Supplier Audit Report

AUDIT SUMMARY			
Company Name	Alara Wholefoods Ltd		
Address	110-112 Camley Street London N1C 4PF		
3rd party accreditations	BRC GSFS rev7, grade B expires 02Sep18 Soil Association Organic expires 30Jun18. ISO14001 2015 – issued 30Jan17	**Product Categories**	Third party manufacturing of Cereal products.
High Risk / High Care	Low risk only	**Number of products Supplied**	40 (1approx.)
Duration of trading relationship	New ☐ <3 years ☐ ✓ 30 years estimated >3 years		
Auditor(s)	P. Hardy		
Audit Scope	Review of corrective actions arising from previous audit.		

Reason for Audit: ~~routine~~☐ Follow up ✓ ~~following incident~~ ☐ ~~other~~ ☐	Previous Audit Date 19Aug17

Audit Outcome			
Supplier Grade	**B**	**Status from Audit**	**Approved***

Number of Non Conformances							
Critical		**Major**	**1***	**Minor**	**4**	**Observations**	
Please provide evidence of corrective actions having been addressed on or before:						**See below.**	

The supplier was notified following the audit conducted on 19Oct17 that production of Holland and Barrett products must cease in unit 1 until urgent matters relating to employee health & safety and product safety have were addressed.

Unit 2 lines have been permitted to be used since that time.

*** Following this re-audit the supplier has been allowed to recommence operations in unit 1, with the proviso's detailed below. The major non-conformances identified on**

Supplier Audit Report

19Oct17 have been addressed, but further supporting documentary evidence is required for NC8.

Company profile

Alara has been a supplier to H&B for approximately 30 years.

A supplier compliance audit was conducted on 19Oct17, whereupon 15 non-conformances were identified, two of which were considered major, and sufficient to impose restrictions on the operation. With immediate effect Alara were instructed to cease packing operations in their unit 1, transferring to unit 2, until the major non-conformances had been addressed.

Since that audit a full reconstruction of the unit 1 packing line has been undertaken. A new superstructure framework has been manufactured and installed. The gantry on which the loading of the mixing vessels takes places has been fully rebuilt using flat stainless steel to aid cleaning, and the general area immediately adjacent to the platform improved by rendering the walls, painting, placing electrical cables into conduit and removing wooden items. The loading platform has been reconstructed to be 20cm higher than previously.

Alara are members of Sedex. Since the previous audit and subsequent improvements being made, they have commissioned a SMETA audit by SEDEX. SMETA is an audit procedure which is a compilation of good practice in ethical audit technique. SMETA methodology uses the ETI code and local law as the measurement tool. It includes four modules: Health and safety; Labour standards; Environment (optional; Business ethics (optional).

The Technical manager Omowunmi Olunloyo ‘Toks’ handed in her resignation immediately in the New Year, feeling she was unable to satisfactorily fulfil the role. Alex Smith informed me that Georgios Margaritis had been appointed Technical Manager. Georgios joined Alara around the time of the initial audit, and has a Master’s degree in Food Science, attained at reading University.

This re-audit focussed purely on a review corrective actions implemented arising out of the non-conformances from the October audit. **The items highlighted in BOLD require further evidence.**

Holland and Barrett use only

Auditor Pete Hardy _____ Date 10Jan18

Audit closed out by _____ Date _____

Supplier Audit Report

NON CONFORMANCE CRITERIA	
Critical	Where there is a critical failure to comply with a food safety or legal issue.
Major	A **significant** deviation from QMS and HACCP systems, which on the basis of available objective evidence raises significant doubt as to the conformity of the product being supplied.
Minor	A **significant** deviation from QMS and HACCP systems, which on the basis of objective evidence, does not impact the conformity of the product.
Observation	Identification of an opportunity for an **improvement**.

GRADING CRITERIA					
Grade	**Critical**	**Major**	**Minor**	**Corrective action**	**Status**
A			**1 to 10**	**Objective evidence within timescale set**	**Quality Assured**
B			**11 to 20**		**Approved**
B		**1**	**1 to 10**		**Approved**
C			**21 to 30**	**Urgent Action. Re-visit within 12 months**	**Acceptable**
C		**2**	**1 to 20**		**Acceptable**
U	**1 or more**			**Re-audit required**	**Unapproved.**
U			**31 or more**		**Unapproved.**
U		**2**	**21 or more**		**Unapproved.**
U		**3 or more**			**Unapproved.**

Supplier Audit Report

Present at Audit					
Name	**Job Title**	**Opening Meeting**	**Site Inspection**	**Document Review**	**Closing Meeting**
Peter Hardy	**Quality Manager**	✓	✓	✓	✓
Alex Smith	**Owner \ Director**	✓	✓		✓
Georgios Margaritis	**Technical Manager**	✓	✓	✓	✓

NON- CONFORMANCE SUMMARY

Non Conformance – Critical		
None.		
Non Conformance – Major		
No.	**Details of Non-conformity**	**Status**
8	The cracked light fitting above the mixing vessel must be replaced. Replaced as part of the refurbishment. Visual inspection during re-audit. The risk assessment for items in open product areas should be reviewed and the frequency of checks should be sufficient to manage risks. The Glass and Hard Plastics register in place is issue 3, still dated 14Oct17. Suggesting no review has been conducted. The list was compared against items in the area, and they do match. PH suggested to GM that the document be formally recorded as reviewed or up-issued with a new revision to reflect that review. The policy of when such items are replaced should be reviewed. Conduct a similar review of the Glass and Plastics SOP \ policies.	**Please provide clear evidence that the G&P register, SOP and policies have been reviewed.**
12	The platform from which the mixing vessel is operated is unsafe, as there is an exposed drop to one side. This must be resolved before any further Holland and Barrett product can be produced on the line in unit 1. A full refurbishment has been conducted. The platform is now 50cm from the floor; 20cm higher than previous. PH expressed concern that there was still no barrier in place. AS informed PH that a SMETA audit had been conducted, and that the mixing platform had been specifically inspected. The SMETA audit had identified some risks during the loading operation which Alara have addressed (operators on the platform at risk of pallets of material toppling, causing crush injuries). No other concerns were identified relating to the loading platform in its modified guise. The improvements made include a revised arrangement to the platform at half-height (level	It has been agreed and acknowledged that cage pallets will be kept in place at all times that the mixing platform is being operated. This is a condition of allowing production to recommence. PH suggested installing a protected chain or gate to be in place at the top of the ladder to prevent accidental falls, as the area is quite restricted in size.

	with the weighing buckets), with the ladder giving access to this area is now a permanent and fixed part of the structure, with a hand-rail.	
Non Conformance – Minor		
No.	**Details of Non-conformity**	**Action Required by**
1	Immediate hygiene improvements are required around the mixing platform area. Area fully refurbished. Cleaning schedules to be reviewed and increased frequency and \ or improved methodology to be implemented. Use of air-lines for cleaning between products is poor practise and introduces the risk of cross contamination between products caused by air-borne particles. Consider alternative cleaning methods such as vacuum cleaners. A vacuum cleaner has been purchased to replace air-lines in cleaning operations. It arrived yesterday and its use has not yet been implemented, nor have procedures been revised to reflect its use. Documents reviewed that require change included 'Allergens Control' iss7 07Jul17; 'End of Week Cleaning Schedule' iss 8 07Jul17; 'Cleaning Procedure' iss7 02May16	**Please provide revised cleaning instructions and schedule.**
2	Documented line clearances between products to be introduced. A copy of the 'Start-up and change over Check Sheet', (Ver. 3.1 Issued 09Jul14) was provided. This was not provided at the original audit, and as part of the corrective actions addressed by email by Toks a revised version (4.1) was sent. After lengthy conversation with GM it was confirmed that version 3.1 is in use. It is embedded within the Company's production and scheduling database. It is not clear what Toks had intended to demonstrate by providing a copy of version 4.1, and it was agreed that version 3.1 in use is sufficient and closes this non-conformance.	Closed.
3	Cleaning regime for formers to be implemented and records retained. Formers should not be put away dirty. 'Start-up and change over Check Sheet', (Ver. 3.1 Issued 09Jul14) documents the cleaning of the formers. The formers were inspected during the re-audit and were found to be clean, with PTFE tape intact, and had been covered with clear polythene bags to prevent contamination whilst not in use. Damaged PTFE tape to be replaced and a system	The tape on the formers was intact but not of the metal detectable type. **GM to confirm when the use of this tape will be implemented.**

	for monitoring introduced. Toks had confirmed that metal detectable tape had been sourced.	
4	Review arrangements for containment of rejected raw materials. If product is rejected 'awaiting a decision' it should not be placed in the yard exposed to the elements. It should also not be kept in the main building if it poses a risk to other materials, such as it there is pest infestation. AS confirmed that in the event raw materials were identified as having infestation during intake inspection, they would be rejected and held in the yard, covered over to protect from the elements, and would in no circumstances be accepted back into the business for use. Couriers are used to return rejected material if issues are identified after the delivery vehicle has left site.	Closed.
5	Always leave a minimum gap of at least 8 inches (200mm) between items in the warehouse and the warehouse walls. This is to allow at minimum the site internal perimeter to be inspected by torch. It also reduced the risks of pest harbourage. A metal 'L' bracket has been fixed to the floor around the whole perimeter of the warehouse, and in general ensures product is away from walls. Pallets in one area were seen to have material overhanging the pallet, negating the influence of the 'L' bracket. PH emphasised that this must be policed during GMP audits. GM confirmed that this is included on the weekly GMP audit by the Technical Team. The form was seen.	Closed. Continue to monitor and enforce via GMP audits.
6	Make provision for rejected material to be stored in a segregated area, away from conforming materials. A clearly defined 'quarantine' area is usually provided for this. A quarantine area has been allocated in the warehouse. It is of sufficient size to hold one pallet of material.	Closed. A conversation was had regarding finding other means of expandable quarantine area – such as the use of Tensa-barriers or the use of 'Quarantine' tape.
7	At minimum any unavoidable exposed wood in open product and storage areas should be painted and monitored for damage. Ideally such items are fully removed and replaced with more robust material, which are less prone to present product contamination risks. All wooden items around the mixing platform have been removed as part of the refurbishment, and no other potential sources of similar contamination were identified during the re-audit.	Closed.
9	The rear labels should be amended to include a revision number, and they should be managed as	**It was agreed that as products are re-introduced**

	per any other controlled document, with a revision history and details of change. Only current and approved labels should be available to the production unit. Label masters have been consolidated into one folder. A copy of each label has been placed on a separate sheet, with the revision number being clearly identified on the sheet. The label still does not contain the revision status of the label.	**to unit 1, the revision status would be added to each product label in turn. The format was approved by PH. It is clear but unobtrusive on the label.**
10	Label masters used in both units should be controlled to ensure correct label information is available for anyone carrying out product checks. As above, label masters have been consolidated into one folder which it is planned to use between both units.	As above. The limitations of having one folder between two units was discussed, and it was agreed that by adding the revision status to the label, it would be possible for the detailed checks to be carried out in unit 2 where the labels are produced, with a more simple check that the correct revision had been placed onto pack in unit 1.
11	Implement a system for retained samples of each and every batch of product produced for Holland and Barrett. It is not acceptable to say there is no space on site. The samples sent to H&B are for our own review of the products being manufactured. Retained samples of each batch of product manufactured for Holland and Barrett are now being retained on site.	Closed
13	Strip curtain in granola production area to be adjusted to close gaps. Completed. Visual review. AS outlined plans for further development of the area, which in the medium term will remove the need for the curtain completely. There is a plan to expand the mezzanine area.	Closed.
14	Fire extinguisher to be made accessible. Now accessible and an additional unit has been area in an adjacent area following review.	Closed.
15	Temporary repairs using tape to be removed and made good. Policy to be reviewed. Tape repairs witnessed in the original audit have been removed and no further were observed. This is now checked on the weekly GMP audit.	Closed. Discussed that for this to be maintained there is a need to change the culture – tape repairs are not acceptable.
Observations		
No.	**Details of Compliance Required**	
1	Please confirm the business details for PW Gates – are they based in Welwyn Garden City? Please	Closed.

	provide a copy of their BRC certification. Provided.	
2	The items in the 'rogues gallery' should ideally be photographed and disposed so they do not pose an ongoing hygiene or foreign body risk. Disposed.	Closed.
3	Clarify how delivery date can identify unique batches of raw materials, in the event that two different batches of the same raw material are received on the same day. Deliveries will be suffixed A, B, C and so on to ensure each batch is identifiable.	Closed.
4	Confirm that McCance and Widdowson revision 6 is not being used to calculate or review nutritional information used on product. Confirmed prior to re-audit not to be in use. Disposed of during re-audit.	Closed.
5	Please provide a full copy of the validation exercises that have been conducted to allow an understanding of allergen alibi statements used on pack. The allergen risk assessment providing is not clear on whether cleaning methods effectively remove allergens in all cases. With peanuts the data suggests that cleaning is not effective throughout the equipment. Other allergens need clarification. The alibi statement on pack mitigates the risk, but should not be used to justify ineffective cleaning regimes. As the cleaning methodology is being altered to remove use of air-lines and to introduce use of a vacuum cleaner, a new validation exercise shall need to be conducted.	**The allergen risk assessment conducted in July is to be reviewed and a summary report prepared and forwarded by Friday 19th January.** **A further validation study of the revised cleaning operations (with vacuum cleaner) to be conducted within a timescale to be agreed following your review above, within one month.**
Additional Information		
	AS informed that a new, digital, linear weigh system has been ordered for the Unit 1 mixing \ packing line. The lead times is 6-8 weeks.	

H&B use only

Copies of report to:

- **Holland and Barrett International Ltd**
  - Legal Director
  - Director of Buying
  - Regulatory Affairs Manager
  - Quality Manager
  - Purchasing Manager

    - Supplier Technical File
- **Customer**