Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary			
Company name	AAK UK Limited	BRC Site Code	7709885
Site name	AAK UK Limited		
Scope of audit	The refining and packing of crude bulk oils and the production and packing of flaked fats, bakery fats, vegetable and flavoured coloured blended fats and speciality oils into plastic lined cartons, drums, sack, plastic pails or IBCS. The bottling of speciality oils, soy sauce, vinegars and vinegar blends into glass and plastic bottles. Offsite storage at Earls Road and Staithes Road, Hull.		
Exclusions from scope	Trade goods.		
Justification for exclusion	Trade goods not audited as a voluntary module.		
Audit Finish Date	2018-04-04		
Re-audit due date	2019-05-19		

Voluntary modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	
Choose a module	Choose an item	

2. Audit Results					
Audit result	Certificated	Audit grade	A+	Audit type	Unannounced option 1
Previous audit grade	AA+	Previous audit date	2017-05-02		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	9

3.Company Details

Address	King George Dock Hull East Riding of Yorkshire, UK		
Country	United Kingdom	Site Telephone Number	+44 1482 701271
Commercial representative Name	Mrs. Janine Blackburn	Email	janine.blackburn@aak.com
Technical representative Name	Mrs. Janine Blackburn	Email	janine.blackburn@aak.com

4.Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Subcontracted processes	No
Other certificates held	Kosher, Halal, Organic, RSPO, ISO 9001, Campden Laboratory accreditation scheme
Regions exported to	Europe North America South America Asia Oceania Choose a region
Company registration number	NA
Major changes since last BRC audit	None.

Company Description

The site was constructed back in 1983, originally as Anglia Oils and was acquired by Aarhus United Group and then merged with Karlshamn Group to form AAK (UK) Ltd. The site is located at the King George Dock, Hull and has direct access for unloading of oils directly from barges and ships as well as by road. Activities undertaken on site include vegetable oil refining, food service and speciality oils filling area, bakery fats area, flaking plant, release agents plant, oil and vinegar blending area and bottling area for blended oils and vinegars. The site operates 24/7. Refining operates 2 x 12 hours shifts all week and 3 x 8 hours for all other dept. Products are sold to a variety of customers including retail, food service and manufacturing customers. The company leases two warehouses at Earls Road and Staithes Road.

Amount of employees: 320 (FTE), Plant size total: 19 ha. Total footprint of buildings in sq metres = 16900. Number of HACCP studies: 3.

5.Product Characteristics

Product categories	13 - Alcoholic drinks and fermented/brewed products 18 - Oils and fats				
Finished product safety rationale	Low aW of oils (<0.5) low pH on vinegar (<3.2). Products are ambient stable with a shelf life up to 2-5 years. Some fats are stored at 16 degrees centigrade for quality purposes.				
High care	No	High risk	No	Ambient high care	No
Justification for area	Decision tree; ambient products, step 3; Yes = Low Risk, beside EPA and NPA.				
Allergens handled on site	Cereals containing gluten Peanuts Nuts Soya Milk Sesame Sulphur dioxide and Sulphites Fish				
Product claims made e.g. IP, organic	Organic, RSPO palm oil				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Walnut oil in 250ml plastic bottles, Sunflower Oil in 190ml spray bottles, Dri FriGold (frying fat), bag in box, Rep ZT in buckets 20l.				

6.Audit Duration Details

On-site duration	18 man hours	Duration of production facility inspection	9 man hours

Reasons for deviation from typical or expected audit duration	Reduction for 2 years with GRADE A
Next audit type selected	Unannounced 1

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2018-04-04	08:30	18:00

	Auditor (s) number(s)	Names and roles of others
Auditor Number	053221	Mr. Peter M. de Bruin – Team Leader
Second Auditor Number	053237	Mr. Anirvan Sen – Team Member

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) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Mr. Paul Foreman - Plant Manager	X	X		X
Mr. David Mather - QM/SAP lead	X	X	X	X
Mr. Pete Scarborough - Supply Chain Manager	X	X		
Mrs. Esther Moulson - Technical Assistant	X	X	X	X
Mr. Geoff Craft - Production Manager – Speciality Oils & Bakery & Warehouse	X	X		X
Mr. Lars Havekost - Graduate Trainee	X	X		X
Mr. Chris Cowling - Refinery operations	X	X		X
Mr. Paul Drewery - Refining Maintenance Manager	X	X		
Mr. George Murphy - Production Manager food services	X	X	X	
Mr. Frank Barber – Training Coordinator		X		
Mr. Tony Bottomley – Purchasing Manager		X		X
Mrs. Ewelina Dickinson – Specification Technologist		X		
Mr. Dean Hardy – Botlling Line Leader		X		
Mr. Dean Hardy – Operator Filling Boxes		X		
Mr. Dennis Barlow – Operator Filling Tubs		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	3.3.2	In practice, records are retained for many years. According to QP3.3 records should be retained for 3 years; not sufficient for Vinegars. (BBD 5 years)	Updated 3.3 record completion and maintenance procedure to reflect BRC requirement on shelf life retained paperwork for vinegars.	Root cause: Not been picked up during new business launch Corrective Action: Section on the PMP process to evaluate QSM paperwork. Verification: Internal audits of procedures.	Provided proof: Evaluation revising QMS and updated procedure 3.3 V4.	2017-04-27	Mr. Peter M. de Bruin
2	3.5.1.1	Seen the supplier evaluation for Gustav Heess (Walnut Oil) from 23.01.2017. There is no annual evaluation carried out.	Requested Gustav Heess to complete SAQ manually.	Root cause: Delays on final approval on the SIM system. Corrective Action: ANBO to brief team to chase Spreadsheet reflected to check for 100% approval on SIM Regular review meetings by ANBO	Provided proof: Action list SIM, emails directed to Gustav Heess and extended supplier evaluation.	2017-04-27	Mr. Peter M. de Bruin

				team to assess status of transferring suppliers. Maintain manual system until suppliers 100% approved within SIM Verification Site & Customer audits.			
3	3.8.1	On Hold materials have stickers without sufficient details (f.e. marking on hold): emulsifier kept on hold, M&H boxes kept on hold in warehouses of speciality oils.	On hold labels amended to show information.	Root cause: Procedures not been followed. Corrective Action: Procedure amended for clarity and retrained back out Caps have been disposed of. Verification: GMP and internal audits to verify procedure been followed.	Provided proof: Updated procedure P22 V4 (26-04-2018), pictures of correctly marked on hold products and updated checklist (16-01-2018) with check on rejected/ hold pallets.	2017-04-27	Mr. Peter M. de Bruin
4	4.4.9	Roller shutter door into the drumming department and the bakery warehouse (Not working for 2 weeks) were	The fault on both doors have now been reported on Maintenance system Pirana.	Root cause: – Staff not sufficiently trained or aware of: Maintenance system	Provided proof: Screenshot of training for	2017-04-27	Mr. Peter M. de Bruin

		left open: directly open to external areas which may lead to pest infestation.		had not been briefed out to all staff. Corrective Action: Line Leaders briefed to put all maintenance on Pirana to create an auditable trail. All Line Leaders Pirana training completed. Review of all shutter doors suitability to be conducted. Verification Pest control & GMP / internal audits monitoring.	Line Leaders and purchase order of repairs of roller door/pictures		
5	4.7.3	IBC Filling station in food services. Pipeline leaking water in the corner of the IBC filling/weighing room, no record of the corrective maintenance in engineering department on Pirana system.	Leaking pipe repaired	Root cause: Maintenance system had not been briefed out to all staff. Corrective Action: Line Leaders briefed to put all maintenance on Pirana to create an auditable trail All Line Leaders	Provided proof: Screenshot of training Managers against Pirana – Raising and Browsing Work Orders and pictures	2017-04-27	Mr. Peter M. de Bruin

				Pirana training completed. Verification Pest control & GMP / internal audits monitoring.			
6	4.8.6	In the hygiene sluice “Food Services” the water for washing hands is too hot, to wash hands carefully; 49˚C.	Warning sign to run water and it will cool before washing.	Root cause: Mixer was set at to higher temperature for legionella management. Corrective Action: Redesign system so it controls outlet temperature and no risk from Legionella – 31/05/18 target completion. Verification: Reduction of free warning, once system redesigned confirmation of temperature.	Provided proof: Workorder 13209.	2017-04-27	Mr. Peter M. de Bruin
7	4.11.5	On the index line: Contamination risk observed from membrane seals inside		Root cause: The knife is programmed to make 1.75	Provided proof: Screenshot of	2017-04-27	Mr. Peter M. de Bruin

		the filling machine; product running on line (Prep ZT)	Ledge where film is gathering is cleaned and monitored hourly and cleaned if needed.	rotations. Corrective Action: Upgrade to software so that the blade only makes one rotation. Staff been briefed in the cell meeting. Verification Online visual checks,GMP / internal audits monitoring.	request and pictures of new situation.		
8	4.15.1	Stored finished products (Sunflower spray) kept in allergen racks next to allergens; Wax stored on the same pallet with unknown pectin powder left in damaged condition.	Re-brief individuals Relocate items	Root cause: Training not adequately completed. Corrective Action: Review of storage procedure. Retraining of all relevant individuals including re briefing of the importance of allergen segregation. Verification GMP / internal audits monitoring.	Provided proof: Allergen re-training document and pictures of storage	2017-04-27	Mr. Peter M. de Bruin

9	4.15.2	"Bakery" department; one not well covered used role with packaging foil, another one covered with a dusty liner.	All items suitably and sufficiently covered.	Root cause: Procedure not easy to follow – pallet covers "Blow off" Corrective Action: This was done on the day. Email sent out to the Line Leaders and Operators informing them to follow the Procedure P20 to ensure all packaging is wrapped and food safe. Verification GMP / internal audits monitoring.	Provided proof: Internal memo with instructions and pictures	2017-04-27	Mr. Peter M. de Bruin

Comments on non-conformities

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,**	**Date reviewed**	**Reviewed by**

					photograph, visit/other		

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

A documented, by the CEO Mr. M. Bense signed policy, (31.01.2018) was shown and is published in the management system and several departments and the canteen.
Objectives are part of the MR about certification, complaints, services (OTIF 90/95%), product conformance details, monitored monthly; f.e. January 2018.
The yearly scheduled MR was carried out and finalised on 27.11.2017 (October 2016-October 2017) and contains all required and relevant items.
QA and monitors items about food safety, legality and quality issues and is presenting results to Management the monthly reports; January/February 2018.
Meeting structures seen; f.e. with MT January/February 2018 and HACCP 26.01.2018.
There is an original English PDF copy of the Standard present.
The Plant Manager attends the opening and closing meeting of the audit.
Root causes of the 4 minor non-conformities of the last BRC audit have been identified. The NC's did not reoccur in the same way.

1.2 Organisational structure, responsibilities and management authority

The organisational structure has been documented for all levels; OP1.2, February 2018.
In the chart all levels are defined; CEO/Plant Manager/Department Leader/Operator.
The Technical Product Manager is direct responsible/involved for food safety, legality and quality items.
Clear responsibilities/competences have been documented including arrangements in case of absence of the responsible staff. Seen the well detailed (including competences) profile for the Line Leader.

Details of non-applicable clauses with justification

Clause reference	Justification
-	-

2 The Food Safety Plan – HACCP

A system, based on the principles of the Codex Alimentarius has been documented and implemented in practice. Input; complaints, legislation, hygiene codes and branch information.

There is a multi-disciplinary team installed available with right experience and knowledge, led by the well experienced Technical Manager, according to T11 v 13.03.2018, meetings ones a year f.e.: 26.01.2018.

Prerequisites (according to the "PRP- document", verified on 16.02.2018) are defined and monitored as part of the risk analysis.

For BRC there are 2 product categories applicable; 13 - Alcoholic drinks and fermented/brewed products 18 - Oils and fats. For the risk analysis, 3 product groups have been defined; Oils, Fats and Specialities. Relevant detailed specifications were shown and are present for all products; see sample in element 3.6. Intended use is partly B2B and in consumer units for retailers/private labels.

Flow diagrams are available and contain all relevant information (f.e. the flow Bottling 16.02.2018).
The several stages can be recognised; receive of goods, refining, bleaching, blending, filling and storage and distribution.
A verified lay out (R78C, updated 03.04.2017) was shown in the manual with attention for process flows, including segregation.

The Food safety system starts with a PRP. Further a hazard analyses for raw materials and per process step; for physical, chemical, microbiological and allergens were mentioned and judged, well-motivated in the study. All based on relevant information; f.e. legal aspects, seminars, newsletters, Alba- information.

The hazard identification method is demonstrable, seen the HiRa with change/effect, depending on the risk value a PRP/CCP evaluated with a Campden decision tree. Seen the HiRa raw materials for Walnut oil, Bleaching agent and Plastic bottles in P82B 18.01.2018 and for the process steps v. 16.02.2018.

CCP' s are applicable; a logical result from the HiRa and relevant for the type of processing.
CCP' s:

- Dosing carbon bleach 1 or 2 ppb (infant/ oils)
- Filtration 0,5µm till 3mm depending on the process
- Function of UV- sterilization (Bakery fats)
- Metal Detection tested with bars: 2,5- 4 mm Fe, 3- 4 mm nFe, 3-4 mm SLS.
- Operating pressure blower inverter (air rinsing glass bottles) 28- 40 PSI depending on the bottle size

Details according to the CCP- summary v. February 2018.

The CCP' s were demonstrated, including a well recording during the audit and in the records of the vertical traceability test, including corrective actions.

At least annually the HACCP-plan and PRP's are reviewed; 16.02.2018, with individual updates.
Results of the verification are communicated during HACCP team meetings. Sufficient records are kept.
Well detailed validation report seen for Apple Cider Vinegar (31.01.2018) and Sunflower Aldi in spray bottles 07.09.2017.

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

3. Food safety and quality management system

3.1 Food safety and quality manual

The management system (last version 21.02.2018) has been based on an indexed overall manual with; flow diagrams, procedures, instructions and forms.

3.2 Documentation control

Relevant work instructions are in general the right version available via the manual, all according to P03, seen f.e. AAK RF 10602 v.21.07.2015. Access in this system for QA and Operations.

3.3 Record completion and maintenance

In practice, records are retained for many years. According to QP3.3 records should be retained for 3 years; not sufficient for Vinegars. (BBD 5 years) **Minor NC 3.3.2.**

3.4 Internal audit

A schedule for internal audits is available for 2017/2018 (v.20.02.2018); frequency at least ones a year for all (primary) processes, spitted over several times a year according to P33.
Records of training could be shown for the internal auditor Mrs. Esther Moulson (Technical Assistant, qualification 02.04.2017)

Records were shown for carried out internal audits; f.e. 23.11.2017 (storage/ transport) and 16.02.2018 (refining). Reports contains conformity as well as non- conformities, used for follow- up. Follow up is discussed in the monthly meetings and monitored via the action list.

Risk based hygiene/fabrication rounds are performed monthly.
Seen records from f.e. 12.01/02.02-2018.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

Suppliers based on risk assessment are in general evaluated yearly according to P04 with certificates, questionnaires, audits, complaints, quality and delivery performance.

Part of the review is also inventory of origin in case of agents/brokers. System present; all origin (manufacturer till last packer) is known, or GFSI- certified, or graded as a low risk supplier.

Supplier evaluation has been evaluated as input for the management review.
Seen the evaluation for raw material suppliers Gustav Heess, Huillerie Du Lapallisse, Alpla and Bericap.

Seen the supplier evaluation for Gustav Heess (Walnut Oil) from 23.01.2017. There is no annual evaluation carried out. **Minor NC 3.5.1.1.**

3.5.2 Raw material and packaging acceptance and monitoring procedures

Further a documented intake for raw materials and packaging materials.
Raw material acceptance is based on visual inspection on receipt, where applicable certificates of analysis, test reports. Intake seen for sea ship oil, pipe/hoses are dedicated for different types of oils (intake 04.04.2018). COA for vinegar – organic apple cider vinegar batch number D01918 date of manufacture 1/3/2018 supplier Ecovinal.
Records form intake seen for packaging materials Alpla (15.11.2017), Bericap (15.12.2017) and walnut oil (25.09.2017) including Lab analyses and COA. COA for avocado oil reviewed during the audit as per purchase contract reference PC00070914 from DIPASA for lot number 0202118 dated 2nd February 2018

3.5.3 Management of suppliers of services

The approval from 2017 according to P05 was shown for all contracted services;

Monitoring was shown for contracted services;

- Pest control (Ecolab)
- Laundry (Johnsons)
- Cleaning (ISS)
- Maintenance (f.e. Loma metal detection)
- Transport (f.e. Abbey Tankers)
- Laboratory testing (f.e. SGS)
- Catering (Dine Contract)
- Waste management (Waste Wise)

No contracted off- site storage.

3.5.4 Management of outsourced processing and packing

No outsourced processing.

3.6 Specifications

Specifications of raw materials and packaging are based on items regarding to suitability for its purpose and (migration) tests/declarations. Specifications contain relevant aspects and requirements.
Specifications are reviewed at least every three years.
Reviewed specifications during the audit:

- Product;
  - Sunflower Oil Spray (Morrissons)
  - Walnut oil (Gustave Heess, Huillerie Du Lapallisse, Alpla and Bericap)
- Bottle type BOT9475 (Alpla)
- Caps type CAP9559 (Bericaps)
- Hose HD&F, Brewflex T5701 (Arco)

- Grease Foodcare 100 as per the H1 category – NSF registration No 125547 as per ISO 21469 cert

3.7 Corrective and preventive actions

Corrective actions based on the non-conformance are implemented so that re-occurrence is avoided. Records are kept. CA' s are discussed during HACCP/team meetings (verified minutes) and recorded in corrective actions list. Verified several actions in C.A-list according to P27.
Good samples seen in the action list regarding follow up; last version March 2018.

3.8 Control of non-conforming product

The company has procedures to investigate the cause of significant non-conformity against standards, specifications and procedures, which are critical to product safety, legality and quality.
Products that are out of specification are clearly identified, labelled and quarantined. QA is responsible for decision making on the use or disposal of products.
Procedure is documented and appropriately implemented, and personnel are aware of the procedure.

On Hold materials have stickers without sufficient details (f.e. marking on hold): emulsifier kept on hold, M&H boxes kept on hold in warehouses of speciality oils. **Minor NC 3.8.1.**

3.9 Traceability

Traceability system operates in BSpoke and paperwork enables trace of raw materials and packaging from supplier through processes to packing and despatch.

Shipments are coded in BSpoke and recorded per tank used for blends and input for the final batch code for packing.

Test for traceability at least yearly; 19.05.2017, including mass balance carried out in less than 1,5 hours, all according to R02.

A vertical test with all required documents, during the audit was tested; "Morrissons Walnut oil 250ml, batch H37787, processed and packed on 05.01.2018"; fast tracing (forwards/backwards, good result mass balance), including packaging was possible in the records.

3.10 Complaint handling

Customer complaints are handled by Sales and recorded in BSpoke.
Beside in monthly meetings, in the management review, there is recorded a trend analyses of complaints. In 2017 0,4% complaints on 1920 deliveries, in 2018 up till now about 0,9%. (increased due to better recording). No food safety complaints or complaints from authorities. Complaints are discussed with all involved employees during meetings. When necessary, corrective actions are taken. Assessed complaints number 63 and 101. Top in amount of complaints; Product related items, packaging related and a few foreign bodies.

3.11 Management of incidents, product withdrawal and product recall

Ref. document: P16 v.28.09.2017.
A system is in place to manage incidents effectively. The system includes product withdrawal and recall procedures, tested at ones a year (f.e. 19.05.2017). A well detailed report was shown, including mass balance, testing the recall procedure etc. Also, authorities and DNVGL (according to T16A) will be informed.
All requirements are included in the procedure (incl. a clear assignment of responsibilities). Scenarios are discussed in the manual regarding incidents. Business continuity is described in AASA1035 v.08.02.2017.

3.12 Customer focus and communication	
Sales has direct contacts with customers. Communicated requirements were direct implemented. Customer requirements and customer satisfaction seen for the project Aldi Sun Flower Spray, the gates/ stages 1-5, artwork, BBD- testing seen in the projects from 31.05.2017.	
Details of non-applicable clauses with justification	
Clause reference	**Justification**
3.5.4	No outsourced processing.

4. Site standards

4.1 External standards

The site has a common border with railway track and a public street. It is located in a mixed area of industry and docks.

The plant has suitable size, location and construction, the area maintained to reduce the risk of contamination. Site boundaries are clearly defined. External areas are in good order, including planted areas. External traffic routes are paved and maintained well.

4.2 Security

A TACCP has been carried out in P44 v.04.04.2017.
A fenced plant with camera supervision. Employees has been trained to speak to unknown people. Visitors has been subscribed at the reception. Seen locked hoses for intake oil per ship.

4.3 Layout, product flow and segregation

Only ambient stored products. Decision tree ambient; via step 3, 'yes, a Low-risk area, beside EPA/NPA. A verified lay out (P81, updated v.20.02.2018) was shown in the manual with attention for process flows, including segregation.

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

Buildings acceptable maintained and suitable for the purpose. In general, well equipped filling departments. No suspended ceilings are accessible. Where windows can be opened they are screened. Glass windows are appropriately protected. In general, external doors are always kept closed and in general close fitting.

Roller shutter door into the drumming department and the bakery warehouse (Not working for 2 weeks) were left open: directly open to external areas which may lead to pest infestation. **Minor NC 4.4.9.**

Adequate lighting is provided. Bulbs and strip lights are adequately protected.

4.5 Utilities – water, ice, air and other gases

Water is used on site is drinking water, not an ingredient, only used for cleaning purposes.
Food grade declarations seen for the Nitrogen from AirProduct. Compressed air only used for valves in the machines and in suitable quality for the air rinser. Air filter change completed on 9/6/2017 for food services.

4.6 Equipment

Maintenance seen in the system Pirana, partly use of SLS, no remarks on condition of equipments. Seen the food contact declaration for Hose HD&F, Brewflex T5701 (Arco)

4.7 Maintenance

The Pirana system is used for planned maintenance and corrective/breakdown maintenance – the planned maintenance work order is generated whenever a maintenance is due – the scheduler has populated the daily, weekly, monthly, quarterly and yearly maintenance schedules and work orders are generated accordingly. Till date no overdue works were noticed.
The corrective maintenance were also noted – verified the same for work order 11536 dated 21/01/2018 – signed by the engineer and cross signed by the production (Customer) and verified for cleanliness in the pre startup check sheets.
There is a separated engineering workshop.
Engineering department using food grade chemicals and are stored separately – verified the same for 'Foodcare 100' as per the H1 category – NSF registration No 125547 as per ISO 21469 cert.

IBC Filling station in food services. Pipeline leaking water in the corner of the IBC filling/weighing room, no record of the corrective maintenance in engineering department on Pirana system. **Minor NC 4.7.3.**

4.8 Staff facilities

Staff facilities are sufficient to accommodate the number of personnel and positioned entry to the production areas. Suitable sized lockers are provided to keep the personal items. Outdoor clothing and work wear is stored separately. In general, hand-wash facilities comply with the requirements.

In the hygiene sluice "Food Services" the water for washing hands is too hot, to wash hands carefully; 49˚C. **Minor NC 4.8.6.**

Toilets are also in line with the requirements. Smoking is not allowed in the factory. Eating is only allowed in the canteen. A refrigerator, which is included in the cleaning schedule, is provided for staff use. Outsourced catering is done well.

4.9 Chemical and physical product contamination control Raw material handling, preparation, processing, packing and storage areas
In general, well handling seen in practise without direct contamination, including the way of storage although three minor NC's are raised in 4.11.5/ 4.15.1/2.
4.9.1 Chemical control
A chemical control procedure is in place which manages the use, storage and handling of non-food chemicals. Stored in a secured basement. MSDS are present for all cleaning agents and all products are suitable for use in a food processing environment. Use of the products is by trained personnel only.
4.9.2 Metal control
Snap-off blade knives are not allowed in the company. Staples and paper clips are not used in open product areas. Metal detection or filtering has been applied and handled as CCP.
4.9.3 Glass, brittle plastic, ceramics and similar materials
All glass and brittle materials present are protected against breakage. A procedure for handling glass and other brittle materials is in place and implemented (P13). A detailed glass/hard plastic register is present. Checks f.e. 12.01/02.02-2018.
4.9.4 Products packed into glass or other brittle containers
Cleanliness – glass jars foreign body removal through rinsing with air, handled as a CCP for the blower invertor operating pressure 28-40 PSI depending on the bottle size. Records seen from week 1-2018. Air filter change completed on 9/6/2017 for food services. CCP records (Blower invertor 28-40 PSI operating pressure) checks verified – Document reference number AAK-SO-713 Issue 31 dated 4/5/2016 for batch H38044 product code RET-7030- dated 4/4/2018 – the same.
4.9.5 Wood
Were pallets could not be avoided, wooden pallets are regularly monitored during site inspections.

4.10 Foreign-body detection and removal equipment

4.10.1 Foreign-body detection and removal equipment

A hazard analysis is conducted. Result is the need for additional metal detection, where only filtering is not sufficient.
Some CCP's related to avoiding foreign bodies:

- Filtration 0,5µm till 3mm depending on the process
- Metal Detection tested with bars: 2,5- 4 mm Fe, 3- 4 mm nFe, 3-4 mm SLS.
- Operating pressure blower inverter (air rinsing glass bottles) 28- 40 PSI depending on the bottle size

Details according to the CCP- summary v February 2018.
The CCP' s were demonstrated, including a well recording during the audit and in the records of the vertical traceability test, including corrective actions.
Seen:

- CCP (Use of 5 micron filter in place and intact) record verified for online – Drumming department – Document reference number AAK-SO-695 version 6 dated 24/03/2017 record checked for the date 3/4/2018 for drum code TDIV252
- Loma Lock metal test pieces calibration certificate verified as per the following – ferrous 2 mm – cert number 497025; non ferrous 2.5 mm – cert number 117569A and stainless steel 5 mm cert number – 100388/1137
- CCP checks for food services verified during the factory tour for metal detection (2.5 mm Fe, 3 mm Non fe and 3 mm stainless Steel) and Filtration (50 micron and 500 micron filters) in place and intact for the batch B5255E at 12:00 as per document reference number AAK FS-660 issue 29 dated 9/3/2018
- CCP records (Blower invertor 28-40 PSI operating pressure) checks verified – Document reference number AAK-SO-713 Issue 31 dated 4/5/2016 for batch H38044 product code RET-7030- dated 4/4/2018 – the same

4.10.2 Filters and sieves

Filters handled as CCP Filtration 0,5µm till 3mm depending on the process

Seen f.e. CCP (Use of 5 micron filter in place and intact) record verified for online – Drumming department – Document reference number AAK-SO-695 version 6 dated 24/03/2017 record checked for the date 3/4/2018 for drum code TDIV252

4.10.3 Metal detectors and X-ray equipment

Metal Detection as a CCP tested with bars: 2,5- 4 mm Fe, 3- 4 mm nFe, 3-4 mm SLS.
Seen f.e.

- Loma Lock metal test pieces calibration certificate verified as per the following – ferrous 2 mm – cert number 497025; non ferrous 2.5 mm – cert number 117569A and stainless steel 5 mm cert number – 100388/1137
- CCP checks for food services verified during the factory tour for metal detection (2.5 mm Fe, 3 mm Non fe and 3 mm stainless Steel) and Filtration (50 micron and 500 micron filters) in place and intact for the batch B5255E at 12:00 as per document reference number AAK FS-660 issue 29 dated 9/3/2018

4.10.4 Magnets

No magnets used for foreign body are applied.

4.10.5 Optical sorting equipment

No optical sorting equipment.

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

Cleanliness – glass jars foreign body removal through rinsing with air, handled as a CCP for the blower invertor operating pressure 28-40 PSI depending on the bottle size. Records seen from week 1-2018. Air filter change completed on 9/6/2017 for food services. CCP records (Blower invertor 28-40 PSI operating pressure) checks verified – Document reference number AAK-SO-713 Issue 31 dated 4/5/2016 for batch H38044 product code RET-7030- dated 4/4/2018 – the same.

4.11 Housekeeping and hygiene

Documented cleaning procedures are in place and maintained for the building, plant and all equipment. Cleaning procedures for processing equipment is in place with responsibility for cleaning, area, frequency of cleaning, method of cleaning, including dismantling equipment for cleaning purposes where required, cleaning chemicals and concentrations, cleaning materials to be used and cleaning records and responsibility for verification.

An external service provider (ISS) for cleaning and disinfection activities is in locker rooms, hygiene sluice, floor TK hall and social areas in using.

Own employees perform the cleaning at the production line. Records of cleaning are available; checks after cleaning are in place. Verification of cleaning is performed by QC.

E.g. Inspection after cleaning in IBC filling area during audit.

On the index line: Contamination risk observed from membrane seals inside the filling machine; product running on line (Prep ZT) **Minor NC 4.11.5.**

Checks on residues and monitoring of environment seen from week 1-2018.

No CIP installation.

4.11.7 Cleaning in place (CIP)

No CIP installation.

4.12 Waste / waste disposal

Procedure Product disposal dated 2014.06.24
Waste disposal is managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.
Waste handled by Wastewise, Reg. no CB/NM3280XQ and records of removal are maintained. Waste bins are clearly identified.

4.13 Management of surplus food and products for animal feed

There is no surplus food and also no products for animal feed produced.

4.14 Pest Control

Pest control is sub contracted to Ecolab: 12 times per year and 4 times per year for EIV's. Actual layout seen from 05.02.2018. Qualification for Mr. P. Jackson. Based on risk yearly in- depth inspection with trend analyses, four times per year, seen with good results from 08.02.2018 (no trends recognized).

4.15 Storage facilities

Seen the two external rented warehouses employed by own people. Ferndale Warehouse – shift temperature record sheet verified fir 5/1/2018 as per document AAK- WA-1582 version 1 dated 31/10/2016 – temperature record showed ranges from 13.9 to 15.7 degrees centigrade throughout the day – target temperature is 16 degrees centigrade. Bespoke system is used for warehouse management system to ensure FIFO is managed.

Stored finished products (Sunflower spray) kept in allergen racks next to allergens; Wax stored on the same pallet with unknown pectin powder left in damaged condition. **Minor NC 4.15.1.**

"Bakery" department; one not well covered used role with packaging foil, another one covered with a dusty liner. **Minor NC 4.15.2.**

4.16 Dispatch and transport

All transport has been outsourced and contracted to f.e. Abbey Tankers (Scopa certified).
Full contracts are in place.
Despatch records verified – container number FLCU2860688 having seal number FLC07343 for ref number SCC0549056.
Haulier performance record verified for cleanliness checks for the date 4/4/2018
Bespoke system is used for warehouse management system to ensure FIFO is managed.

Details of non-applicable clauses with justification	
Clause reference	**Justification**
4.3.1	There are no high-risk, high-care or ambient high-care areas
4.3.5 /4.7.5 /4.8.4 /4.11.2 /4.4.13	There are no high-risk areas
4.3.6 /4.7.5 /4.8.4 /4.11.2	There are no high-care areas
4.3.7	There are no ambient high-care areas
4.10.4	There are no magnets in use.
4.10.5	There are no optical sorting machines in use.
4.11.7	No CIP in use.

5. Product control

5.1 Product design/development

Ref. document: P17 and related checklist.
Well detailed validation report seen for Apple Cider Vinegar (31.01.2018) and Sunflower Aldi in spray bottles 07.09.2017.

Shelf life test results verified for physical and chemical properties for batch number B2868E – manufactured on 13/02/2017. Also seen BBD- testing for the new Aldi Sunflower Spray via NHL (ISO17025 number 1463) on 21.06.2017.

5.2 Product labelling

Packaging and labelling of the products is as per the legislative requirement and as per the customer guidelines.
Label details according to the requirement of the EG 1169:2011. Checked labels Aldi Spray Light Sunflower Oil and the sample of the vertical traceability test: Morrisons Walnut oil 250ml.

5.3 Management of allergens

The site has a system for the management of allergenic materials which minimises the risk of allergen contamination of products and meets legal requirements for labelling in the country of sale.
In the plant are following allergens in using: gluten, peanuts, nuts, soya, milk, sulphur dioxide and sulphites, fish, and sesame.

There are following procedures in place: P26 Allergen control, P35 allergen spillage, P36 Allergen material receipt and storage, P37Weighing and P39 Allergen tool hygiene.

Allergen handling is performed about separation of raw materials, production plan, cleaning after allergen use and cleaning validation.
There are no allergen free claims. May contain labelling is based on VITAL (Voluntary Incidental Trace Allergen Labelling).

AAK has done a lot of work to validate cleaning methods. This shows that a flushing with 60 kilos of oil gives a reduction between 98 and 99%. Check used C8 and C10 as markers.

External testing is performed by SGS. Seen results from April 2017 on wheat, milk and soy. All results ok. Elisa and PCR method. Allergen handling is also a training subject seen for the employee Mr. D.H. (31.05.2017) and Mr. D.B. (02.01.2018).

5.4 Product authenticity, claims and chain of custody

As part of the HiRa, a vulnerability assessment is carried out for raw materials; VACCP v.18.02.2018. Evaluated oils and bleaching earth. Result is no high-risk combinations as result of the VACCP.
Per raw material measures seen like; COA, laboratory testing: organoleptic, chemical with f.e. gas chromatography, tested at intake and where necessary external analysis. Further attention for the relation with the supplier approval.
No special claims made.

5.5 Product packaging

Suitable packaging seen and evaluated in the sample of the vertical traceability test including tests for migration. Bottle/ Cap specifications reveals food safe declaration; see element 3.6.1 (EU-directives, 10/2011).

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Product inspection according to a year schedule, used as input for communication structures and verification/MR. No specials trends could be recognized.

Shelf life test results verified for physical and chemical properties for batch number B2868E – manufactured on 13/02/2017 – tests date 9/3/2018 – checks done for appearance, taste, FFA, PV, Colour, Iodine value. Micro test results verified from the external lab results (Northern Hygiene UKAS accredited lab) for batch 2570E manufacturing date 3/1/2017 tested on 8/2/2018 for TPC, coliforms, E.coli, Yeasts, S.aureus, Lacic acid bacterias, clostridium perfringes, B.cereus, salmonella, Listeria, Thermoduric bacterias, fecal streptococcus and moulds
COA for avocado oil reviewed during the audit as per purchase contract reference PC00070914 from DIPASA for lot number 0202118 dated 2nd February 2018.

5.6.2 Laboratory testing

Separated laboratory facilities on-site. Physical, Organoleptic and Chemical testing methods certification according to the Campden Laboratory accreditation scheme.
Subcontracted micro analyses via f.e. NHL, accredited for ISO17025 under number 1463.

5.7 Product release

Product release after checks QC. Records seen from week 1-2018.

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

6. Process control

6.1 Control of operations

The company shows sufficient control over its process operations. This is demonstrated from personnel, equipment installed, machinery and clearly documented procedures. Effective monitoring of all process parameters is demonstrated by record keeping and constant product quality.
The CCP- monitoring was shown during the audit and in records from the vertical traceability test.

Seen f.e.:

CCP (Use of 5 micron filter in place and intact) record verified for online – Drumming department – Document reference number AAK-SO-695 version 6 dated 24/03/2017 record checked for the date 3/4/2018 for drum code TDIV252

Finished product pass certificate verified as Per document reference number AAK-SO-713 issue 12 dated 12/07/2015 for batch number F83814 dated 27/3/2018

CCP records (Blower invertor 28-40 PSI operating pressure) checks verified – Document reference number AAK-SO-713 Issue 31 dated 4/5/2016 for batch H38044 product code RET-7030- dated 4/4/2018 – the same

Loma Lock metal test pieces calibration certificate verified as per the following – ferrous 2 mm – cert number 497025; non ferrous 2.5 mm – cert number 117569A and stainless steel 5 mm cert number – 100388/1137

CCP checks for food services verified during the factory tour for metal detection (2.5 mm Fe, 3 mm Non fe and 3 mm stainless Steel) and Filtration (50 micron and 500 micron filters) in place and intact for the batch B5255E at 12:00 as per document reference number AAK FS-660 issue 29 dated 9/3/2018

Weighing scales for calibration for the laboratory verified as per certificate number M8923 dated 7th April 2017 done by Humber Authorities.

Finished product spec for sunflower oil spray (438020 batch number) verified – for Morrisons – checks for weight, FFA %, PV meg/kg, Refractive Index, colour, Iodine Value, Taste, viscosity, appearance and pH.

Despatch records verified – container number FLCU2860688 having seal number FLC07343 for ref number SCC0549056.

COA for vinegar – organic apple cider vinegar batch number D01918 date of manufacture 1/3/2018 supplier Ecovinal

6.2 Labelling and pack control
Right checks seen on labels, packaging materials (and cleanness) at the start of a production/packing and every product change, recorded on the production form. Seen during the audit labels checks for Spray light sunflower 190ml, L8094 and Walnut oil Morrissons as well as label checks for Prep ZF in 20L buckets. Checks were also recorded in the sample of the vertical traceability test.
6.3 Quantity, weight, volume and number control
Seen during the audit weight checks for Spray light sunflower 190ml, L8094 and Walnut oil Morrissons as well as label checks for Prep ZF in 20L buckets. Checks were also recorded in the sample of the vertical traceability test: the checks for e-sign according to legislation.
6.4 Calibration and control of measuring and monitoring devices
Seen examples from calibration according to P77; • Weighing scales for calibration for the laboratory verified as per certificate number M8923 dated 7th April 2017 done by Humber Authorities. • NMR calibration (MQ20) verified for the date 31/3/2018 by the use of standard solution inhouse – as per document ref number DR.5.2.1 version 3 dated 7/11/2016 • Loma Lock metal test pieces calibration certificate verified as per the following – ferrous 2 mm – cert number 497025; non ferrous 2.5 mm – cert number 117569A and stainless steel 5 mm cert number – 100388/1137

Details of non-applicable clauses with justification

Clause reference	Justification
-	-

7. Personnel

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

Ref. document: P32.
Training has been well recorded including evaluation of performance and competences. Seen for Mrs. K.Z. (evaluation 20.02.2018, CCP training 23.03.2017). Mr. D.H. (evaluation 19.02.2018, allergen and hand washing training according to SOP7.2 on 31.05.2017). Mr. D.B. (evaluation 19.02.2018, CCP training 11.04.2017 and allergen training according to P26 on 02.01.2018). Mr. I.A. (training bottling weight checks 20.02.2018).

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

Hand washing according to SOP7.2 and personal hygiene P09. All required elements are included in P09, no HR/HC.

7.3 Medical screening

Documented procedure with evidence of records seen for Mrs. K.Z., Mr D.H./D.B./I.A. This is included in the hygiene rules P09. Also visitors and contractors have to sign for the requirements in the hygiene rules at reception.

7.4 Protective clothing: employees or visitors to production areas

Facility provides sets of protective cloths (Different clothing for different zones) to all employees as well as protective shoes. Clothes are washed by Johnsons Apparelmaster which is ISO 9001 and 14001 certified. Certificates valid 2019.05.07. Protective hairnets are used and when applicable, men wear snoods.
Also, employees from leasing companies get company protective cloths, as well as visitors. Protective shoes provided by company as well. Procedure P14, v 3 Factory visitors. P14a Visitors questionnaire.
Working clothes must be removed before entering canteen or toilets.

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.1./7.4.4/7.4.5	No HR/HC area.

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	
12.1 Senior management	
12.2 Management of suppliers of raw materials and packaging	

12.3 Outsourced production

12.4 Specifications

12.5 Management of gluten cross-contamination

12.6 Management of incidents, product withdrawal and product recall

12.7 Labelling

12.8 Product inspection and laboratory testing

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. 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.		

		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: • economic adulterants which affect food safety • 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 • radiological hazards • 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: • notifying consignees of how to return or dispose of recalled product • conducting effectiveness checks to verify recall is carried out		

		• 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. 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. 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: • sampling procedure to include method, quantity, frequency, and number of samples • analytical method • laboratory conducting an analysis • 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: • adequate number and location of sample sites • timing and frequency of sampling • analytical method • laboratory conducting the analysis • 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. Document the PCQI's training or qualifications via job experience.		
18	117.305	All records required by 21 CFR § 117 must include: • the date and time of the activity being documented • signature/initials of individual performing the activity or conducting the record review • information to identify the		

		facility (e.g., name and location) • 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. 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. 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.		