowns and at the end of run. Tests performed include, where appropriate, memory tests, failsafe systems and rejection. A check was demonstrated effectively during the inspection by: Team Leader AL.

### 4.10.4 Magnets

N/A

## 4.10.5 Optical sorting equipment

N/A

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

Syrups are packed into PET squeezy bottles and tubs. The filling process is manual with the operator visually inspecting each container prior to filling.

## 4.11 Housekeeping and hygiene

The site has a clean-as-you go policy in place and a deep clean on Fridays, however the overall state of the open product areas was not seen to be clean and hygienic, ref. below minor NC.

Detailed cleaning procedures are in place for all areas and equipment. Cleaning is carried out at the end of shift, or in between different production runs, with air blowing by operatives.

Colour coded, and dedicated cleaning utensils are used, based on usage which is defined in the Factory colour coding document V7 dated 5/3/18 e.g. allergen cleaning equipment is orange, yellow for production and warehouse areas, blue for common areas, white for maintenance etc.

Cleaning records viewed included the following as part of the trace test:

- End of week machine cleaning CCP2 on V11 dated 26/5/17 completed 6/4/18 (previous Friday).
- Start-up and change over sheet for 11/4/18 with QA inspection.

Start-up hygiene checks are documented for all key processes and equipment. Environmental swabbing is carried out to detect gluten residues, although this is mainly controlled via time segregation, with Gluten Free and Free From products being produced on a Monday and Tuesday of each week.

Validation records are available to show that cleaning regimes are effective, with product testing and before and after swab testing carried out for each allergen handled on site as detailed in section 5.3.

Limits of acceptable and unacceptable cleaning are defined by visual inspection. Cleaning is verified by Line Leaders and QAs.

**Minor NC3**: 4.11.1 The overall state of the open product areas was not seen to be clean and hygienic (though there was no perceived risk of product contamination that would compromise the low risk nature of the product).

## 4.11.7 Cleaning in place (CIP)

N/A

## 4.12 Waste / waste disposal

All waste is cleared regularly from the processing areas and stored in suitable and identified containers. The waste collectors list V4 dated 4/6/18 specifies the contractors used and the collection dates:

- General waste: First Mile Ltd. CBDU80647
- Recycled and general waste: Edwards Waste Paper Ltd, CBDU108760
- Food waste: FR Cawley Ltd. CBDU143067

Unsafe products/trademarked waste would be stripped down and disposed of via waste contractors listed above.

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

Surplus customer branded products are held until required on a shelf. If not used within an appropriate time period, they are opened, the packaging is removed and they are disposed of through the normal waste channels.

No customer branded products would be sold/given to staff or charitable organisations. Out of date Alara products however are given to staff.

No materials are supplied specifically for animal feed.

## 4.14 Pest Control

The external contract dated 5/2/18 with Check Services (BPCA M15/102 exp. 28/2/19) consists of 12 routine visits and 4 inspections annually. Full records of pest control are maintained including site plan signed 1/3/18, bait data sheets, operative training records, records of inspections and treatments.

The last visit to site was a follow-up visit carried out on 28/6/18, with one proofing action identified which was closed on the same day. The previous visit on 26/6/18 was a routine inspection with one action still open and due 14/7/18 (to move two EFK's). There have been some call outs for rodent activity and beetle seen in 2018 however these have been appropriately addressed.

EFKs are situated throughout the site and catch tray analysis is performed quarterly, last service carried out 16/4/18. Trending shows no concerns.

In-depth pest control surveys are undertaken at a frequency based on risk and the last one was 5/2/18, some proofing and housekeeping actions identified. One action is outstanding, to proof a gap which is high level and therefore a longer-term action. However, the gap was baited when the issue was identified.

All toxic baits are secured. Recommendations are generally completed by the company in a timely manner.

No evidence of infestation was found or has been identified during visits. No significant issues highlighted through trending reports.

Employees have been trained to understand the signs of pest activity and to report any evidence of this to senior management.

## 4.15 Storage facilities

No temperature controlled storage is required. A small chest freezer is used for NPD samples only.

Products are long shelf life and are stored on site and off site at contracted storage facilities PW Gates BRC S&D exp. 28/11/18.

There are 2 warehouse areas, Unit 1 houses raw materials, some packaging and finished products, Unit 2 which also holds some raw materials and packaging and houses WIP and labels.

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

Some systems are in place to prevent cross-contamination during storage: Allergens/non-allergens are stored in segregated areas. Organic products are segregated by label (red) and dedicated locations.

There is no controlled atmosphere or outside storage.

Packaging is stored away from raw materials and finished goods. Part used packaging is inspected for suitability/cleanliness and covered or returned to store at the end of run. Obsolete packaging is marked as non-conforming product and is held in a segregated area awaiting disposal.

## 4.16 Dispatch and transport

The company have no own vehicles other than for loading.

Traceability is maintained during transportation through full product and pallet labelling and delivery documentation.

All products are sold as ambient stable. Vehicle checks are carried out prior to loading and documented on the sales collating document as viewed during the trace test.

The site conducts some on-line sales through large on-line retailers and some customers collect.

Approved third party hauliers are used for storage and distribution: PW Gates BRC S&D exp. 28/11/18.

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

| Clause reference | Justification |
|---|---|
| 4.2.3 | No external storage tanks or intake pipes |
| 4.3.5 | No high risk/care areas. |
| 4.36 | No high risk/care areas. |
| 4.3.7 | No high risk/care areas. |

| | |
|---|---|
| 4.4.4 | No high risk/care areas. |
| 4.4.8 | No glass windows which pose a risk to product. |
| 4.4.13 | No high risk/care areas. |
| 4.5.3 | Only potable water is used. |
| 4.7.5 | No high risk/care areas. |
| 4.8.4 | No high risk/care areas. |
| 4.8.5 | No high risk/care areas. |
| 4.8.10 | No catering facilities provided. |
| 4.9.1.2 | No strongly scented or taint forming materials are used. |
| 4.9.4 | No packing into glass or brittle containers. |
| 4.10.4 | Magnets are not used. |
| 4.10.5 | Optical sorting equipment is not used. |
| 4.11.7 | No CIP. |
| 4.13.3 | No products for animal feed. |
| 4.14.3 | Pest control is contracted externally. |
| 4.15.4 | No controlled atmosphere storage areas required. |
| 4.15.5 | No outside storage required for product. |
| 4.16.3 | No temperature controlled transport required. |

## 5. Product control

### 5.1 Product design/development

New product variations include products which are similar in composition and process/packing requirements, but trials are undertaken to validate formulation and processing where necessary. There are no stated restrictions to scope.

NPD is led by the Technical Manager (and HACCP team leader). Proposals are referred for HACCP evaluation and development of a process flow diagram.

An NPD procedure is in place V5 dated 1/2/18 with HACCP a key part of the development procedure, which identifies criteria for the processing and packing of cereal based products. There is an NPD action list V7 dated 20/11/17 which is used to capture the essential checks and this was viewed completed for Cool Green Instant Mix Organic GF 12x240g on 19/2/18.

Full development systems are in place based on a development checklist which needs to be followed prior to launch and includes a HACCP sign off.

Documented recipe development and production trials are undertaken.

Shelf life is determined and validated through EOL testing. Most of the shelf life testing is based on retained 5 pack sample undertaken on a sensory basis, for months 3, 6, 9 and 12, with the 5th sample sent for lab testing at end of life.

### 5.2 Product labelling

Labelling reviewed during the audit, included products being made at the time of the inspection were noted to meet legal requirements, e.g. FT muesli exotic fruit 750g; Irish muesli 750g; Trail mix 10kg; Raisin granola and golden syrup.

May contain alibi labelling is used on all products.

Finished product labelling information is verified against legal criteria and the requirements of 5.2.2 by the Founder Director and the Technical Manager.

Products with the following nutritional/suitability/compositional claims are produced:

- High protein – validated via recipe checks for protein levels to a prescribed analytical formula and verified as required through nutritional analysis.
- Vegetarian – validated by supplier controls and raw material checks.
- Vegan – validated via recipe checks and the responsibility of the customer for the relevant contract packed product.

Labels are printed daily from the Production Office, the labels are checked and placed on a segregated shelf for collection. Date and label checks are then carried out by the QA on line.

## 5.3 Management of allergens

The following allergens are handled on site: Gluten, nuts, peanuts, sesame, milk, SO2, soya.

An allergen policy, allergen matrix and allergen procedures are in place:

- Allergen handling procedure V8 dated 5/2/18
- Gluten free production procedure – roasting room V5 dated 1/4/18.
- Gluten free handling procedure V7 dated 20/4/18

A hazard analysis has been carried out as part of the HACCP study.

All raw materials, products and the process have been risk assessed. Supplier declarations are obtained for raw materials.

Separate areas are dedicated for allergen use with colour coded equipment.

All allergens are identified with allergen labelling and stored in a dedicated area of the warehouse.

Visitor questionnaires include questions relating to allergens.

Production is scheduled to enable allergen containing products to be produced from Wednesday to Friday. The gluten free production days are specifically Mondays and Tuesdays which follow a thorough wet clean of the mixing and packing lines. Overcoats are not dedicated to gluten free production, but clean overcoats are received every Friday from the laundry so that Mon and Tue runs are produced with clean coats which are then worn for the rest of the week or changed as required.

Rework is limited to the product code, in accordance with Rework Procedure V4 dated 19/6/18 and as detailed in section 3.9 Traceability.

For some products the risk of cross contamination cannot be avoided because several allergens are used within the same area and the following warnings are included on product labels: May contain wheat, gluten, milk, sulphites, sesame, nuts and peanuts.

The following ‘free from’ claims are made: ‘Free From gluten’, ‘Gluten Free’ and ‘Free From Wheat’. These are validated by environmental swabbing and finished product testing, results are documented.

Allergen validation reports (all through FAC) were viewed for all the allergens handled on site with the following reports sampled:

- Swabs: report dated 9/5/18 for 4 x sabs of the Boxing Line: mixer and platform areas before and after cleaning with after results at 2.5 and 0.75 mg/swab (the lab has advised that 1ppm relates to approximately 1.1mg/swab).
- Swabs: report dated 9/5/18 for Boxing line before and after cleaning for casein with after result of 2.5 mg/swab.
- Swabs: report dated 9/5/18 for Portion line before and after cleaning for peanuts with after result of 5.0 mg/swab.
- Raw material: Report dated 13/4/18 for Organic Buckwheat batch PTR170954-03 BB May 19, with <5ppm gluten detected by R5-sandwich ELISA (Mendez method).

Cleaning verification swabs are carried out for gluten following deep wet cleaning at the end of the week,

prior to gluten free production on Mondays. This is documented on CCP2 Gluten swab record, as seen completed for all 5 mixing and packing lines on 29/6 and 6/7/18.

WIP is limited to Granola, which is used as a base product.

## 5.4 Product authenticity, claims and chain of custody

The site obtains information on threats to the supply chain which could lead to adulteration/substitution of raw materials by subscription of Campden BRI (membership number 884892), the Soil Association, Coeliac Society and the Food and Drink Federation and official websites and industry alerts from the FSA and Food Fraud site. These are reviewed by horizon scanning by the Founder Director and the Technical Manager.

A documented vulnerability assessment has been carried out ref. TACCP Risk Assessment V4 dated 26/6/18. All risks have been assessed as low. Another risk assessment has been carried out specifically for gluten free / organic products and some moderate risks have been identified however appropriate controls are in place.

Risks identified include substitution, such as the purchase of non-organic organic raw materials, in the place of organic ingredients. Control measures implemented to manage the risk include supplier controls and all suppliers of organic raw materials are required to maintain current organic certification.

The following claims are made on finished packs which are dependent on a status of a raw material, or regarding the methods of production:

- Scottish Oat (customer responsible for labelling and provides raw material oats)
- Vegan (customer responsible for labelling)
- Fairtrade, validated as part of third party certification audit
- Organic, validated as part of third party certification audit

The site has certification by:

- Fairtrade – expiry 20/11/18.
- Organic – Soil Association, licence P1301, expiry 30/06/19.

There is a policy and work instructions and a process flow is in place.

A traceability test and mass balance is carried out, for Organic and Fairtrade products at six monthly intervals and the last recorded test was for Buckwheat raw organic gluten free, undertaken on 20/6/18. The Buckwheat received on 9/4/18 was batch PTR170954-03 and the supplier analytical report was viewed, confirming the Organic status of the product.

A trace and mass balance was carried out on Alara Gluten Free Organic Scottish Oats Granola, batch 157944 on 9/5/18.

## 5.5 Product packaging

A number of packaging formats are used, these include:

- Polyethylene clear film bags

- Kraft paper bags with internal laminate and tin tie closure
- 3 ply Kraft paper sacks
- Various films (PE, PP, biodegradable PP, co-ex)
- Pouches
- Plastic pot & lid and paper pot & lid
- Inner and outer cardboard boxes
- Plastic Jar with metal lid - On The Earth (OTE) products

Food contact information and suitability for the intended product has been provided by suppliers of all food contact packaging. A statement from the supplier P was viewed dated 29/6/16 regarding the absence of Bisphenol and the compliance with food contact regulations.

No product contact liners are used.

Traceability for all packaging used is recorded and maintained.

## 5.6 Product inspection and laboratory testing

### 5.6.1 Product inspection and testing

Microbiological product analysis is sub contracted to ALS, which is carried out as surveillance only with a schedule covering all product ranges annually or more frequently if customer required.

Gluten testing is subcontracted to FAC. Tests are carried out on raw materials.

Chemical tests are carried out on a 6-monthly basis, according to schedule V1 dated 27/1/18 :

- Multi pesticide residue Glyphosate & Chlormequat<10ppb – on raw matrial organic oats, sultanas.
- Aflatoxin (B1, B2, G1, G2) <2ppb to <10ppb as appropriate– on raw material peanuts, almonds, hazelnut and brazil nuts and other tree nuts
- Ochratoxin A <10ppb on raw material vine fruits and organic wheat
- S02, <600ppm to <2000ppb as appropriate on tropical fruits
- PV and FFA, <10miliequivalent/kg. FFA <1% seeds, <0.05% on nuts.

Finished product testing is carried monthly against an annual schedule, viewed for 2018 which includes shelf life sampling, (tested to the end of life). Tests include TVC $<10^5$, Moulds, <5000 and Yeasts <5000 and between 2 and 5 products are tested each month. In addition, microbiological tests are carried out as per retailer customer standards on a 6-monthly basis, these include: TVCs, Yeast, Mould, Coli-aerogenes bacteria, E. coli, S. aureus, B. cereus and Salmonella.

Other tests carried out include environmental swabbing, operative hand swabbing and visual and breakout testing of some raw materials at goods in; for appearance, smell, texture, content against specification and packaging as appropriate.

The following test reports were viewed:

- Report dated 13/4/18 from FAC for Organic Buckwheat batch PTR170954-03 BB May 19, with <5ppm gluten detected by Elisa.
- Finished product micro report dated 12/6/18 from ALS for Kitano Deluxe Muesli BB 29/5/19 with TVC of 30 cfu/g, staphylococcus, yeasts and moulds <20 cfu/g and salmonella ND.

Trend analysis and reviews of all test results are carried out by the Technical Manager and any out of specification results are risk assessed and the customer consulted if appropriate.

### 5.6.2 Laboratory testing

The external laboratories used are accredited as follows:

- ALS (UKAS 1282)
- FAC for gluten testing (UKAS 4400)

There is no on-site laboratory.

### 5.7 Product release

No finished products are positively released.

### Details of non-applicable clauses with justification

| Clause reference | Justification |
|---|---|
| 5.6.2.2 | No onsite lab. |
| 5.7.1 | No products are positively released from site |

## 6. Process control

### 6.1 Control of operations

Documented process specifications and work instructions are in place, these comprise the packing of the product, mixing and packing and are specifically the product recipes which are printed from the Alara database for each run and then form the batch records when completed. These were viewed for a number of products in production during the facility inspections.

Raw materials are picked onto the mezzanine floor and are then transferred to the mixer, or milled, then deposited via gravity by specific weight into the appropriate packing vessels, or hand packed. Bulk products are sold in 10kg bags or 25kg sacks, which are weighed, and metal detected in the same way as the smaller packs. Once the order has been fulfilled, any residual product is packed and stored (in the same packaging and same date/traceability code), for future picking.

The following process monitoring checks are carried out and recorded for every batch: picking sheets, recipes, metal detection sensitivity checks, weight checks and labelling. In addition, visual inspection of the roasting process is the key parameter for process control, over time and temperature.

The Pre-pack goods check sheet is used to document the QA inspection of product at the start of each

run, these checks include organoleptic assessment, seal check, labelling check etc. and further checks are then carried out every 2 hours.

Finished product checks are also carried out by QA and recorded on the Finished Goods Check Sheet.

Checks were observed as part of the line changeover from Raisin granola and golden syrup BB 10/7/19 to Pecan and maple crisp mix BB 12/7/19.

There is no in-line monitoring.

There are no temperature controlled storage areas, apart from a small freezer being used to store new ingredients for NPD. All products are dispatched as ambient stable.

Procedures are in place in the case of equipment failure or deviation of the process from specification, for example the Control of Non-conforming Product Procedure, ref: AWQM3.8, V9 dated 13/11/17.

## 6.2 Labelling and pack control

Packaging is allocated to packing lines by the Line Leader, based on the production schedule.

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

The Labelling and Pack Control procedure is in place, covering clause requirements, to ensure that products are packed into the correct packaging and correctly labelled and coded.

The Label Controller pre-prints labels using the Nice Label Pro software which was demonstrated as able to produce reports of all labels printed and quantities. An online label log was implemented in Mar 18, detailing the variable parameters printed on each label, i.e. lot / BB etc. Technical carry out a start-up and 2-hourly check of labels. Labels are applied to the back of batch records to retain the documented checks. Left over labels on completion of packing runs are destroyed.

Packaging checks, including coding and any other printing, are carried out at the start and end of packing runs, when changing batches of packaging materials and approximately every 2 hours throughout the run, (where applicable) for longer runs.

## 6.3 Quantity, weight, volume and number control

The following checks are in place to meet customer and legal requirements: weight checks. An operator on the boxing line in Unit 2 was seen to carry out check-weigher reject challenge checks and recorded the result as passed for all checks carried out in the morning, when the reject mechanism was not working, ref. below minor NC. The actual weights were not of concern as sample-based checks were carried out.

Retail products are packed to average weight, monitored either by in-line check-weighers or manual weight checking of 5 samples at 20-minute intervals (approx.).

10kg bulk packs are each check-weighed. The quantity contained in bulk tonne packs is controlled by minimum weight with checks undertaken at start, end and hourly intervals. Tonne packs are compiled of 25kg bags, which are packed to average weight.

Underweights are usually split open and fed back into the start of the packing process.

**Minor NC4**: 6.3.1 An operator recorded pass for several check-weigher challenges when the reject mechanism was not working. The actual weights were not of concern as sample-based checks were carried out.

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

The company maintains a calibration list V8 dated 5/6/18 which identifies the item, location, receipt of certificate, calibration date and next due date.

Scales are calibrated weekly internally against standard weights, which are calibrated annually by an accredited calibration service provider. This is recorded on the Scales and Checkweigher Record, V22 dated 18/6/18. The record was viewed completed on 11 and 12/7/18.

Calibration certificates observed included:

- Auto Scales calibration of 12 weighing scales with capacities varying between 6 and 200kg on 5/10/17. These are calibrated annually and serviced / inspected by Auto Scales every 4 months, with the most recent visit on 14/6/18.
- Calibration of test weights 2kg, 1kg, 500g, 200g by London Bourough of Havering UKAS 0294 on 29/6/18.
- 4 x Metal detector validation and 3 x check-weigher calibration reports from Sparc Systems dated 7/6/18.

There are no critical temperatures.

Individual procedures detail the corrective action procedures.

### Details of non-applicable clauses with justification

| Clause reference | Justification |
|---|---|
| 6.1.3 | There are no inline monitoring devices |
| 6.2.4 | No on-line vision equipment is used |

## 7. Personnel

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

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

Agency staff are not used.

Detailed individual training records are kept.

Specific training procedures and records are available and were challenged for the following CCP points:

- Training for QC staff: JK, RG and MJ for CCP's 1, 2 and 3 on 1/6/18 by the TM.

Other training records viewed included:

- Full training records for RD QA Controller covering several years and including training to procedures, hygiene, glass policy, moth prevention and pest awareness, CCP's, allergen handling, gluten free, organic handling and clocking in/out (site security).
- DE, Production Manager: L2 Food safety through CIEH on 14/10/08, L3 HACCP through Highspeed on 11/12/13.
- GM, Technical Manager: L2 HACCP on 24/10/17 and L3 Food Safety on 14/4/18, both through CIEH. Master of Science degree through University of Reading on 10/12/15.
- HACCP training for TF and AS delivered internally by the TM on 8/3/18 (with training materials viewed).

Staff interviewed during the audit were competent in their roles e.g. MS and AL, other than the error referenced in the minor NC in section 6.3.

A programme of refresher training on updated procedures is in place ant takes place on an annual basis.

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

Personal hygiene standards, which meet clause requirements, are documented and covered during induction training and basic food hygiene training (carried out in house). The site Personal Hygiene Procedure V6 dated 6/2/18 documents the site rules and policies and is displayed in the staff amenities area.

The Visitor and contractor questionnaire V10 dated 13/6/18 is in place, covering clause requirements.

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

Plasters are controlled by the Technical Manager via a register and are batch tested through the metal detector.

The use and storage of personal medicines is controlled by the Technical Manager and are not permitted into the factory as per the hygiene procedure.

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

## 7.3 Medical screening

Employees are made aware of the symptoms of infection, disease or conditions which would prevent them from working with open food via induction training.

The Medical Screening Procedure V7 dated 5/2/18 is in place to enable staff, including temporary staff, to notify the site of any relevant symptoms, infection, disease or condition which they may have been in

contact with or be suffering from.

A visitor health questionnaire is in place with a verification check by the company host.

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

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

Documented procedures are in place for the wearing of protective clothing. Company issued and externally laundered protective clothing is provided with daily changes.

The external laundry (Johnsons Apparel Master) operates procedures which meet clause requirements.

There are no high risk/care areas

Disposable nitrile and heavy-duty oven gloves are worn, which are both disposable.

Footwear is worn for safety only.

Hi-vis jackets which are not suitable for laundering are disposable.

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

| Clause reference | Justification |
|---|---|
| 7.4.4 | There are no high risk or high care areas |

## Module 8 - Traded Goods

| Scope | |
|---|---|
| 8.1 Approval and performance monitoring of manufacturers/packers of traded food products | |
| | |
| 8.2 Specifications | |
| | |
| 8.3 Product inspection and laboratory testing | |
| | |
| 8.4 Product legality | |
| | |
| 8.5 Traceability | |
| | |

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

| Scope | |
|---|---|
| 9.1 Management Commitment | |

## 9.2 HACCP

## 9.3 Outsourced Production

## 9.4 Specifications

## 9.5 Traceability

## 9.6 Chemical and Physical Product Contamination Control

## 9.7 Labelling

## 9.8 Training

## Module 11: Meat supply chain assurance

| Scope | |
|---|---|

**11.1 Traceability**

**11.2 Approval of meat supply chain**

**11.3 Raw material receipt and inspection**

**11.4 Management of cross-contamination between species**

**11.5 Product testing**

**11.6 Training**

## Module 12: AOECS Gluten-free Foods

| Scope | Gluten-free breakfast cereals including granola and muesli. |
|---|---|

**12.1 Senior management**

The site has a genuine, original copy of the current AOECS Standard and this module.
The company is aware of the need to share a copy of this BRC audit report, including this module, with the designated AOECS contact.

**12.2 Management of suppliers of raw materials and packaging**

The company has carried out a documented risk assessment of each raw material. TACCP Risk Assessment V4 dated 26/6/18 has been carried out specifically for gluten free / organic products and some moderate risks have been identified however appropriate controls are in place.

There are no high-risk suppliers or raw materials. Never-the-less, the site is supplied with a certificate of analysis that is specific to every consignment and every consignment of gluten-free raw materials is tested through the third-party laboratory either by the supplier or by the site.

**12.3 Outsourced production**

N/A

**12.4 Specifications**

Specifications for raw materials are in place. Raw materials do not contain gluten above 20 mg/kg, the site applies the max limit of 5 mg/kg.

**12.5 Management of gluten cross-contamination**

There is physical labelling on all materials at all stages of production.

The same lines are used for gluten free and standard products however they are time segregated. A full wet clean is carried out at the end of the week and gluten swabs are taken on all 5 production lines. Gluten-free production is then carried out across all lines on Mondays and Tuesdays.

Allergen cleaning validation has been carried out (including gluten). Reports (all through FAC) were viewed as detailed in BRC Food 7 section 5.3.

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

Procedures are in place and the decision to withdraw is understood. The requirement to notify the national coeliac society is included in the Product recall and withdrawal procedure V18 dated 11/5/18.

**12.7 Labelling**

The correct symbol is used and ‘gluten free’ stated on labelling. Coeliac UK certificate of licence detailing the approved product list and licence number CUK-G-033 for displaying the symbol in territories outside Europe and under various licence numbers for display in Europe.

**12.8 Product inspection and laboratory testing**

Every GF finished product batch is tested through FAC UKAS 4400, the following test report was viewed as part of the trace test: FAC report dated 6/7/18 for Customer M FF Pure Oats BB 2/7/19 with a result of <5ppm by Elisa Mendez method.

## Module 15 FSMA Preventive Controls Preparedness Module

| Item no. | Clause | Module item | Conforms (Y/N) | Comments |
|---|---|---|---|---|
| 1 | 117.20 | Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting. | | |
| 2 | 117.37 | The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage. | | |
| 3 | 117.40 | All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant.<br>Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact. | | |
| 4 | 117.80 | Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117. | | |
| 5 | 117.110 | Where defect action levels (DALs) are established for a food, quality control operations must reduce defects to the lowest level possible.<br>Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot. | | |
| 6 | 117.130 (a) | The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility:<br>• economic adulterants which affect food safety<br>• environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step<br>• radiological hazards<br>• unintentional adulterants that affect food safety. | | |
| 7 | 117.130 (b) | All identified, known, or reasonably foreseeable hazards must be evaluated to determine 'hazards that require a preventive control' (i.e., significant hazards). | | |

| | | | | |
|---|---|---|---|---|
| 8 | 117.135 | Establish one or more preventive control(s) for each identified 'hazard that require a preventive control' (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act. | | |
| 9 | 117.139 | Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following:<br>• notifying consignees of how to return or dispose of recalled product<br>• conducting effectiveness checks to verify recall is carried out<br>• appropriate disposal of recalled product (i.e., destroy, divert, repurpose). | | |
| 10 | 117.145 | Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10. | | |
| 11 | 117.150 | Establish corrective action procedures when preventive controls are not implemented in a manner consistent with the requirements of BRC sections 2.11 and 3.7.<br>Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring). | | |
| 12 | 117.160 | Validate all established process controls prior to implementation of the food safety plan, upon changes requiring revalidation or within 90 calendar days of the first food production.<br>Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility. | | |
| 13 | 117.165 (a) | The PCQI (or authorized designee) reviews the monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. | | |

| | | | | |
|---|---|---|---|---|
| | | The PCQI (or their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been created. | | |
| 14 | 117.165 (b) | Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following:<br>• sampling procedure to include method, quantity, frequency, and number of samples<br>• analytical method<br>• laboratory conducting an analysis<br>• corrective action procedure where a pathogen is detected. | | |
| 15 | 117.165 (c) | Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following:<br>• adequate number and location of sample sites<br>• timing and frequency of sampling<br>• analytical method<br>• laboratory conducting the analysis<br>• corrective action procedure where a pathogen is detected. | | |
| 16 | 117.165 | Devices used to **verify** preventive controls must be calibrated. | | |
| 17 | 117.180 | Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan.<br><br>Document the PCQI's training or qualifications via job experience. | | |
| 18 | 117.305 | All records required by 21 CFR § 117 must include:<br>• the date and time of the activity being documented<br>• signature/initials of individual performing the activity or conducting the record review<br>• information to identify the facility (e.g., name and location)<br>• the identity of the product and lot code where applicable. | | |
| 19 | 117.310 | The owner, operator or agent in charge of the facility must sign and date the | | |

| | | | | |
|---|---|---|---|---|
| | | written food safety plan initially and again upon any changes following reanalysis. | | |
| 20 | 117.315 | All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours, with the exception of the food safety plan, which must remain onsite. | | |
| 21 | 117.405 | Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities.<br>Where a hazard requiring a supply-chain-applied control is identified **and** the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control. | | |
| 22 | 117.420 | Supplier approval must be documented **before** receiving and using raw materials and ingredients.<br>Verification activities must be conducted **before** receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers. | | |
| 23 | 117.430 | One or more supplier verification activities (as defined in 21 CFR § 117.410(b)) must be conducted for each supplier **before** using raw materials and ingredients **and** periodically thereafter at an adequate frequency. | | |