

# Audit Report

## Standard - Global Standard for Food Safety Issue 5 : January 2008

**Audit grade:** A

**Audit result:** CERTIFICATED

**Audit type:** ANNOUNCED

**Previous audit grade:** A

**Audit Frequency:** 12 months

### Company Details

**BRC Site Code:** 5519116

**Company Name:** Coalescence LLC

**Site Name:** Coalescence LLC

**Address:** 3455 Millennium Court, Columbus, OH

**Country:** USA

**Postcode:** 43219

**Telephone:** 614-861-3639

**Fax:** 614-861-1379

**Company Representative Name:** Regina Weaver

**Email:** regina@coalescencellc.com

### Certification Body Details

**Name of Certification Body:** SAI Global Assurance Services Ltd

**Auditor Number**  
123139

**Auditor Name**  
Thomas S. Tucker

# Audit Report

**Audit Start Date:** 2011-10-11      **Audit Finish Date:** 2011-10-12  
**Re-audit Due Date:** 2012-11-02      **Previous Audit Date:** 2010-11-02

## Scope Details

### Product Categories

15 - Dried food and ingredients

**Scope of Audit** Production, storage and dispatch of mixed blends of dry ingredients, spices and flavors for the food industry.

**Exclusions from Scope** None

### Products in production at the time of the audit

Dry blends packaged in Kraft bags and Bag-in-a-box.

## Key Personnel

Name/Job Title	Present at Audit (x)			
	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.12)				
Craig Thompson – VP Operations/General Manager	x	x	x	X
Angela Cauley - CEO				x
Regina Weaver - QA Director	x	x	x	x
Ian Blount - COO				x
Kermit Montague – Supply Chain Director				x
Theang Ngo – Warehouse Manager		x	x	
Monte Cozzins – Production Control Manager		x	x	x
Dave Parron – Raw Ingredients Manager		x	x	x

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX  
Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com

Issue 6_2007 EFSIS-13.10F	Page 2 of 83	Report No: A-00162263	Auditor: Tom Tucker
------------------------------	--------------	-----------------------	---------------------

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

# Audit Report

## Company Profile

Coalescence LLC , located in Columbus OH USA, is a 35,000 sq. ft (3251.61 square meters). modern facility that produces dry spice blends for further food manufacturing. The process includes dry blending, blending and packaging in liner corrugated boxes or Kraft bags. 45 employees at the site.

Note: For further information see detailed company profile section at the end of this report.

## Audit Duration Details

**On-site audit duration** 16 man hours

**Duration of production facility audit** 6 man hours

**Reasons for deviation from typical or expected on-site audit duration or typical site inspection duration**

Reasons for deviation

**Has customer opted for unannounced option for subsequent audits?** No

## Audit Duration per day

	Start time	Finish time
<b>Day 1</b>	0800	1700
<b>Day 2</b>	0800	1500

# Audit Report

## NON-CONFORMITY SUMMARY SHEET

### List of Non Conformities

#### Critical Or Major Non Conformities Against Fundamental Requirements

No.	Requirement ref.	Detail of Non-Conformity	Critical or Major?	Anticipated Re-audit date

#### Critical

No.	Requirement ref.	Detail of Non-Conformity	Corrective action	Anticipated re-audit date	Reviewed by

#### Major

No.	Requirement ref.	Detail of Non-Conformity	Corrective action taken	Evidence provided Document Photograph Visit/Other	Reviewed by

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 4 of 83	Report No: A-00162263	Auditor: Tom Tucker

This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd

**Minor**

No.	Requirement ref.	Detail of Non-Conformity	Corrective action taken	Evidence provided Document Photograph Visit/Other	Reviewed by
1	2.9.1	The stated monitoring program includes Metal Detectors challenged at beginning, end and each 2 hours of a production day. Pathogen testing is conducted on each composited production lot. During the audit it was noted that the end of day challenge was not being conducted. All bagged product observed being run during audit was put thru a metal detector and a CCP non-conformance was opened. Re-training of challenge operators was conducted before end of audit.	The corrective action included the update of Quality Procedure C03-003.A (Document Initiation and Change Control Form, revision date 19-October-2011 and Document Number C42-002.B (Coalescence Metal Detector Form, dated 19-October-2011. The corrective action included Training Sign-In Sheet Form C05-010.A. Training was a review of Critical Control Point-metal detector policy review and procedure change.	Revised copy of new procedure and form regarding metal detection challenges and training sign-in sheet with instructors names.	Thomas S. Tucker, 24-October-2011

### Detailed Audit Report

BRC Requirement No.	REQUIREMENT	Conforms Y, N or N/A	Details
<b>1 SENIOR MANAGEMENT COMMITMENT AND CONTINUAL IMPROVEMENT</b>			
1.0 <b>FUNDAMENTAL</b> Statement of Intent	<b>The company's senior management shall demonstrate they are fully committed to the implementation of the requirements of the Global Standard for Food Safety. This shall include provision of adequate resources, effective communication, systems of review and actions taken to effect continual improvement. Opportunities for improvement shall be identified, implemented and fully documented.</b>	<b>Y</b>	The senior management demonstrated commitment to the implementation of the Global Standard for Food Safety through involvement in the HACCP Plan, development of the Quality Policy and participation in the annual quality system review. No items were noted during the course of the audit which indicated a lack of provision of adequate resources. Continuous improvement activities include achievement of Quality objectives and update to sanitation programs.
1.1	The company's senior management shall provide the human and financial resources required to implement and improve the processes of the quality management system and the food safety plan.	<b>Y</b>	The quality function to includes a Director of Quality Assurance. The facility has purchased and validated a new labeler for finished cases and bags.
1.2	There shall be clear communication and reporting channels to senior management for departments responsible for monitoring compliance with the Global Standard for Food Safety. The departments shall report regularly on effective compliance.	<b>Y</b>	The Director of Quality Assurance reports to the CEO, who is part of senior management. Production management reports to COO who reports to CEO.

**F002: Global Standard for Food Safety  
Issue 5 : January 2008  
Audit Report**

1.3	The company's senior management shall ensure that food safety and quality objectives are established, documented, monitored and reviewed.	<b>Y</b>	Senior management establishes, document, monitor, and review KPIs, complaints, weight control, and non-conforming product. These are reviewed monthly with management staff. The management has posted and discussed company Quality and Food Safety Policy statement and policies through continual training and supervision.
1.4	The company's senior management shall ensure that there is a process to identify and address any safety or legality issue at a strategic level.	<b>Y</b>	See clause 1.0 above.
1.5	The company's senior management shall take responsibility for the review process.	<b>Y</b>	The management is on site and directly involved in daily operation. Senior management meets weekly to discuss any quality issues.
1.6	The review process shall be undertaken at appropriate planned intervals, as a minimum annually, to ensure critical evaluation of the food safety plan and the HACCP system's suitability, adequacy and effectiveness.	<b>Y</b>	All systems are scheduled for review at least annually.

1.7	<p>The review process shall include the evaluation of:</p> <ul style="list-style-type: none"> <li>• internal, second party and third party audits</li> <li>• previous management review documents, action plans and time frames</li> <li>• customer performance indicators, complaints and feedback</li> <li>• incidents, corrective actions, out-of-specification results and non-conforming materials</li> <li>• process performance and deviation from defined parameters</li> <li>• reviews of the HACCP-based system</li> <li>• developments in scientific information associated with the products in scope</li> <li>• resource requirements.</li> </ul>	<b>Y</b>	<p>The system review is conducted over a calendar year. The 2010 review was completed in January 2011 by the Director of QA and General Manager. The review covered areas of the clause including results of audits, customer feedback, review of non-conforming products, returns, HACCP review and resource requirements.</p>
1.8	Records of management reviews shall be comprehensively documented and retained.	<b>Y</b>	Records of the management review were available at the site and were reviewed. The review back-up is a power point presentation.
1.9	The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed time scales. The records shall be updated to show when actions have been completed.	<b>Y</b>	Time scales are agreed and subsequent actions documented. By March 2011 a project was completed to more efficiently utilizing raw materials and reducing the number of partials returned to warehouse.
1.10	The company shall have the current issue of the Global Standard for Food Safety available.	<b>Y</b>	A copy is available and noted during audit.

1.11	The company shall maintain certification to the Global Standard for Food Safety by effective timescale planning to ensure that certification does not expire (refer to Section III, paragraph 12).	<b>Y</b>	A copy of current certification is in date and reviewed. Re-audit is due by 2-Nov-2011.
1.12	The most senior production or operations manager on site shall attend the opening and closing meetings of the audit for Global Standard for Food Safety certification.	<b>Y</b>	The General Manager attended both the opening and closing meetings.
1.13	The company's senior management shall ensure that non-conformities identified at the previous audit against the Standard are effectively actioned.	<b>Y</b>	The Non-Conformities noted in previous BRC audit have been adequately dealt with.
<b>2 THE FOOD SAFETY PLAN – HACCP</b>			
<b>2.0 FUNDAMENTAL Statement of Intent</b>	The company's food safety plan shall be based on a HACCP system which shall be systematic, comprehensive, thorough, fully implemented and maintained. Codex Alimentarius HACCP principles shall be used and reference shall be made to relevant legislation, codes of practice or guidelines.	<b>Y</b>	There are two HACCP plans covering products in scope of this audit. The plans follow the Codex principles including regulatory requirements. The plan is systematic, comprehensive, thorough, fully implemented and maintained.
<b>2.1 The HACCP Food Safety Team – Codex Alimentarius Step 1</b>			
2.1.1	The HACCP plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for Quality/Technical, Production Operations, Engineering and other relevant functions. The team members shall have specific knowledge of HACCP and relevant knowledge of product, process and associated hazards.	<b>Y</b>	The HACCP team consists of Director of QA, CEO, Production Manager, V-P of Manufacturing, Corporate Engineer, QA Lab Technician, R&D Chef and Raw Material Coordinator.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 9 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

2.1.2	The HACCP food safety team shall have a designated and qualified team leader who shall be able to demonstrate competence and experience of HACCP.	<b>Y</b>	The Team Leader is Director of QA. Her certificate was available for review. An on-line training was completed in 2008 from 360 degree training.
2.1.3	Records shall be maintained that demonstrate the HACCP food safety team has the required knowledge and understanding of HACCP. In the event of the company not having appropriate in-house knowledge, external expertise may be sought, but day-to-day management of the food safety system shall remain the responsibility of the company.	<b>Y</b>	All training records were viewed during the audit. The Corporate Engineer and Lab Tech have had formal training at Ohio State University. Site has HACCP Training for all members of the HACCP team including joint training May 2011 conducted by Team Leader.
2.1.4	The company's senior management shall demonstrate commitment and support to the HACCP food safety team.	<b>Y</b>	The senior operations management is part of HACCP team.
<b>2.2 Describe the Product – Codex Alimentarius Step 2</b>			
2.2.1	The HACCP food safety team will define the specific products and/or processes that are the subject of the HACCP plan.	<b>Y</b>	The HACCP plans for Client Blend Bags and Client Blend Boxes were audited.



2.2.2	<p>All relevant information needed to conduct the hazard analysis shall be collected, maintained, documented and updated. The company will ensure that the HACCP plan is based on comprehensive information sources, which are referenced and available on request. This may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> <li>• the latest scientific literature</li> <li>• historical and known hazards associated with specific food products</li> <li>• relevant codes of practice</li> <li>• recognised guidelines</li> <li>• food safety legislation of products in destination countries</li> <li>• customer requirements.</li> </ul>	<p><b>Y</b></p>	<p>Technical information is from FDA notices, 21CFR, Codex and relevant food safety legislation.</p>
-------	---	-----------------	--

2.2.3	<p>A full description of the product shall be developed, which includes all relevant information on food safety. As a guide, this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> <li>• composition (e.g. raw materials, ingredients, recipe)</li> <li>• origin of ingredients</li> <li>• physical or chemical properties that impact food safety (e.g. pH, a<sub>w</sub>)</li> <li>• treatment and processing (e.g. heating, freezing, salting)</li> <li>• packaging system (e.g. modified atmosphere, vacuum)</li> <li>• storage and distribution conditions (e.g. chilled, ambient)</li> <li>• target safe shelf life under prescribed storage and usage conditions</li> <li>• instructions for use (e.g. storage, preparation)</li> <li>• consideration of potential misuse (e.g. storage, preparation).</li> </ul>	<b>Y</b>	<p>The HACCP Plan includes a full description of the product, covering the relevant portions of this clause. The Plan covers, raw materials, process steps, packaging, shelf life, storage and distribution and other requirements of this section.</p> <p>The product is dry blends.</p>
<b>2.3 Identify Intended Use – Codex Alimentarius Step 3</b>			
2.3.1	<p>The intended use of the product by the customer shall be described defining the consumer target groups, including the suitability of the product for vulnerable groups of the population, e.g. infants, elderly, allergy sufferers.</p>	<b>Y</b>	<p>The product is not intended to be consumed as received. The potential consumer is as an ingredient in further food processing.</p>
<b>2.4 Construct a Process Flow Diagram – Codex Alimentarius Step 4</b>			

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 12 of 83	Report No: A-00162263	Auditor: Tom Tucker

2.4.1	<p>A flow diagram shall be prepared to cover each product, product category or process. This shall set out all aspects of the food process operation within the HACCP scope, from raw materials selection through processing, storage and distribution. As a guide, this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> <li>• plan of premises and equipment layout</li> <li>• raw materials including introduction of utilities and other contact materials ( e.g. water, packaging)</li> <li>• sequence and interaction of all process steps</li> <li>• outsourced processes and subcontracted work</li> <li>• process parameters</li> <li>• potential for process delay</li> <li>• rework and recycling</li> <li>• low/high risk and clean/dirty area segregation</li> <li>• finished products, intermediate/semi-processed products, by-products and waste.</li> </ul>	<b>Y</b>	<p>The site has prepared a flow chart, which includes sequence and interaction of all process steps, introduction of most utilities and other contact materials. The flow chart was reviewed October 4, 2011. The 2010 update included the labeling step and correct amount of rework that can be added-back.</p>
<b>2.5 Verify Flow Diagram – Codex Alimentarius Step 5</b>			
2.5.1	<p>The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit and challenge. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.</p>	<b>Y</b>	<p>The verification of the flow diagrams by the HACCP team via an on-site audit was conducted as part of this audit. Annual verifications are conducted. There are no daily and/or seasonal variations.</p>
<b>2.6 List All Potential Hazards Associated with Each Process Step, Conduct a Hazard Analysis and Consider any Measures to Control Identified Hazards – Codex Alimentarius Step 6, Principle 1</b>			

2.6.1	The HACCP food safety team shall confirm the scope of the HACCP plan and identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities which may not be controlled by existing prerequisites. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and allergen risks (refer to clause 5.2). It shall also take account of the preceding and following steps in the process chain.	<b>Y</b>	At each step in the flow diagram, the site HACCP team has considered potential chemical, physical and biological hazards which may occur. Prerequisite programs include sanitations, pest control, traceability, specifications, allergens, glass/brittle plastic, supplier assessment, internal audits, training, and quality systems.
2.6.2	The HACCP food safety team shall conduct a hazard analysis to identify hazards which need to be prevented, eliminated or reduced to acceptable levels. Consideration shall be given to the following as a minimum: <ul style="list-style-type: none"> <li>• likely occurrence of hazard</li> <li>• severity of the effects on consumer safety</li> <li>• vulnerability of those exposed</li> <li>• survival and multiplication of micro-organisms of concern</li> <li>• presence or production of toxins, chemicals or foreign bodies</li> <li>• contamination of raw materials, intermediate/semi-processed product, or finished product</li> <li>• potential for adulteration/deliberate contamination.</li> </ul>	<b>Y</b>	The likely occurrence and severity of each hazard is considered. The plan identifies bacterial, chemical, and physical potential risk.

2.6.3	The HACCP food safety team shall consider the control measures necessary to prevent, eliminate or reduce the hazard to acceptable levels. Consideration may be given to using more than one control measure. Justification for acceptable levels in the finished product for each hazard shall be determined and documented.	<b>Y</b>	There are control measures established for each hazard identified. The acceptable levels are determined based on regulatory and scientific requirements.
<b>2.7 Determine the Critical Control Points(CCP) – Codex Alimentarius Step 7, Principle 2</b>			
2.7.1	For each hazard that requires control, control points shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree. CCPs shall be those control points which are required in order to prevent, eliminate or reduce a food safety hazard to acceptable levels. If a hazard is identified at a step where control is necessary for safety but the control does not exist, the product or process shall be modified at that step, or at an earlier or later step, to provide a control measure.	<b>Y</b>	The hazard review for bagged product has one CCP, metal detection. The hazard review for boxed product has one CCP, pathogen detection.
<b>2.8 Establish Critical Limits for each CCP – Codex Alimentarius Step 8, Principle 3</b>			

2.8.1	For each CCP, the appropriate critical limits shall be defined in order to identify clearly if the process is in or out of control and if the identified acceptable level of the food safety hazard in the finished product is likely to be exceeded. Critical limits shall be measurable wherever possible (e.g. time, temperature, pH) and the rationale for their establishment clearly documented. The HACCP food safety team shall take into account relevant legislation or codes of practice when establishing critical limits.	<b>Y</b>	The Critical Limit for Metal Detection is Fe 2.0 mm, non-Fe 2.0 mm, and 316 stainless steel is 2.0 mm. The Critical Limit for Pathogen Testing for Salmonella is none found in 25 g sample and E. coli of <3/MPN in 25 g sample.
2.8.2	Any critical limits based on subjective data (such as visual inspection) shall be supported by clear guidance or examples.	<b>N/A</b>	Critical limit is based on objective measure.
2.8.3	The HACCP food safety team shall validate each CCP. Documented evidence shall show that the control measures selected are capable of consistently controlling the hazard to the level specified by the critical limit.	<b>Y</b>	Routine monitoring verifies the Process is in control.
<b>2.9 Establish a Monitoring System for each CCP – Codex Alimentarius Step 9, Principle 4</b>			
2.9.1	The HACCP food safety team shall establish a monitoring system for each CCP to ensure compliance with critical limits.	<b>N</b>	The stated monitoring program includes Metal Detectors challenged at beginning, end and each 2 hours of a production day. Pathogen testing is conducted on each composited production lot. During the audit it was noted that the end of day challenge was not being conducted. All bagged product observed being run during audit was put thru a metal detector and a CCP non-conformance was opened. Re-training of challenge operators was conducted before end of audit.

2.9.2	<p>Each defined CCP shall be under control. The monitoring system shall be able to detect loss of control of CCPs and wherever possible provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> <li>• online measurement</li> <li>• offline measurement</li> <li>• continuous measurement (e.g. thermographs)</li> <li>• where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product.</li> </ul>	<b>Y</b>	The Metal Detection is on-line. The Pathogen Testing is off-line.
2.9.3	Records associated with monitoring CCPs must be signed by the person responsible for the monitoring and verified, as appropriate, by an authorised person. Recorded details shall include the date and result of measurements carried out.	<b>Y</b>	All records checked were signed by the individual conducting the monitoring. Verification is by designate in QA department.
<b>2.10 Establish a Corrective Action Plan – Codex Alimentarius Step 10, Principle 5</b>			
2.10.1	The HACCP food safety team shall specify and document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel with regard to any products that have been manufactured during the period when the process was out of control.	<b>NA</b>	There have not been any requirements for CCP corrective actions in the last year.

2.10.2	Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until confirmed as suitable for release.	<b>Y</b>	Any potentially unsafe product will be secured and segregated under corporate hold policy.
<b>2.11 Establish Verification Procedures – Codex Alimentarius Step 11, Principle 6</b>			
2.11.1	Procedures of verification shall be established to confirm that the HACCP plan is effective. Examples of verification activities are: <ul style="list-style-type: none"> <li>• internal audits</li> <li>• review of records where acceptable limits have been exceeded</li> <li>• review of complaints by enforcement authorities or customers</li> <li>• review of incidents of product withdrawal or recall.</li> </ul>	<b>Y</b>	The HACCP Plan acceptability is verified though several procedures including the annual internal audit which encompasses the HACCP Plan review, as well as the review of customer and regulatory (US FDA) complaints. The facility conducted a recall on a raw material that was part of a vendor recall protocol. The US FDA monitored the recall.
2.11.2	Verification results shall be recorded and communicated to the HACCP food safety team.	<b>Y</b>	The review of the site records confirmed they were adequate to verify the HACCP controls were in place.
<b>2.12 HACCP Documentation and Record Keeping – Codex Alimentarius Step 12, Principle 7</b>			
2.12.1	Documentation and record keeping shall be sufficient to assist the company to verify that the HACCP controls are in place and maintained.	<b>Y</b>	Records are kept for a minimum of 3.0 years in-plant.
<b>2.13 Review the HACCP Plan</b>			

2.13.1	<p>The HACCP food safety team shall ensure that procedures exist to review the HACCP plan prior to any changes which may affect product safety. As a guide, these may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> <li>• change in raw materials or supplier of raw materials</li> <li>• change in ingredients/recipe</li> <li>• change in processing conditions or equipment</li> <li>• change in packaging, storage or distribution conditions</li> <li>• change in staff or management responsibilities</li> <li>• change in consumer use</li> <li>• developments in scientific information associated with ingredients, process or product.</li> </ul> <p>Appropriate changes resulting from the review shall be incorporated into the HACCP plan, fully documented and validated.</p>	<b>Y</b>	<p>The HACCP plan calls for the revision of the plan should any change to process, packaging, ingredient, structure, scientific information, product handling, and/or equipment as noted in the clause occur.</p>
2.13.2	<p>Irrespective of any of the above changes, the HACCP plan will be reviewed at least annually and records shall be maintained.</p>	<b>Y</b>	<p>The last review was dated Oct 4, 2011.</p>
<b>3.0 FOOD SAFETY AND QUALITY MANAGEMENT SYSTEM</b>			
<b>3.1 Food Safety and Quality Policy</b>			
<p><b>3.1</b> Statement of Intent</p>	<p><b>The company's senior management shall develop and document a food safety and quality policy which is authorised, reviewed, signed and dated by an appropriate senior manager.</b></p>	<b>Y</b>	<p>The site has an established Quality Policy reviewed August 25, 2011 and signed by the General Manager/Vice President.</p>

3.1.1	The policy shall state the company's intention to meet its obligation to produce safe and legal products to the specified quality, and its responsibility to its customers. This shall include the commitment for review and continual improvement. The company's senior management shall ensure the policy is communicated to all staff involved with activities relating to product safety, legality and quality.	<b>Y</b>	The corporate quality statement is signed by General Manager, dated August 25, 2011, and posted in employee break room, information and office areas. The statement includes product safety and quality issues.
<b>3.2 Food Safety and Quality Manual</b>			
<b>3.2</b> Statement of Intent	<b>The company shall have a food safety and quality manual which describes how the requirements of the Global Standard for Food Safety are met. These requirements shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary.</b>	<b>Y</b>	The Food Safety and Quality Manual is in several sections, and was determined to address the requirements of the Global Standard for Food Safety. The management and staff were observed to be working to the requirements listed in the standard. The manual showed revisions based on information from its technical resources, buyers, regulatory agencies, and third party auditors.
3.2.1	The food safety and quality manual shall contain an outline of working methods and practices or references to where such an outline is documented.	<b>Y</b>	The manual contains an outline to working methods and practices.
3.2.2	The food safety and quality manual shall be readily available to key staff.	<b>Y</b>	The master copy is kept on the corporate internal computer system.
<b>3.3 Organisational Structure, Responsibilities and Management Authority</b>			

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 20 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

<b>3.3</b> <b>Statement of Intent</b>	<b>The company shall have a clear organisational structure and define the responsibilities, reporting relationships and job functions of those personnel whose activities affect product safety, legality and quality.</b>	<b>Y</b>	The company has a clear organizational structure as delineated in the organizational chart dated October 5, 2011 which lists those individuals which could affect product safety, legality and quality.
3.3.1	The company shall have an organisation chart demonstrating the structure of the company.	<b>Y</b>	The existence and relevance of the organization chart was confirmed and a copy obtained.
3.3.2	Documented, clearly defined responsibilities shall exist and be communicated to key staff with responsibility for product safety, legality and quality systems.	<b>Y</b>	Job descriptions including responsibilities were available for all key staff. They were noted to have been revised as appropriate. Examples reviewed included Director of QA, Lab Technician, Production Manager, Production Associate, Warehouse Associate and Raw Ingredient and Kosher Coordinator.
3.3.3	There shall be appropriate documented arrangements in place to cover for the absence of key staff.	<b>Y</b>	Documented as part of Job Descriptions.
3.3.4	The company's senior management shall ensure a description of general duties or work instructions are in place and communicated to all staff involved with activities relating to product safety, legality and quality.	<b>Y</b>	The site has full job descriptions for all work positions and all CCP monitoring stations.
3.3.5	The company's senior management shall have a system in place to ensure that the company is kept informed of all relevant legislative, scientific and technical developments, and industry codes of practice applicable in the country of raw material supply, production and, where known, the country where the product will be sold.	<b>Y</b>	The company obtains technical and legislative updates and support through its membership in trade and state agencies including OH State Department of Agricultural.

3.4 Contract Review and Customer Focus			
3.4 Statement of Intent	<b>The company's senior management shall ensure that processes are in place to determine any customer requirements and expectations with regard to product safety and quality, and ensure these are fulfilled.</b>	<b>Y</b>	Specifications are submitted to customer for approval.
3.4.1	The company shall clearly identify those individuals responsible for communication with customers and shall have an effective system for communication.	<b>Y</b>	Communication with customers is handled by either Sales or R&D Departments based on need or issue.
3.4.2	Customer requirements relating to the development, specification, manufacture and distribution of product shall have been agreed with the customer and, where appropriate, documented and agreed prior to order fulfilment (refer to clause 3.7.2.3).	<b>Y</b>	The facility receives a signed specification returned.
3.4.3	Customer needs and requirements shall be reviewed on a suitable predetermined frequency. Any changes to existing agreements or contract shall be agreed, documented and communicated to appropriate departments.	<b>Y</b>	Each lot is monitored against documented specification.
3.4.4	Performance indicators shall be established relating to customer satisfaction. These shall be communicated to appropriate staff and performance reviewed against these targets.	<b>Y</b>	The QA Department conducts and documents daily check.
3.5 Internal Audit			

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 22 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

<b>3.5</b> <b>FUNDAMENTAL</b> <b>Statement of Intent</b>	<b>The company shall audit those systems and procedures which cover the requirements of the Global Standard for Food Safety to ensure that they are in place, appropriate and complied with.</b>	<b>Y</b>	The company has conducted an internal audit of the entire Quality Management System for the site.
3.5.1	Internal audits shall be planned and their scope and frequency shall be established in relation to the risks associated with the activity. Audits shall be scheduled so that all aspects of the food safety and quality management system are audited at least annually.	<b>Y</b>	The internal audits include: GMPs, sanitation, documentation, break areas and CCPs. The audits are conducted for each shift daily. The daily audits are conducted by quality team. This audit includes external areas.
3.5.2	Internal audits shall be carried out by appropriately trained competent auditors, who are independent from the audited department.	<b>Y</b>	Internal audits are carried out by trained competent auditors under the direction of the QA department, who are independent from the audited department.
3.5.3	Internal audit reports shall identify and verify conformity as well as non-conformity.	<b>Y</b>	The audit utilizes a description of each audit which notes conformity as well as non-conformity.
3.5.4	Results of the internal audit shall be reported to the personnel responsible for the activity audited. Corrective actions and timescales for their implementation shall be agreed.	<b>Y</b>	Internal audit results are reported to the relevant personnel with corrective actions and associated timescales agreed.
3.5.5	The completion of corrective action shall be verified.	<b>Y</b>	Corrective actions are noted on daily internal audit sheets.
3.5.6	A record of all programmed internal audits and associated corrective actions shall be maintained.	<b>Y</b>	The records are maintained in the QA office.
<b>3.6 Purchasing – Supplier Approval and Performance Monitoring</b>			

3.6	<b>The company shall control all purchasing processes which are critical to product safety, legality and quality to ensure that products and services procured conform to defined requirements.</b>	<b>Y</b>	All purchasing is handled by Purchasing Department.
3.6.1	The company shall have a documented supplier approval procedure and continual assessment programme in place, based on risk assessment.	<b>Y</b>	The reviewed supplier list is continually updated on internal computer.
3.6.2	These procedures shall include clear criteria for ongoing assessment and standards of performance required. Ongoing assessment may take the form of monitoring performance through the following, although this is not an exhaustive list: <ul style="list-style-type: none"> <li>• in-house checks</li> <li>• certificates of analysis</li> <li>• supplier audit as appropriate.</li> </ul> Records of this monitoring shall be retained.	<b>Y</b>	The company receives COAs on each shipment and conducts analytical tests of raw materials as required. Customers are notified of suppliers and any required corrective actions. Annual third party audit of each supplier location is required.
3.6.3	The procedures shall define how exceptions are handled, e.g. the use of products or services where audit or monitoring has not been undertaken.	<b>Y</b>	No unapproved vendors are allowed.
3.6.4	The company shall review the performance of new suppliers against defined criteria within a specified 'trial' period and thereafter at a specified frequency to decide the level of ongoing supplier performance monitoring.	<b>Y</b>	They do not use a trial period for new vendors. All new vendors are reviewed against defined criteria by facility, client or broker. All ingredient suppliers are reviewed at least annually as to third party audits.
<b>3.7</b>	<b>General Documentation Requirements</b>		
<b>3.7.1</b>	<b>Documentation Control</b>		

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 24 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

3.7.1 Statement of Intent	<b>The company's senior management shall ensure that all documents, records and data critical to the management of product safety, legality and quality are in place and effectively controlled.</b>	<b>Y</b>	Documentation is controlled by the QA Department.
3.7.1.1	All documents in use shall be properly authorised and be the correct version.	<b>Y</b>	The documents reviewed were signed and dated.
3.7.1.2	Documents shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. They shall be readily accessible to relevant staff at all times.	<b>Y</b>	All documents reviewed were found to be clearly legible and unambiguous and written in English. They are made available manually and/or electronically. A number of employees are fluent in both languages.
3.7.1.3	The reason for any changes or amendments to documents critical to product safety, legality or quality systems and procedures shall be recorded.	<b>Y</b>	The site maintains a document amendment tracking system which notes any changes and the reasons they were made.
3.7.1.4	A procedure shall be in place to ensure obsolete documentation is rescinded, and where necessary replaced with a revised version.	<b>Y</b>	This is handled by the QA Department.
<b>3.7.2 Specifications</b>			
3.7.2 Statement of Intent	<b>The company shall ensure that specifications exist for raw materials including packaging, intermediate/semi-processed and finished products (where relevant), and any product or service which could affect the integrity of the finished product.</b>	<b>Y</b>	The site maintains specifications for raw materials. including packaging and finished products. For the production code chosen for the traceability challenge, the following specification applies: Meatless Burger Mix, internal lot B5762.
3.7.2.1	Specifications shall be adequate and accurate and shall ensure compliance with relevant safety and legislative requirements.	<b>Y</b>	Specifications have been developed for all raw ingredients, packaging and finished products and are fully detailed.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: <a href="mailto:foodsafety@saiglobal.com">foodsafety@saiglobal.com</a> website: <a href="http://www.saiglobal.com">www.saiglobal.com</a>			
Issue 6_2007 EFSIS-13.10F	Page 25 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

3.7.2.2	Manufacturing instructions shall comply with recipes as detailed in agreed customer specifications and shall be implemented.	Y	Manufacturing instructions are based on recipes which have been developed by the R&D and Quality Departments. They are stored in the computer system and printed for each day's production.
3.7.2.3	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that they have taken steps to ensure formal agreement is in place.	Y	Copies of all specifications are signed by facility and agreed to by either supplier or customer electronically.
3.7.2.4	There shall be a documented procedure for the amendment and approval of specifications for all parts of the process including regular reviews to ensure adequacy and status.	Y	Specifications for are reviewed annually.
3.7.2.5	Specifications and/or their contents shall be accessible to relevant staff.	Y	All the specifications are held on company computer system and are available electronically.
<b>3.7.3 Record Completion and Maintenance</b>			

<p>3.7.3 Statement of Intent</p>	<p><b>The company shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.</b></p>	<p align="center"><b>Y</b></p>	<p>The company has a system of files to ensure the records are retained. All records requested were readily retrieved, were complete, appeared to be genuine and were presented for review.</p> <p>Records reviewed relating to code chosen for traceability challenge included:</p> <ul style="list-style-type: none"> <li>QC net weight report</li> <li>QC online production evaluation</li> <li>Purchased order receipt proof</li> <li>QC lot verification form</li> <li>Receiving, Product Inspection &amp; Testing report</li> <li>Distribution of product lot history report</li> <li>Finished product lot history</li> <li>Raw material lot history</li> <li>Job output report, QC f.p. verification</li> <li>Job input report, batch sheet</li> <li>Vendor packing list</li> <li>Client finished product specification</li> <li>Raw material supplier specification</li> <li>Daily production schedule</li> <li>ATP sanitation verification</li> <li>F.P. COA</li> </ul>
<p>3.7.3.1</p>	<p>The records shall be legible, genuine, appropriately authorised and retained in good condition for an appropriate defined time period.</p>	<p align="center"><b>Y</b></p>	<p>The records reviewed were found to be legible, genuine, and appropriately authorized, with their retention requirements listed in the Quality Manual. The records are retained on site for at least the shelf-life of the product.</p>
<p>3.7.3.2</p>	<p>Any alterations to records shall be authorised and justification for alteration shall be recorded.</p>	<p align="center"><b>Y</b></p>	<p>No alterations to records observed during audit.</p>

3.7.3.3	The company's senior management shall ensure that procedures are operated for the collation, review, maintenance, storage and retrieval of all records relating to product safety, legality and quality.	<b>Y</b>	The company has a system of files to ensure the records are retained. All records requested were readily retrieved and presented for review.
3.7.3.4	The period of retention for records shall relate to shelf life of the product and take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer, e.g. freezing.	<b>Y</b>	Records are to be retained for at least 3 years which exceeds the longest declared shelf life of 12 months.
3.7.3.5	Any legal and customer specific requirements relevant to record retention shall be taken into account.	<b>Y</b>	Record retention is based on FDA guidelines. There are no customer record retention requirements.
<b>3.8 Corrective and Preventive Action</b>			
<b>3.8</b> <b>FUNDAMENTAL</b> Statement of Intent	<b>The company's senior management shall ensure that procedures exist to record, investigate, analyse and correct the cause of non-conformity against standards, specifications and procedures which are critical to product safety, legality and quality.</b>	<b>Y</b>	When non-conformances against standards, specifications and procedures have occurred, the company has systems in place to investigate. The system accepts entry of problems encountered that are not noted on routine monitoring such as consumer complaints or items noted during audits. The reports follow computer template which includes description of problem, root cause analysis, corrective actions, action due dates, preventative and follow-up actions. Corrective actions are fully documented.
3.8.1	Corrective actions shall be accurately documented, assigning responsibility and accountability.	<b>Y</b>	Corrective actions are documented through the Quality System.
3.8.2	Corrective actions shall be undertaken as soon as possible to prevent further occurrence of non-conformity.	<b>Y</b>	A review of the Corrective Action records did not reveal any significant on-going problems.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 28 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

3.8.3	Any corrective action plan relating to food safety, legality or quality shall only be agreed by personnel who have a defined responsibility and accountability for these areas of control.	<b>Y</b>	Corrective action plans are agreed by authorized personnel (Director of Quality or CEO). They are formally verified to ensure satisfactory completion.
3.8.4	The completion of corrective actions shall be monitored and recorded to ensure their effectiveness and completion within an appropriate timescale.	<b>Y</b>	Records seen relating to a customer complaint review showed good tracking of the status of the corrective action and verification of its completion.
<b>3.9 Traceability</b>			
<b>3.9</b> <b>FUNDAMENTAL</b> Statement of Intent	<b>The company shall have a system to identify and trace product lots and follow this through all raw materials (including primary and any other relevant packaging materials and processing aids), all stages of processing and the distribution of the finished product to the customer in a timely manner.</b>	<b>Y</b>	The traceability system was tested during the audit and found to be satisfactory. The item chosen for traceability challenge was ingredient: Tex-Mex Seasoning Powder. Records reviewed in conjunction with this code are noted in clause 3.7.3.
3.9.1	Identification of raw materials including primary and any other relevant packaging and processing aids, intermediate/semi-processed products, part-used materials, finished products and materials pending investigation, shall be adequate to ensure traceability.	<b>Y</b>	Records are maintained of identity of all ingredients and packaging throughout the production chain. Every pallet of raw material is tagged to lot and product by supplier. All ingredients have identifying codes marked on their packaging. All finished cartons are laser coded.

3.9.2	The company shall test the traceability system to ensure traceability can be determined from raw material to finished product and vice versa and include <b>quantity check/mass balance</b> (refer to glossary). This shall occur at a predetermined frequency and results shall be retained for inspection. The test shall take place at least annually.	<b>Y</b>	The company conducts a mock recall/traceability tests at least 2x/year. Traceability exercise check/mass balance is calculated a results and possible corrective actions are documented. The site insures that the system is checked both forward and backwards at least annually. A mock recall was conducted during this audit. One received lot of ingredient was traced to finished product. 5000# of ingredient was received. 1486.57# of product was used 10/5/2011. The ingredient product was found in inventoried finished goods staged for shipping 10/12/2011 and under bin control. 99.98% of traced ingredient was found by recall team in 45 minutes.
3.9.3	Where there is a requirement to ensure identity preservation within the supply chain, e.g. to use a logo or to make a claim to a product characteristic or attribute, appropriate controls and testing procedures shall be in place.	<b>Y</b>	They produce products certified as Kosher.
3.9.4	Where rework or any reworking operation is performed, traceability shall be maintained. In addition, the company must be able to demonstrate that this does not affect the safety or legal status of the finished product, e.g. ingredient declaration, allergy information or identity preservation.	<b>Y</b>	Rework that is placed into same lot is not treated any differently from repackaging. Rework from a different lot is handled as a mixed raw material and traceable as such.
<b>3.10 Complaint Handling</b>			
<b>3.10</b> <b>Statement of Intent</b>	<b>The company shall have a system for the effective capture, recording and management of product complaints.</b>	<b>Y</b>	The complaint procedure is Customer Complaint Procedure covering the handling, investigation, and documentation of complaints.
3.10.1	All complaints shall be recorded, investigated and the results of the investigation recorded.	<b>Y</b>	All complaints are handled by the on-site Corporate Office.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 30 of 83	Report No: A-00162263	Auditor: Tom Tucker

3.10.2	Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.	<b>Y</b>	Any illness claim complaints and foreign material complaints are thoroughly investigated and forwarded to the plant for review and action.
3.10.3	Complaint data shall be analysed and used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.	<b>Y</b>	Complaint data is summarized, trend analyzed reviewed annually. All complaints are logged onto Customer Complaint Log. I reviewed Log for 2011 and found in order including CAs.
<b>3.11 Management of Incidents, Product Withdrawal and Product Recall</b>			
<b>3.11 Statement of Intent</b>	<b>The company shall have a plan and system in place to effectively manage incidents including product withdrawal and recall procedures.</b>	<b>Y</b>	The company has a comprehensive crisis management procedure to cover all types of incidents and product recall.
3.11.1	The company shall have procedures designed to effectively manage incidents and potential emergency situations that impact food safety, legality or quality and have effective product withdrawal and product recall procedures in place. This may include consideration and contingency planning for business continuity and product withdrawal or recall in the event of the following, although this is not an exhaustive list: <ul style="list-style-type: none"> <li>• disruption to key services such as water, energy, transport, staff availability and communications</li> <li>• events such as fire, flood or natural disaster</li> <li>• malicious contamination or sabotage.</li> </ul>	<b>Y</b>	The company has a formal Crisis Response procedure documents which cover multiple situations and are outlined in a series of documents called Food Defense and Security Program. The document covers disruption of key services, events such as fire and natural disaster, malicious contamination or sabotage.

3.11.2	The company shall provide written guidance to relevant staff regarding the type of event that would constitute an incident or emergency situation that impacts food safety, legality or quality and a documented reporting procedure shall be in place.	<b>Y</b>	Relevant guidance is in place. The procedure defines the types of incident which might occur and details the action to be taken. The procedures are based on the FDA Class I, II and III recall definitions and other incidences.
3.11.3	<p>An incident management procedure shall be documented, implemented and maintained. This shall include as a minimum:</p> <ul style="list-style-type: none"> <li>• identification of key personnel constituting the incident management team with clearly identified responsibilities</li> <li>• an up-to-date list of key contacts, e.g. incident management team, emergency services, suppliers, customers, certification body, regulatory authority</li> <li>• a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner</li> <li>• details of external agencies providing advice and support as necessary, e.g. specialist laboratories, regulatory authority and legal expertise</li> <li>• product withdrawal and/or recall procedures</li> <li>• corrective action and business recovery.</li> </ul>	<b>Y</b>	The current recall procedure is dated Oct 9, 2011, rev 3. It has contact information for all team members, suppliers and regulatory bodies.
3.11.4	The procedures relating to incident reporting, product withdrawal and product recall shall be appropriate, formalised and capable of being operated at any time, and will take into account stock reconciliation, logistics, recovery, storage and disposal. The procedures shall be regularly reviewed and, if necessary, revised.	<b>Y</b>	The protocol was found to be appropriate, formalized and takes into account stock reconciliation, logistics, recovery, storage and disposal.

3.11.5	The product recall and withdrawal procedures shall be regularly tested, at least annually, in a way that ensures their effective operation. Results of the test shall be retained and shall include timings of key activities.	<b>Y</b>	Recall/withdrawal procedures are tested at least 2x/year with the last test being done March 2011 of ingredient Pepperoni Pizza Seasoning – one raw material lot was involved, it was successfully tracked to first distribution and from supplier. The mock recall was completed in less than 35 minutes. Effectiveness was declared as 100%.
3.11.6	The company’s senior management shall ensure that results of this test shall be used to implement improvements as necessary.	<b>Y</b>	Test results are reviewed by management. The procedure calls for the results of the test recall to be used to implement improvements should a problem be identified, however no problems were noted.
3.11.7	In the event of a product recall, the certification body issuing the current certificate for the site against the Global Standard for Food Safety and the appropriate authority shall be informed in a timely manner.	<b>Y</b>	The recall procedure includes certification body notification.
<b>4.0 SITE STANDARDS</b>			
<b>4.1 External Standards</b>			
<b>4.1</b> Statement of Intent	<b>The site shall be of suitable size, location, construction and design to facilitate maintenance, prevent contamination and enable the production of safe and legal finished products.</b>	<b>Y</b>	As delineated in the following clauses the site was found to be of suitable size, location, construction and design to enable the production of food products that is both safe and legal.

4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site from any potential contaminants, they shall be regularly reviewed to ensure they continue to be effective, e.g. dust or odour control.	<b>Y</b>	The factory is located in a light industrial and office site in the City of Columbus, OH and suitably maintained. The boundary is not fenced per city ordinance.
4.1.2	The external areas shall be maintained in good order. Where buildings are surrounded by grassed or planted areas, they shall be regularly tended and well maintained. The condition of the site shall be included within the internal audit process.	<b>Y</b>	All external areas are finished and maintained to an appropriate standard and are minimally planted. Buildings are surrounded by grass or planted areas, and are regularly tended and well maintained. The condition of the site is included within the internal audit process. The truck docks have a cement pad.
4.1.3	Where natural drainage is inadequate, external drainage shall be installed.	<b>Y</b>	Adequate external drainage was observed to have been installed.
4.1.4	External traffic routes, under site control, shall be suitably surfaced and maintained in good repair to avoid contamination of the product.	<b>Y</b>	Surfaces are suitable for the intended use and maintained in satisfactory condition. The product is protected from any contamination arising from external traffic.
4.1.5	The building fabric shall be maintained to minimise potential for product contamination, e.g. pipe work shall be appropriately sealed to prevent pest entry, ingress of water and other contaminants.	<b>Y</b>	The building fabric was observed to be maintained to an acceptable standard to minimize potential of product contamination.
<b>4.2 Security</b>			
<b>4.2</b> Statement of Intent	<b>Security shall be maintained to prevent access of unauthorised persons to production and storage areas.</b>	<b>Y</b>	The site operates a documented site security program. Site security is monitored daily.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 34 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.2.1	Access to the site by employees, contractors and visitors shall be controlled and a visitor reporting system shall be in place.	<b>Y</b>	The plant is securely enclosed with electronically controlled doors. Signs are posted directing all visitors to report to the office, once there they are required to sign a visitor log.
4.2.2	Staff shall be trained in site security procedures and encouraged to challenge unidentified or unknown visitors.	<b>Y</b>	As part of induction training the site staff are instructed to challenge unfamiliar visitors.
4.2.3	Measures shall be in place to maintain site security and to ensure only authorised staff have access to production and storage areas via designated access points. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled.	<b>Y</b>	Building access points are controlled by locked doors. The machinist shop is designated restricted access, as is the lab. The chemical storage is in a secure area within the plant parameter. There is a controlled access waiting area for truck drivers. There are external cameras covering shipping and main facility entrance. There are internal cameras in each processing rooms. The cameras are on a continual record loop.
4.2.4	Based on risk assessment, procedures shall be in place to ensure the secure storage of all materials including ingredients, packaging, chemicals and equipment.	<b>Y</b>	The cleaning compounds are stored in a locked designated area, away from the production area.
4.2.5	Procedures shall be in place to ensure that finished product is held under secure storage and transportation conditions, e.g. tamper evident packing, contractual handling agreements.	<b>Y</b>	All finished products are stored with limited access. Full loads are shipped in sealed trucks, which are loaded on site and closed with a numbered single use seal.
4.2.6	Where required by legislation, the site shall be registered with, or approved by, the appropriate authority.	<b>Y</b>	The site is registered with the US FDA under the Bioterrorism Act of 2002 and has a registration number which is confidential.

**4.3 Internal Site Standards**

**4.3.1 Layout, Product Flow and Segregation**

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 35 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

<b>4.3.1</b> <b>FUNDAMENTAL</b> <b>Statement of Intent</b>	<b>Premises and plant shall be designed, constructed and maintained. Procedures shall be in place to control the risk of product contamination and to comply with all relevant legislation.</b>	<b>Y</b>	The plant audit confirmed it was designed, constructed and maintained to control the risk of product contamination and comply with all relevant legislation.
4.3.1.1	The process flow from intake to dispatch shall be arranged to minimise the risk of product contamination.	<b>Y</b>	The product flow is straight line, with no crossing of the finished product with the raw or intermediate processed products.
4.3.1.2	Physical barriers or demonstrably effective procedures shall be in place to minimise the risk of the contamination of raw materials, intermediate/semi-processed products, packaging and finished products with particular consideration given to handling requirements for specific materials (refer to clause 5.2).	<b>Y</b>	There is effective segregation in place between operations, including physical barriers, segregated areas and appropriate and effective procedures.
4.3.1.3	Segregation shall take into account the flow of product, nature of materials, equipment, personnel, waste, airflow, air quality and utilities provision.	<b>Y</b>	The flow of product, nature of materials, equipment, personnel, waste, airflow, air quality and utilities are used to control any contamination.
4.3.1.4	Based on risk assessment, the cleaning of production utensils shall be carried out in segregated areas or at specific time periods separated from the production process.	<b>Y</b>	Utensils are cleaned in an area separated from the production areas by sufficient space to prevent cross contamination.
4.3.1.5	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.	<b>Y</b>	There is sufficient space to enable all operations to be carried out properly under safe hygienic conditions.
4.3.1.6	Cleaning and inspection of areas and equipment shall be aided by the avoidance of obstructions and where appropriate the provision of adequate space.	<b>Y</b>	There is sufficient cleaning and inspection space provided throughout the facility.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 36 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.3.1.7	Temporary structures constructed during building work or refurbishment, etc., shall be designed and located to avoid pest harbourage and potential contamination of products.	<b>NA</b>	No temporary structures were observed.
4.3.1.8	The location of all transfer points shall not compromise high-risk and low-risk segregation and practices shall be in place to minimise risk of product contamination, e.g. disinfection.	<b>NA</b>	There are no high-risk products produced.
4.3.1.9	Where <b>high-risk products</b> (refer to glossary) are manufactured, there shall be physical segregation between processing and finished product handling areas. This high risk area shall be fabricated and designed to a high standard of hygiene, and practices shall be in place to control ingredients, equipment, packaging, environment and personnel to prevent product contamination.	<b>NA</b>	There are no high-risk products produced.
4.3.1.10	In <b>high-care areas</b> (refer to glossary) where there is a significant risk of contamination of chilled ready to eat/heat products by pathogenic micro-organisms, the processing or handling of food in these areas shall be appropriate to minimise product contamination by such micro-organisms.	<b>NA</b>	There are no high-care areas of facility.
<b>4.3.2 Building Fabric – Raw Material Handling, Preparation, Processing, Packing and Storage Areas</b>			
<b>4.3.2</b> Statement of Intent	<b>The fabrication of the site, buildings and facilities shall be suitable for the intended purpose.</b>	<b>Y</b>	The fabric of the facility observed was suitable for its intended purpose.
<b>4.3.2.1 Walls</b>			

4.3.2.1.1	Walls shall be designed, constructed, finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.	<b>Y</b>	The walls of the facility observed were suitable for its intended purpose.
<b>4.3.2.2 Floors</b>			
4.3.2.2.1	Floors shall be designed to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious and maintained in good repair.	<b>Y</b>	The floors of the facility observed were suitable for its intended purpose and in good repair.
4.3.2.2.2	Drainage, including drains from laboratories, where provided, shall be sited, designed and maintained to minimise risk of product contamination and not compromise product safety. Machinery and piping shall be arranged so that, wherever feasible, process waste water goes directly to drain.	<b>Y</b>	The stainless steel drains are in good condition and appeared adequate.
4.3.2.2.3	Where significant amounts of water are used, or direct piping to drain is not feasible, floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage.	<b>Y</b>	Floors in all areas have adequate falls towards the drains.
<b>4.3.2.3 Ceilings/Overheads</b>			
4.3.2.3.1	Ceilings and overheads shall be designed, constructed, finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.	<b>Y</b>	Ceilings are satisfactory. They generally are corrugated iron. The ceilings were high for ventilation and equipment placement. The ceilings in production are white vinyl laminate. Ceilings and overheads are designed, constructed, finished and maintained to prevent the accumulation of dirt, minimize condensation and mold growth, and facilitate cleaning.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 38 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.3.2.3.2	Where suspended ceilings are used, adequate access to the void shall be provided to facilitate cleaning, maintenance of utilities and inspection for pest activity.	<b>Y</b>	The false ceilings in production are accessible to facilitate inspection and cleaning.
<b>4.3.2.4 Windows</b>			
4.3.2.4.1	Where there is a risk to product, windows and roof glazing which are designed to be opened for ventilation purposes shall be adequately screened to prevent the ingress of pests.	<b>Y</b>	There are no externally opening windows in production and storage areas.
4.3.2.4.2	Where they pose a risk to product, glass windows shall be protected against breakage.	<b>NA</b>	There are no windows in processing area.
<b>4.3.2.5 Doors</b>			
4.3.2.5.1	Where external doors to raw material handling, preparation, processing, packing and storage areas are opened, suitable precautions shall be taken to prevent pest ingress. Doors and dock levellers in these areas shall be close fitting or adequately proofed.	<b>Y</b>	All doors observed are tight fitting. Dock levellers are secure.
4.3.2.5.2	Doors shall be in good condition and easy to clean, where required.	<b>Y</b>	All doors observed were in good condition.
<b>4.3.2.6 Lighting</b>			
4.3.2.6.1	Suitable and sufficient lighting shall be provided for a safe working environment, correct operation of processes, inspection of product, and effective cleaning.	<b>Y</b>	The light levels throughout the factory were observed to be adequate.

4.3.2.6.2	Where they constitute a risk to product, bulbs and strip lights, including those on electric fly-killer devices, shall be adequately protected. Where full protection cannot be provided, alternative management such as wire mesh screens or monitoring procedures shall be in place.	<b>Y</b>	Where they constituted a risk to product all lights and EFK tubes were noted to be suitably protected against breakage.
<b>4.3.2.7 Air Conditioning/Ventilation</b>			
4.3.2.7.1	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.	<b>Y</b>	Ventilation and extraction throughout the site is satisfactory. There were no signs of off odors or condensate in the facility.
4.3.2.7.2	Where the process requires screened or filtered air, the equipment used for this purpose shall be easily accessible and adequately maintained.	<b>Y</b>	The process requires filtered air. The equipment used for this purpose shall be easily accessible and adequately maintained.
4.3.2.7.3	Where appropriate, positive air-pressure systems shall be in place.	<b>Y</b>	Positive air pressure is used in this process.
<b>4.4 Utilities</b>			
<b>4.4 Statement of Intent</b>	<b>All utilities to and within the production and storage areas shall be designed, constructed, maintained and monitored to control the risk of product contamination.</b>	<b>Y</b>	Service provision is of satisfactory design and suitably maintained. All water is drawn from the City of Columbus water mains. The site monitors that utility's website where a required posting of microbiological and chemical testing is found. Water is not used in processing. No steam is utilized in processing. Electrical supply is from the local power company.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 40 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.4.1	All water used as a raw material in the manufacture of processed food, the preparation of product, or for equipment or plant cleaning shall be supplied in sufficient quantity, be potable or pose no risk of contamination according to applicable legislation, either being drawn from mains supply or suitably treated according to its source.	<b>Y</b>	Only municipal water is used on site. During the audit we reviewed report sent to outside lab of September 2011 and city report from 2010. The result from outside lab indicated no coliform from sites in sanitation room and one blending room.
4.4.2	Based on risk assessment, the microbiological and chemical quality of water, steam, ice, air, compressed air or other gases that does not constitute an ingredient but comes in direct contact with food or packaging shall be regularly monitored. It shall present no risk to product safety or quality and comply with relevant legal regulations.	<b>Y</b>	Based on risk assessment, the water used is not a potential micro hazard. The site does not utilize any ice.
<b>4.5 Equipment</b>			
<b>4.5</b> <b>Statement of Intent</b>	<b>Equipment shall be suitably designed for the intended purpose and shall be used to minimise the risk of contamination of product.</b>	<b>Y</b>	All equipment is of suitable design for the process and used correctly so as to minimize risk of contamination. The major equipment includes four mixer-blender and two metal detectors.
4.5.1	All equipment shall be properly specified before purchase, constructed of appropriate materials, be of a suitable design to ensure it can be effectively cleaned, and shall be tested and commissioned prior to use.	<b>Y</b>	New equipment is fully specified and commissioned prior to use under procedure. A new equipment team is used to certify and approve equipment after placement.

4.5.2	Equipment shall be positioned to give access under, inside and around it for ease of cleaning, inspection and servicing, or where permanently sited shall be properly secured and sealed to the floor.	<b>Y</b>	Portable equipment is positioned to give access for cleaning. All permanently sited equipment is sealed to the floor or on moveable rails.
4.5.3	Certificates of conformity or other evidence shall be available for equipment in direct contact with food to confirm its suitability for use, e.g. conveyor belts.	<b>Y</b>	The site has certificates of conformity for all materials with direct contact with food confirming its suitability for use. All product contact equipment is stainless steel.
<b>4.6 Maintenance</b>			
4.6 Statement of Intent	<b>A documented system of planned maintenance shall be in place, covering all items of equipment and plant which are critical to product safety, legality and quality.</b>	<b>Y</b>	A maintenance program is manually based system of planned maintenance covering all items of equipment critical to product safety, legality and quality. Maintenance is mainly carried out by the company's own mechanics with the use of outside specialist contractors as required.
4.6.1	Equipment, including fixtures and fittings, shall be maintained to minimise the risk of product contamination.	<b>Y</b>	All equipment observed appeared properly maintained with no obvious risks of product contamination.
4.6.2	When commissioning new equipment and plant, a maintenance programme shall be established and put into place based on risk assessment.	<b>Y</b>	The new Zebra ZM 400 Labeler was installed and commissioned August 2011.
4.6.3	The company shall ensure that the safety or legality of product is not jeopardised during maintenance and cleaning operations.	<b>Y</b>	Preventative Maintenance is scheduled for off shift time periods.

4.6.4	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment failure, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.	<b>Y</b>	The company has a in-line metal detectors. The plant engineer is trained to make required adjustments.
4.6.5	Where temporary repairs are made, these shall be controlled to ensure the safety or legality of product is not jeopardised. These temporary measures shall be permanently repaired as soon as practicable and within a defined timescale.	<b>Y</b>	Temporary repairs are not allowed by policy. There were no temporary repairs noted during audit.
4.6.6	Contractors involved in maintenance or repair activities shall be under the supervision of a nominated person.	<b>Y</b>	Contractors are under the general supervision of the Corporate Engineer for the facility where they are working.
4.6.7	Maintenance work shall be followed by a documented hygiene clearance procedure, which records that product contamination hazards have been removed from machinery and equipment. On completion of any maintenance work, machinery and equipment shall be clean and free from contamination hazards.	<b>Y</b>	There is a formal checklist which must be completed after any maintenance before the line is released back to production. It includes accounting for parts, tools and cleaning and must be signed by the mechanic.
4.6.8	Materials used for equipment and plant maintenance and that pose a risk by direct or indirect contact with raw materials, intermediate and finished products, such as lubricating oil and paints, shall be suitable for the intended use.	<b>Y</b>	All lubricants used in the food production areas are food grade. MSDS documentation was in place for all items. Food grade lubricants are segregated and secure.
4.6.9	Engineering workshops shall be controlled to prevent contamination risks to the product, e.g. provision of swarf mats where workshops open directly into production areas.	<b>Y</b>	Workshops do not open directly onto the production areas.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 43 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.7 Staff Facilities			
4.7	<b>Statement of Intent</b>		
	<b>Staff facilities shall be sufficient to accommodate the required number of personnel, and shall be designed and operated to minimise the risk of product contamination. Such facilities shall be maintained in good and clean condition.</b>	<b>Y</b>	The staff facilities observed appeared sufficient to accommodate the plant personnel, they were in good working and clean condition.
4.7.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly, e.g. the provision of cleaning facilities for footwear.	<b>Y</b>	Changing facilities have been provided for all personnel entering production, packing and storage areas. The changing areas are located within the building. The facility does have a captive shoe program.
4.7.2	Storage facilities of sufficient size to accommodate all reasonable personal items shall be provided for all personnel who work in raw material handling, processing, preparation, packing and storage areas.	<b>Y</b>	There are lockers for both male and female staff for personal items.
4.7.3	Outdoor clothing and other personal items shall be stored separately from work wear within the changing facilities.	<b>Y</b>	No mixing of work wear and personal items and outdoor clothing was noted.

4.7.4	<p>Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-wash facilities shall provide as a minimum:</p> <ul style="list-style-type: none"> <li>• sufficient quantity of water at an appropriate temperature</li> <li>• liquid soap</li> <li>• single use towels or suitably designed and located air driers</li> <li>• appropriate instructions for use (including consideration of appropriate language).</li> </ul> <p>Where <b>high-risk products</b> (refer to glossary) are handled, the following additional requirements shall be provided:</p> <ul style="list-style-type: none"> <li>• water taps with hand-free operation</li> <li>• hand disinfection.</li> </ul>	Y	<p>Entry from wash rooms for staff into the production areas is through the locker rooms which adjoin the restrooms which were observed to be equipped as per standard. The washrooms have sufficient temperature and water pressure, liquid disinfectant soap, single use towels and hand wash instructions.</p>
4.7.5	<p>Toilets shall be adequately segregated and shall not open directly into storage, processing or production areas. Toilets shall be provided with hand washing facilities comprising:</p> <ul style="list-style-type: none"> <li>• basins with soap and water at a suitable temperature</li> <li>• adequate hand-drying facilities</li> <li>• advisory signs to prompt hand washing (including consideration of appropriate language).</li> </ul> <p>Where hand-washing facilities within toilets are the only ones provided before re-entering production, then the requirements of 4.7.4 shall apply.</p>	Y	<p>Toilets are situated outside the production and storage areas. They were observed to be equipped as required by the clause.</p>

<p>SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com</p>			
Issue 6_2007 EFSIS-13.10F	Page 45 of 83	Report No: A-00162263	Auditor: Tom Tucker

This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd

4.7.6	Designated controlled smoking areas shall be isolated from production areas to an extent that ensures smoke cannot reach the product. Where smoking is allowed under national law, sufficient extraction to the exterior of the building shall be ensured. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations. Facilities shall be available, with adequate reminders, for hand washing after smoking.	<b>Y</b>	The entire plant is designated non-smoking. Smoking is allowed off-site of the facility.
4.7.7	All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas.	<b>Y</b>	There is a break room but no food is provided other than vending machines. Microwaves are provided for staff use and refrigerators are present for chilled storage of food brought by staff.
4.7.8	Where catering facilities are provided, they shall be suitably controlled to prevent contamination of product.	<b>NA</b>	The site does not have a catering facility.
4.7.9	Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.	<b>Y</b>	Any food items consumed outside during breaks must be consumed in designated areas. Break areas for staff were observed to have appropriate trash receptacles present.
4.7.10	Facilities for visitors and contractors shall be such as to enable compliance with the company's hygiene policy.	<b>Y</b>	Visitors and contractors use the staff facilities.
4.7.11	Where an operation involving <b>high-risk products</b> (refer to glossary) exists, personnel shall enter via a specially designated changing facility, and shall follow specified procedures for applying visually distinctive clean overalls, headwear and footwear.	<b>NA</b>	The product is not considered high-risk.
<b>4.8</b>	<b>Chemical and Physical Product Contamination Control, Raw Material Handling, Preparation, Processing, Packing and Storage Areas</b>		

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 46 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

<b>4.8</b> Statement of Intent	<b>Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product.</b>	<b>Y</b>	As noted in the following observations generally appropriate facilities and procedures were observed to be in place to control the risk of chemical or physical contamination of the product.
4.8.1	Based on risk assessment, the company shall identify, control and manage any potential risks from chemical, physical or taint contamination. This may include risks associated with the following, although this is not an exhaustive list: <ul style="list-style-type: none"> <li>• storage</li> <li>• production operation or processes or machinery</li> <li>• any maintenance or building work carried out</li> <li>• hygiene and cleaning operations.</li> </ul> These shall be verified through regular site audits carried out at a frequency determined by risk assessment.	<b>Y</b>	The HACCP Plan addresses the potential chemical and physical risks. Most are handled through the site's SSOPs and noted on the various sanitation inspections. The chemicals have a controlled storage area.
<b>4.8.2 Chemical Control</b>			

4.8.2.1	<p>A chemical control procedure shall be in place which manages the use, storage and handling of non-food chemicals. This shall include as a minimum:</p> <ul style="list-style-type: none"> <li>• approved purchase</li> <li>• availability of material safety data sheets and specifications</li> <li>• where appropriate, confirmed suitability for food use</li> <li>• avoidance of strong scented products</li> <li>• identification of chemicals at all times</li> <li>• segregated and secure storage with restricted access to authorised personnel</li> <li>• use by trained personnel only.</li> </ul>	<b>Y</b>	<p>All food contact chemicals must be listed on the approved compound list provided by the Corporate office, MSDS sheets are maintained for all chemicals handled at the site, chemicals are stored in identified restricted access areas. All chemical containers are identified. The chemicals are stored away from raw materials, packaging and finished product.</p>
<b>4.8.3 Metal Control</b>			
4.8.3.1	<p>There shall be a documented policy for the control of the use of sharp metal implements including knives, cutting blades on equipment, needles and wires. This shall include suitable controls both into and out of the factory, and safe disposal.</p>	<b>Y</b>	<p>The site has controls on knives which are used to open bags. There is a log maintained. Suitable controls of knives, both into and out of the factory, and safe disposal.</p>
4.8.3.2	<p>Snap-off blade knives shall not be used.</p>	<b>Y</b>	<p>Snap-off knives are not allowed at the site.</p>
4.8.3.3	<p>Non-production blades, equipment and tools shall not be left in a position that allows them to contaminate the product.</p>	<b>Y</b>	<p>No issues were noted during the audit.</p>
4.8.3.4	<p>Where staples or other items are used which are likely to cause contamination in packaging, appropriate precautions shall be taken to minimise the risk of product contamination.</p>	<b>NA</b>	<p>No staples are utilized by the site in non-office areas.</p>

<p>SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX          Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com</p>			
Issue 6_2007 EFSIS-13.10F	Page 48 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.8.4 Glass, Brittle and Hard Plastic, Ceramics and Similar Materials			
4.8.4.1	In areas where a risk assessment has identified a potential for product contamination from glass, the presence of glass shall be excluded. Where this cannot be avoided, but the risk is managed, glass shall be protected against breakage.	<b>Y</b>	A glass/hard plastic risk assessment has been conducted as part of HACCP and GMPs. The entire production area is a glass controlled area. All glass items in the exposed product areas which cannot be avoided such as lights are protected from breakage.
4.8.4.2	<p>Documented procedures for handling glass, brittle or hard plastic, ceramic or other similar materials shall be in place and implemented to ensure that necessary precautions are taken. Procedures shall include as a minimum:</p> <ul style="list-style-type: none"> <li>• list of items detailing location, number, type and condition</li> <li>• recorded checks of condition of items carried out at a specified frequency based on risk assessment</li> <li>• details on cleaning or replacing items to minimise potential for product contamination.</li> </ul>	<b>Y</b>	The site has an extensive glass/plastic register, and most items challenged were listed on it. Any unprotected glass items above exposed foods is audited daily as part of sanitation inspection. Protected or shatterproof items located in exposed food areas are audited monthly. Areas audited include production, caged areas, lab, restrooms and warehousing.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 49 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.8.4.3	<p>Based on risk assessment, documented procedures detailing the action to be taken in case of breakage of glass, brittle or hard plastic, which includes glass packaging and similar material, shall be implemented and include the following:</p> <ul style="list-style-type: none"> <li>• quarantining the products and production area that were potentially affected</li> <li>• cleaning the production area</li> <li>• inspecting the production area and authorising to continue production</li> <li>• changing of work wear and inspection of footwear</li> <li>• specifying those staff authorised to carry out the above points</li> <li>• recording the breakage incident.</li> </ul>	<b>Y</b>	<p>A comprehensive glass and brittle material breakage procedure, HACCP Glass, Brittle and Hard Plastic, Ceramics and Wood Policy is in place which designates QA to sign-off on cleaning, inspecting, clothes changing, product quarantine, footwear cleaning and record keeping. Monthly Glass/Brittle Plastic Audits are conducted. I reviewed audit for October 4, 2011.</p>
<b>4.8.5 Wood</b>			
4.8.5.1	<p>In areas where a risk assessment has identified the potential for product contamination from wood, the use of wood shall be excluded. Where the use of wood cannot be avoided, and the risk is managed, the condition of wood shall be regularly checked to ensure it is in good condition and clean.</p>	<b>Y</b>	<p>The use of wood has been minimized. Wood Pallets are used in both the incoming and outgoing shipping areas. Wooden pallets are used in processing if kept below the top of any blending equipment. Plastic pallets are used in areas above top of blending equipment.</p>
<b>4.8.6 Other</b>			
4.8.6.1	<p>Filters, sieves and magnets used for foreign body control shall be regularly inspected and properly maintained. Such activities shall be recorded and investigated.</p>	<b>Y</b>	<p>Filters are used in each blender and are inspected each time there is a product change. Magnets are used in each blender and are inspected each time there is a product change.</p>

4.8.6.2	Based on risk assessment, procedures shall be implemented to minimise foreign body contamination of packaging during filling operations, e.g. covered conveyors, container inversion and foreign body removal through rinsing or air jets.	<b>Y</b>	The filling lines are maintained in a closed system to minimize potential contamination.
<b>4.9 Housekeeping and Hygiene</b>			
<b>4.9</b> <b>FUNDAMENTAL</b> <b>Statement of Intent</b>	<b>Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of contamination is minimised.</b>	<b>Y</b>	Satisfactory standards of hygiene and housekeeping were seen during the audit. Systems are in place to ensure appropriate standards of hygiene are maintained at all times and that risk of contamination is minimized. Cleaning is carried out by operatives during shift and by an outside company on third shift for heavy cleaning of equipment, structure and break room. Cleaning is COP.
4.9.1	Documented cleaning procedures shall be in place and maintained for the building, utilities, plant and all equipment. Cleaning procedures shall include the following information as a minimum: <ul style="list-style-type: none"> <li>• responsibility for cleaning</li> <li>• item/area to be cleaned</li> <li>• frequency of cleaning</li> <li>• method of cleaning</li> <li>• cleaning materials to be used</li> <li>• cleaning records and responsibility for verification.</li> </ul>	<b>Y</b>	Appropriate cleaning schedules are followed. The site washes between batches and undergoes a thorough cleaning and sanitation on the third shift. The SSOPs for each piece of food contact equipment is available from Coalescence and Kaiser's Contract Cleaning Specialists. The SSOPs cover all sections of the clause. I reviewed daily cleaning reports for October 2011.

4.9.2	Cleaning-in-place (CIP) facilities shall be monitored and maintained to ensure effective operation. Consideration shall be given to frequency, cycle time, temperature, chemical concentration and spray ball location and coverage. CIP shall have adequate separation from active product lines.	<b>NA</b>	The site does not have any CIP facilities.
4.9.3	Cleaning and housekeeping shall be carried out by trained personnel in accordance with documented procedures and records shall be maintained.	<b>Y</b>	Training for records are maintained by Operations Manager and Kaiser's in SSOPs were available for review by auditor.
4.9.4	Cleaning chemicals and equipment shall be: <ul style="list-style-type: none"> <li>• fit for purpose</li> <li>• suitably identified for intended use, e.g. colour coded or labelled</li> <li>• stored in a hygienic manner to prevent contamination.</li> </ul>	<b>Y</b>	Cleaning chemicals are all designed for food factory use and stored and used appropriately, being fully labeled, held in closed containers and used in accordance with manufacturers instructions.
4.9.5	The effectiveness of the cleaning and disinfection procedures shall be verified and recorded. Corrective actions shall be documented.	<b>Y</b>	All food contact surfaces are disinfected prior to use by the application of either a quaternary ammonium or chlorine terminal sanitizer. This is verified by ATP checks conducted after the daily clean-ups. The effectiveness of the cleaning and sanitation procedures are verified by hygiene audits inspections; any deficiencies are recorded and corrected prior to start-up.
4.9.6	Cleaning and disinfection procedures shall be revalidated following building or maintenance work, new product introduction or changes to equipment.	<b>Y</b>	The procedures call for revalidation following building or equipment changes.

**4.10 Waste/Waste Disposal**

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 52 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

<b>4.10</b> <b>Statement of Intent</b>	<b>There shall be adequate systems for the collection, collation and disposal of waste material.</b>	<b>Y</b>	Suitable and sufficient systems are in place for the collection, collation, and disposal of waste.
4.10.1	Systems shall be in place to avoid the accumulation of waste in production areas, and shall prevent the use of unfit materials.	<b>Y</b>	Waste is removed from production areas regularly by the hygiene team utilizing dry capture in totes as well as a floor drain system. Internal waste containers are clearly identified to prevent the accidental use of unfit materials.
4.10.2	Where appropriate, waste shall be categorised according to legislative requirements based on the intended means of disposal, segregated and collected in appropriate designated waste containers.	<b>NA</b>	The waste is not categorized and is considered non-edible.
4.10.3	Waste disposal shall meet legislative requirements. Where licensing is in operation for disposal of categorised waste, it shall be removed by licensed contractors and records of disposal shall be maintained and available for audit.	<b>Y</b>	Waste disposal meets legislative requirements. General garbage is removed by licensed contractors.
4.10.4	External waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be: <ul style="list-style-type: none"> <li>• clearly identified</li> <li>• designed for ease of use and effective cleaning</li> <li>• well maintained to allow cleaning and where required, disinfection</li> <li>• emptied at appropriate frequencies</li> <li>• covered or doors kept closed as appropriate.</li> </ul>	<b>Y</b>	External waste collection containers are well managed and removed frequently to prevent the attraction of pests and the surrounding area kept clean and free from spillage.

4.10.5	If substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in secure product or waste disposal and shall provide records of material destruction or disposal.	<b>NA</b>	They do not have trademarked material.
<b>4.11 Pest Control</b>			
<b>4.11</b> Statement of Intent	<b>The company shall be responsible for minimising the risk of pest infestation on the site.</b>	<b>Y</b>	The company is responsible for minimizing the risk of pest infestation on the site; from the records seen there appears to be no ongoing problem with pests on the site.
4.11.1	A preventive pest control programme shall be maintained covering all areas of the site to minimise pest infestation.	<b>Y</b>	As noted in the following clauses the company's pest control program was shown to cover all areas of the site to minimize pest infestation.
4.11.2	The company shall either contract the services of a competent pest control organisation, or shall have appropriately trained staff, for the regular inspection and treatment of the site to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. Where the services of a pest control contractor are employed, the service contract shall be clearly defined and reflect the activities of the site.	<b>Y</b>	The company employs the services of a pest control company which is responsible for the control of rodents, flying and crawling insects. The contract calls for, and records indicate, twice monthly interior and exterior. The contract company is Ehrlich Pest Control. The contract company is responsible for changing bulbs on light traps.

4.11.3	<p>Written procedures and inspection documentation shall be maintained. This shall include as a minimum:</p> <ul style="list-style-type: none"> <li>• an up-to-date, signed and authorised site plan identifying numbered pest control device locations</li> <li>• identification of the baits and/or monitoring devices on site</li> <li>• clearly defined responsibilities for site management and the contractor</li> <li>• details of pest control products used and instructions for their effective use.</li> </ul>	<b>Y</b>	<p>A plan of all site pest control measures including external bait stations is available and up to date. The site map is dated October 6, 2011. Position of internal traps 25, 17, 14, 41, 22 and external bait stations 3, 5 and 6 were checked against site plan during audit and found to be correct.</p> <p>The use of poison baits is limited to the exterior only. MSDS data is available and records of application are maintained for baits and other pest control chemicals.</p>
4.11.4	Bait stations shall be robust, of tamper resistant construction, secured in place and appropriately located to prevent contamination risk to product.	<b>Y</b>	The bait stations were observed to be secured in place.
4.11.5	Fly-killing devices and/or pheromone traps shall be correctly sited and operational. If there is a danger of insects being expelled from any extermination device and contaminating the product, alternative systems and equipment shall be used.	<b>Y</b>	The site has two electric fly killers with glue boards sited in waste collection area.
4.11.6	In the event of infestation, immediate action shall be taken to eliminate the hazard. Action shall be taken to identify, evaluate and authorise the release of any product potentially affected.	<b>Y</b>	There was no indication of major infestation on the monitoring records and no signs observed of any pests were noted during the plant tour.

4.11.7	Detailed records of pest control inspections, recommendations and actions taken shall be maintained. It shall be the responsibility of the company to ensure all of the relevant recommendations made by their contractor or in-house expert are carried out and monitored. The completion of corrective action shall be demonstrated by documented evidence.	Y	The facility reacts positively to any noted recommendations from pest control contractor. The pest control contractor and QA note the completion of corrections.
4.11.8	Results of pest control inspections shall be assessed and analysed for trends regularly, but as a minimum: <ul style="list-style-type: none"> <li>• in the event of an infestation</li> <li>• annually.</li> </ul> This shall include a catch analysis from trapping devices to identify problem areas. Any such problems shall be suitably rectified.	Y	Detailed records are kept of inspections and treatments, with actions and recommendations being completed and signed off.
<b>4.12 Storage and Transport</b>			
4.12 Statement of Intent	<b>All facilities used for the storage and transportation of product, movement around the site, and dispatch of finished product shall be suitable for the purpose, maintained in good repair and in a hygienic condition.</b>	Y	The facilities used for storage and transport were suitable for the purpose, maintained in good repair and hygienic conditions as noted in the following clauses.

4.12.1	<p>Procedures to maintain product safety and quality during storage, loading and transportation shall be developed on the basis of risk assessment and implemented accordingly. These may include as appropriate the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> <li>• controlling temperature</li> <li>• cleaning storage areas and vehicles</li> <li>• segregating to avoid cross contamination or taint uptake</li> <li>• storing materials off the floor and away from walls as appropriate</li> <li>• ensuring that vehicles such as bulk tankers are of hygienic design and designated for food use; putting in place procedures to prevent cross contamination from previous loads</li> <li>• vehicle pre-loading and unloading inspection</li> <li>• vehicle loading or unloading in covered bays</li> <li>• maintaining product security and preventing damage.</li> </ul>	<b>Y</b>	<p>Packaging material and raw materials are stored in racks away from the walls allowing for proper inspection and cleaning. All finished product in the scope is stored at ambient conditions. Packaging and raw materials are stored at ambient conditions. The site receives all its raw materials by truck and it does an incoming trailer check as well as a preloading trailer inspection. The shipping containers are not loaded in covered bays, but have rubber dock seals to protect product.</p>
4.12.2	<p>Where temperature control is required, the storage area or transport facility shall be capable of maintaining product temperature within specification, under minimum and maximum load and under worst case ambient temperature. Storage areas shall be dry and well ventilated.</p>	<b>Y</b>	<p>A few raw materials are stored in a refrigerated trailer backed-up to warehouse door. The trailer is maintained between 30-50F. The temperature is verified daily and recorded. The recorded temperature for 12-Oct-2011 was 42F. The trailer is emptied, inspected and cleaned, if necessary on a monthly schedule.</p>

<p>SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com</p>			
Issue 6_2007 EFSIS-13.10F	Page 57 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.12.3	Where temperature control is required, documented procedures shall be in place to ensure product temperature requirements are met. This shall include temperature data-logging devices which can be interrogated to confirm time/temperature conditions <b>or</b> a system to verify and record at predetermined frequencies the correct operation of refrigeration equipment.	<b>Y</b>	There are no temperature controls required in shipping of finished product.
4.12.4	Where storage outside is necessary, items shall be protected from contamination and deterioration.	<b>NA</b>	No outside storage is used for raw materials, WIP, finished product or packaging.
4.12.5	Receipt documents and/or product identification shall facilitate correct stock rotation of goods in storage and ensure materials are used in the correct order and within the prescribed shelf life.	<b>Y</b>	All incoming ingredients receive an inspection, details of which vary depending on the nature of the item. Each pallet receives an identification tag noting its status and where appropriate, shelf life, a Use by Date calculated from the date of manufacture and allergen status.
4.12.6	Where the company employs third-party contractors, all the requirements specified in this section shall be clearly defined in the contract or the company shall be certificated to the <b>Global Standard for Storage and Distribution</b> .	<b>Y</b>	The site does has responsibility for choice of transportation company. They arrange shipments from a list of contractors supplied by the customer. The ownership of the product changes at the time the driver signs acknowledging receipt of each load.
4.12.7	Traceability shall be ensured during storage and transportation. There shall be a clear record of dispatch and receipt of goods and materials demonstrating that sufficient checks have been completed during the transfer of goods.	<b>Y</b>	Traceability is maintained starting at receipt, during storage and at time of dispatch as was demonstrated in the traceability challenge.
4.12.8	Documented maintenance and hygiene procedures shall be maintained for all vehicles and equipment used for loading/unloading (e.g. hoses of silo installations). There shall be records of the measures taken.	<b>NA</b>	There is no bulk receiving or shipping.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 58 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

4.12.9	Procedures shall, where appropriate, be in place in the case of vehicle or refrigeration equipment breakdown. All incidents of vehicle or refrigeration equipment breakdown shall be recorded and corrective action documented.	<b>Y</b>	The product is stable and alternative transport would be provided.
<b>5.0 PRODUCT CONTROL</b>			
<b>5.1 Product Design/Development</b>			
<b>5.1</b> Statement of Intent	<b>Product design and development procedures shall be in place to ensure manufacturing processes are capable of producing a safe and legal product.</b>	<b>Y</b>	All new product development is controlled by the Corporate Office and custom pack clients.
5.1.1	A HACCP-based study shall be part of the product design and development process.	<b>Y</b>	The NPD procedure includes a review of the HACCP for all new products. The company has a dedicated team manning this department.
5.1.2	Production trials shall be carried out and thorough testing shall validate that product formulation and manufacturing processes are capable of producing a safe and legal product against the proposed shelf life.	<b>Y</b>	Factory trials are carried out for all new products and, where appropriate, and for recipe changes.
5.1.3	Shelf-life trials shall be undertaken using documented protocols reflecting conditions during storage and handling throughout shelf life. Results shall be recorded and retained and shall confirm compliance with relevant microbiological, chemical and organoleptic criteria.	<b>Y</b>	Shelf life studies are conducted by technical service. This includes micro studies.
5.1.4	Where new products are introduced, the company shall ensure control of handling requirements for specific materials (refer to clause 5.2).	<b>Y</b>	Allergen content is considered when conducting NPD.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 59 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

5.1.5	Procedures shall be in place to confirm that product packaging conforms to relevant food safety legislation and specification and is suitable for its intended use.	<b>Y</b>	New products are based on existing formulas and utilize existing containers. Letters of conformity are required of all packaging providers covering the intended marketing country.
5.1.6	The company's senior management shall ensure that a system is in place to confirm that labelling of the product or other forms of customer information meets legislation for the designated country of use and in accordance with the appropriate product specification.	<b>Y</b>	The QA & R&D department check all pack copy and art work before printing.
5.1.7	Where a product is designed to enable a claim to be made to satisfy a consumer group, e.g. a nutritional claim of reduced sugar, the company shall ensure that the product formulation and production process is fully validated to meet the stated claim.	<b>NA</b>	They do not make any nutritional claims.
5.1.8	The product design/development process shall be documented and effectively communicated throughout the organisation, to ensure that changes in formulation are adequately assessed for safety and legality.	<b>Y</b>	The NPD procedure covers both new products and recipe changes. Records are maintained of product development to demonstrate that changes are adequately assessed for safety and legality. All changes to recipe are entered in the computer. Operation receives recipe from formulation cards. QA is responsible for ensuring the correct recipe is used.

**5.2 Handling Requirements for Specific Materials – Materials Containing Allergens and Identity Preserved Materials**

5.2 <b>FUNDAMENTAL</b> Statement of Intent	<b>Where raw materials and finished products require special procedures for handling specific materials (e.g. material containing allergens or the requirement for Identity Preserved status such as Genetically Modified Organisms, assured organic status or special designated origin) these shall be in place to ensure that product safety, legality and quality are maintained.</b>	<b>Y</b>	The allergens in raw materials and finished products are all reviewed and identified.
<b>5.2.1 Materials Containing Allergens</b>			
5.2.1.1	The company shall carry out risk assessment of raw materials to establish the presence and likelihood of contamination by <b>allergens</b> (refer to glossary). This shall include approval of raw material specifications. The company shall implement systems to specify the integrity of the raw material and compliance with specification throughout the purchasing and supply chain.	<b>Y</b>	Each raw material from each supplier will have a supplier specification as well as allergen information on each bag or pallet.
5.2.1.2	The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, intermediate and finished products.	<b>Y</b>	The facility uses Wheat, Soy Protein, Dairy, and Egg containing ingredients.

5.2.1.3	<p>Risk assessment shall be carried out to identify routes of contamination and establish documented policies and procedures for handling raw materials, intermediate and finished products to ensure cross contamination is avoided. This shall include as appropriate:</p> <ul style="list-style-type: none"> <li>• physical or time segregation whilst allergen containing materials are being stored, processed or packed</li> <li>• use of identified, dedicated equipment for processing or cleaning</li> <li>• a policy for all food brought onto site including that by staff.</li> </ul>	<b>Y</b>	<p>The allergen program risk assessment and operation include storage, segregation of raw materials, WIP and finished product. An allergen clean-up, Neogen type antigen and ATP test is conducted on equipment between allergens. Food brought in for lunches must not be brought into operations and storage areas of plant. Peanuts and peanut containing products are not allowed to brought into facility or vending machines.</p>
5.2.1.4	<p>Where rework is used, or reworking operations carried out, procedures shall be implemented to minimise cross contamination from allergen-containing materials and ensure the safety, legality and quality of the finished product.</p>	<b>Y</b>	<p>When rework is used, it will only be 'like into like' of the same recipe and therefore cross contamination is greatly minimized.</p>
5.2.1.5	<p>Where a claim is made regarding the suitability of a food for allergy or food sensitivity sufferers, the company shall ensure that the production process is fully validated to meet the stated claim. This shall be documented.</p>	<b>NA</b>	<p>No claims are made as to allergy sufferers.</p>
5.2.1.6	<p>Based on risk assessment, documented equipment or area cleaning procedures shall be undertaken to remove or reduce to acceptable levels any potential cross contamination in compliance with finished product specifications. This shall include validation of cleaning methods and appropriate waste handling and spillage controls.</p>	<b>Y</b>	<p>As part of HACCP risk assessment, consideration of cleaning and waste handling procedures were reviewed to reduce potential for cross-contamination. Only one product is run at a time in isolated packaging rooms.</p>

<p align="center">SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX          Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: <a href="mailto:foodsafety@saiglobal.com">foodsafety@saiglobal.com</a> website: <a href="http://www.saiglobal.com">www.saiglobal.com</a></p>			
Issue 6_2007 EFSIS-13.10F	Page 62 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

5.2.1.7	All relevant personnel, including temporary staff and contractors, shall be appropriately trained in handling procedures for allergen containing materials prior to commencing work and shall be adequately supervised throughout the working period.	<b>Y</b>	All staff is trained in allergen policy.
5.2.1.8	Any non-conformities relating to allergen control shall be included in the management review process (refer to clause 1.7) and may include, as appropriate, internal or external incidents and customer complaints such as labelling or cross-packing errors. The review process shall also consider updates or changes in allergen legislation or scientific information.	<b>Y</b>	Management meetings consider allergen related incidents & changes to requirements and knowledge.  There have been no incidents in last 12 months.
<b>5.2.2 Identity Preserved Materials</b>			
5.2.2.1	Where an identity preserved claim is made, e.g. that a product is organic, or where products brought onto site may contain materials which require segregation, e.g. Genetically Modified Organisms, the company shall carry out a risk assessment of raw materials to specify the integrity of the raw material and compliance with specification throughout the purchasing and supply chain.	<b>NA</b>	No claims per clause are made. Products are all dry blends with low moisture.
5.2.2.2	Risk assessment shall be carried out to identify routes of contamination and establish documented policies and procedures for handling raw materials, intermediate and finished products to ensure cross contamination is avoided and that controls are in place to maintain identity preserved status.	<b>NA</b>	No claims per clause are made.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 63 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

5.3 Foreign Body Detection			
5.3 Statement of Intent	<b>The company shall have appropriate foreign body detection equipment in place and ensure its effective operation.</b>	<b>Y</b>	The site has a metal detector equipment on packaging lines. This is a CCP in HACCP plan.
5.3.1	Foreign body detection equipment shall be in place unless it can be justified as not necessary. This justification shall be documented. Detection equipment shall be situated to maximise foreign body detection within the finished product.	<b>Y</b>	The metal detector is placed after the product is bagged.
5.3.2	The sensitivity of detection shall be specified and best practice applied with regard to the nature of the food, the location of the detector and any other factors influencing the sensitivity of the detector.	<b>Y</b>	The company has applied best practice and established appropriate limits for detection. The limits are 2.0 mm Ferrous, 2.0 mm non-ferrous and 2.0 mm 316 stainless steel.
5.3.3	The metal or foreign body detector shall incorporate the following based on best practice: <ul style="list-style-type: none"> <li>• an alarm on a belt stop system</li> <li>• an automatic rejection device which shall either divert contaminated product out of the product flow or to a secure unit accessible only to authorised personnel</li> <li>• in-line detectors which identify the location of the contaminant and effectively segregate the affected product.</li> </ul> There shall be documented procedures specifying corrective and investigative action to be taken in the event of the detection of metal or a foreign body.	<b>Y</b>	All metal detectors are equipped with line stop mechanisms, buzzer and light alarms. The nature of the material precludes reintroduction of the rejected material. The QA department is responsible for investigating any metal detected.

5.3.4	The company shall establish and implement procedures for the operation, routine monitoring, testing and calibration of the metal or other foreign body detectors. This shall include as a minimum: <ul style="list-style-type: none"> <li>• frequency and sensitivity of checks</li> <li>• authorisation of trained personnel to carry out specified tasks</li> <li>• documentation of checks.</li> </ul>	<b>Y</b>	The metal detectors are calibrated annually by representative from supplier. The challenge checks are carried out by trained technicians and associates. All calibrations and challenges are documented.
5.3.5	The company shall establish and implement corrective action and reporting procedures in the event of the monitoring and testing procedure identifying any failure of the metal or foreign body detector. Action shall include a combination of isolation, quarantining and re-inspection of all product produced since the last acceptance test of the metal or other foreign body detector.	<b>Y</b>	In the event of failure of a metal detector, documented procedures are followed, which include the isolation, quarantining and evaluation of product as noted in clause 2.10.1. Any required corrective action would be part of a CCP corrective action program.
<b>5.4 Product Packaging</b>			
<b>5.4</b> Statement of Intent	<b>Product packaging shall be appropriate for the intended use and shall be stored under conditions to minimise contamination and deterioration.</b>	<b>Y</b>	Based on the observations noted in the following clauses, product packaging was judged appropriate for its intended use, is properly handled, and stored in suitable conditions to minimize the risk of contamination and deterioration.
5.4.1	Certificates of conformity or other evidence shall be available for product packaging to confirm its suitability for use.	<b>Y</b>	Certificates of conformity for primary packaging is available. It notes conformity with 21 CFR 177.
5.4.2	Where appropriate, packaging shall be stored away from raw materials and finished product.	<b>Y</b>	The packaging material is stored on separate racks from the dry raw product racks. The packaging material is stored separately from finished goods.
5.4.3	Any part-used packaging materials suitable for use shall be effectively protected before being returned to an appropriate storage area.	<b>Y</b>	Part-used packaging is fully covered with a cardboard slip-sheet before being returned to storage.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 65 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

5.4.4	Product contact liners (or raw material/work-in progress contact liners) shall be appropriately coloured and of sufficient gauge to prevent accidental contamination where appropriate.	<b>Y</b>	Colored bags (blue) are used for partial ingredient or weighed materials. Finished product bags and boxes are lined with colored plastic.
5.4.5	Where packaging materials pose a product safety risk, special handling procedures shall be in place to prevent product contamination.	<b>NA</b>	There are no packaging materials that of themselves pose a safety risk. The site does not pack in glass or any similar brittle material.
<b>5.5 Product Inspection and Laboratory Testing</b>			
<b>5.5</b> Statement of Intent	<b>The company shall undertake or subcontract inspection and analyses which are critical to confirm product safety, legality and quality, using appropriate procedures, facilities and standards which prevent risk to product safety.</b>	<b>Y</b>	The company has a schedule of inspection and analysis of finished product covering all critical product safety, legality and quality parameters.
<b>5.5.1 Product Inspection</b>			
5.5.1.1	Based on risk assessment, testing and inspection schedules shall be established to ensure specified product requirements are met. Inspection and testing methods and frequency shall be documented.	<b>Y</b>	Monitoring of raw materials are based upon risk assessment. Materials are delivered accompanied by a certificate of analysis which is reviewed against specification at the time of receipt.
5.5.1.2	Test and inspection results shall be recorded and reviewed regularly to identify trends. Appropriate actions shall be implemented promptly to address any unsatisfactory results or where trends indicate unsatisfactory results.	<b>Y</b>	The results of inspections are reviewed daily by the QA staff, and any unsatisfactory results are handled through the QA Hold Procedure.
5.5.1.3	Where validation of finished product quality attributes is required, organoleptic tests shall be carried out regularly in accordance with specifications and shall be recorded.	<b>Y</b>	All lots of finished product are subject to cutting tests and organoleptic grading, based on lot control.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 66 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

5.5.1.4	The company shall ensure that a system of ongoing shelf life assessment is in place. This shall be based on risk and shall include microbiological and sensory analysis as well as relevant chemical factors such as pH and a <sub>w</sub> . Records and results from shelf life tests shall validate the minimum shelf life period indicated on the product.	<b>Y</b>	Random shelf life studies are conducted as needed or requested by customer(s).
<b>5.5.2 Laboratory Testing</b>			
5.5.2.1	Pathogen testing shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be remote from the manufacturing site.	<b>Y</b>	The site utilizes an external laboratory (Siliker) which has ongoing certifications from AALA, Certificate Number 1105.06 expiry 28-Feb-2012.
5.5.2.2	Where routine testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. Controls shall be documented, implemented and shall include consideration of the following: <ul style="list-style-type: none"> <li>• design and operation of drainage and ventilation systems</li> <li>• access and security of the facility</li> <li>• movement of laboratory personnel</li> <li>• protective clothing arrangements</li> <li>• processes for obtaining product samples</li> <li>• disposal of laboratory waste.</li> </ul>	<b>Y</b>	The laboratory only utilizes basic equipment and operates to the requirements of this clause. The floor drains flow into the main drain system. They do not have a micro lab. The laboratory is located within a secure area of the facility. Wastes do not present a hazard and are disposed through the normal means.

5.5.2.3	Where the company undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory, or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025. Documented justification shall be available where accredited methods are not undertaken.	<b>Y</b>	See clause 5.5.2.1 above. The outside lab operates under ISO 17025.
5.5.2.4	Procedures shall be in place to ensure reliability of laboratory results, other than those specified in 5.5.2.3. These shall include: <ul style="list-style-type: none"> <li>• use of recognised test methods, where available</li> <li>• documented testing procedures</li> <li>• ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required</li> <li>• use of a system to verify the accuracy of test results, e.g. ring or proficiency testing</li> <li>• use of appropriately calibrated and maintained equipment.</li> </ul>	<b>Y</b>	The QA staff is trained and annual refresher training is conducted by Director of QA. The training is documented.
<b>5.6 Control of Non-conforming Product</b>			
5.6 Statement of Intent	<b>The company shall ensure all out-of-specification product is clearly identified, labelled and quarantined.</b>	<b>Y</b>	Appropriate procedures are followed for the subsequent handling of non-conforming product and are fully documented. All such product is handled by the Hold Procedures. Out of specification product is identified, clearly labeled, blocked on the computer and quarantined as appropriate.

5.6.1	Procedures for the control of non-conforming material, including rejection, acceptance by concession, or regrading for an alternative use, shall be in place and understood by all relevant staff. Decisions shall be approved by authorised staff.	<b>Y</b>	The procedure addresses destruction, reblend or relabel as possible options. Product on detention status must be released by QA department.
5.6.2	Corrective actions shall be implemented to avoid recurrence of non-conformance. Details of the non-conformance and action taken shall be documented.	<b>Y</b>	Appropriate corrective actions have been implemented for all examples of non-conformance seen, to avoid recurrence of non-conformance, and have been documented through non-conformance reports.
5.6.3	All non-conforming material shall be clearly identified and quarantined as appropriate, and handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.	<b>Y</b>	Out of specification product is identified, clearly labeled, blocked on the computer and quarantined as appropriate. Final disposition must include consideration of customer requirements.
<b>5.7 Product Release</b>			
<b>5.7</b> Statement of Intent	<b>The company shall ensure that finished product is not released unless all agreed procedures have been followed.</b>	<b>Y</b>	Product is released only on the acceptable completion of all process evaluation, QA required evaluation and micro testing.
5.7.1	A procedure shall be in place, based on risk assessment, to ensure that only products conforming to specification are dispatched, and this shall include release by authorised staff.	<b>Y</b>	The company's computerized inventory system places all product on an automatic hold and cannot be released until all criteria, including micro, are met.
<b>6.0 PROCESS CONTROL</b>			
<b>6.0</b> Statement of Intent	<b>The company shall be able to demonstrate effective control of all operations undertaken.</b>	<b>Y</b>	Procedures were noted to be in place to verify that the processes and equipment employed are producing safe and legal product with the desired quality characteristics in compliance with its HACCP & Quality Plan.
<b>6.1 Control of Operations</b>			

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 69 of 83	Report No: A-00162263	Auditor: Tom Tucker

<b>6.1</b> <b>FUNDAMENTAL</b> Statement of Intent	<b>The company shall operate procedures that verify that the processes and equipment employed are capable of producing consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan.</b>	<b>Y</b>	The day-to-day controls were observed to correspond to the requirements of the HACCP & Quality Plan. Product design and equipment commissioning procedures ensure that process validation, including worse case scenarios, is undertaken prior to initial production.
6.1.1	A process shall ensure that all Critical Control Points and specified limits identified through HACCP are transferred into day-to-day production controls and are fully validated.	<b>Y</b>	Day to day production controls are suitably designed and implemented. They were observed to correspond to the requirements of the HACCP & Quality Plan.
6.1.2	Process monitoring such as temperature, time, pressure and chemical properties shall be established and adequately controlled to ensure that product is produced within the required process specification.	<b>Y</b>	Process monitoring includes weight control and packaging. All checks noted were within specification.
6.1.3	Process monitoring shall be carried out by trained staff and shall be documented.	<b>Y</b>	The staff conducting the process monitoring were adequately trained.
6.1.4	In circumstances where process parameters are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.	<b>Y</b>	The only automatic reject system is the metal detector.
6.1.5	In the case of equipment failure or deviation of the process from specification, procedures shall be in place to establish the safety status of the product, prior to release.	<b>Y</b>	In the case of held product, sampling increase has been established to assure consistent quality. If product safety is a concern product would be destroyed.

6.1.6	Corrective action shall be taken in the event of deviation of process from specification. This shall be recorded.	<b>Y</b>	Procedures are in place to establish the safety status of product where equipment failure and process deviation have occurred; product is released only with management authorization. Corrective actions are noted on the non-conforming product documentation.
6.1.7	Procedures shall be in place to ensure that products are packed into the correct packaging and correctly labelled with due consideration given to product changeover.	<b>Y</b>	The QA department and operation associate are responsible for verifying correct labeling.
6.1.8	In the event of changes to product formulation, processing methods, equipment or packaging, monitoring of the specified process shall be re-established based on HACCP.	<b>Y</b>	Any major changes in product formulation, processing methods, equipment, and/or packaging must be approved by HACCP team before release of product.
<b>6.2 Quantity – Weight, Volume and Number Control</b>			
<b>6.2</b> Statement of Intent	<b>The company shall operate a quantity control system which conforms to legal requirements and additional industry sector codes or specified customer requirement in the country where the product is sold.</b>	<b>Y</b>	The site's equipment is designed to produce finished bags and boxes of product which conform to legal, label and customer requirements. The quality control programs are designed to confirm the compliance.
6.2.1	The frequency and methodology of quantity checking shall meet the requirements of appropriate legislation governing quantity verification.	<b>Y</b>	Weight control is on-line manual weight checks of every bag or box. Five completed bags/boxes of product are weighed per batch on a calibrated scale for minimum label claim.
6.2.2	Where the quantity of the product is not governed by legislative requirements (e.g. bulk quantity), the product must conform to customer requirements.	<b>Y</b>	All product is governed by legislative requirements.
<b>6.3 Calibration and Control of Measuring and Monitoring Devices</b>			

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 71 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

<p><b>6.3</b> Statement of Intent</p>	<p><b>Measuring equipment used to monitor Critical Control Points and product safety and legality shall be identified. The identified measuring equipment shall be calibrated to a recognised national or international standard. Where a traceable calibration is not possible, the company shall demonstrate the basis by which standardisation is carried out.</b></p>	<p align="center"><b>Y</b></p>	<p>All measuring equipment used to monitor CCPs, safety and legality is of appropriate accuracy, calibrated to an appropriate frequency and traceable to a national standard or demonstrable standardization base with records retained of that calibration.</p>
<p>6.3.1</p>	<p>The company shall identify measuring equipment used to monitor CCPs and product safety and legality.  This shall include as a minimum:</p> <ul style="list-style-type: none"> <li>• a documented list of equipment</li> <li>• equipment identified and marked in accordance with requirements (e.g. numbered, calibration due date).</li> </ul>	<p align="center"><b>Y</b></p>	<p>The site has a basic list of measuring equipment which meets the requirements of the clause.</p>
<p>6.3.2</p>	<p>All identified measuring devices shall be checked and where necessary adjusted:</p> <ul style="list-style-type: none"> <li>• at a predetermined frequency, based on risk assessment</li> <li>• by trained staff</li> <li>• to a defined method traceable to a recognised national or international standard where possible.</li> </ul> <p>Results shall be documented.</p>	<p align="center"><b>Y</b></p>	<p>All critical equipment (scales, metal detectors) is calibrated. Scales are checked twice/shift to calibrated weights by trained operation staff following documented methods.</p>
<p>6.3.3</p>	<p>The prescribed measuring and monitoring devices shall be:</p> <ul style="list-style-type: none"> <li>• prevented from adjustment by unauthorised staff</li> <li>• protected from damage, deterioration or misuse.</li> </ul>	<p align="center"><b>Y</b></p>	<p>The measuring equipment observed was protected from damage and adjustment by unauthorized persons.</p>

6.3.4	Procedures shall be in place to record actions taken when the prescribed measuring and monitoring devices are found not to be operating within specified limits.	<b>Y</b>	Appropriate tolerances have been set for all critical measuring devices used to monitor CCPs and procedures are in place to record the action taken when these are exceeded.
<b>7.0 PERSONNEL</b>			
<b>7.1 Training – Raw Material Handling, Preparation, Processing, Packing and Storage Areas</b>			
<b>7.1</b> <b>FUNDAMENTAL</b> Statement of Intent	<b>The company shall ensure that personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.</b>	<b>Y</b>	As noted below the company has taken steps to ensure that all employees are adequately trained, instructed and supervised commensurate with their activity and are demonstrably competent to carry out that activity.
7.1.1	All relevant personnel, including temporary staff and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period.	<b>Y</b>	All employees (including temporary staff and contractors) are inducted prior to commencing work and are adequately supervised throughout the working period. All staff receive hygiene training at induction. All relevant personnel challenged had received training for their duties. Supervisory staff were apparent throughout the facility.
7.1.2	Where personnel are engaged in activities relating to Critical Control Points, relevant training and documented monitoring procedures shall be in place.	<b>Y</b>	The QA technicians and production associates, who monitor CCPs, are trained to handle all aspects of the HACCP Plan.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 73 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

7.1.3	<p>The company shall put in place documented programmes covering the training needs of relevant personnel. These shall include as a minimum:</p> <ul style="list-style-type: none"> <li>• identifying the necessary competencies for specific roles</li> <li>• providing training or other action to ensure staff have the necessary competencies</li> <li>• reviewing and auditing the implementation and effectiveness of training and competency of the trainer</li> <li>• consideration of the delivery of training in the appropriate language of trainees.</li> </ul>	<b>Y</b>	<p>The training program was observed to train against documented material, which is reviewed as part of the internal audit. The site's employees' working language is English as are the training records.</p>
7.1.4	<p>Records of all training shall be available. This shall include as a minimum:</p> <ul style="list-style-type: none"> <li>• name of trainee and confirmation of attendance</li> <li>• date and duration of training</li> <li>• title or course contents as appropriate</li> <li>• training provider.</li> </ul>	<b>Y</b>	<p>Training records, and job descriptions were available for the individuals requested.  Sanitation Lead: GMP, Sanitation, HACCP, Allergen; June 2011, 4 hours.  QC Technician: HACCP, SOPs, Food Safety, Allergen; June 2011, 4 hours.  General Labor: GMP, allergen, Food Safety; June 2011, 2 hours.  Line Operator: GMP, Allergen, Food Safety; June 2011, 4 hours.  Receiving Clerk: GMP, Food Safety, Allergen; Glass/Brittle Plastic Policy; June 2011, 4 hours.  All training and documentation is overseen by Director of QA.</p>
7.1.5	<p>The company shall routinely review the competencies of staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.</p>	<b>Y</b>	<p>The internal audit addresses competencies. GMP training is provided every year. Job specific refresher training is based on need.</p>

7.2 Access and Movement of Personnel			
<b>7.2</b>	<b>The company shall ensure that access and movement of personnel, visitors and contractors shall not compromise product safety.</b>	<b>Y</b>	As noted below the company has taken steps to ensure access and movement of persons to avoid compromising product safety.
7.2.1	There shall be a plan of the site which defines access points for personnel, travel routes and staff facilities.	<b>Y</b>	The site has a plan noting access points and routes.
7.2.2	If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials.	<b>Y</b>	The site has designated walkways at several areas in the plant.
7.2.3	All facilities shall be designed and positioned, where possible, so that movement of personnel is by simple, logical routes.	<b>Y</b>	The employee pathways and travel routes observed were direct and logical.
7.2.4	Contractors and visitors, including drivers, shall be made aware of all procedures for access to premises and the requirements of the areas they are visiting, with special reference to hazards and potential product contamination.	<b>Y</b>	All visitors are required to sign in prior to being allowed access to the facility. The briefing materials provided to visitors at that time includes the requirements of the facility.
7.3 Personal Hygiene – Raw Materials Handling, Preparation, Processing, Packing and Storage Areas			
<b>7.3</b>	<b>The company's personal hygiene standards shall be documented and adopted by all personnel, including contractors and visitors to the production facility. These standards shall be formulated with due regard to risk of product contamination.</b>	<b>Y</b>	The company was observed to have documented hygiene standards (GMP Employee Practices, 10-Oct-2011) which were noted to be adopted by all the individuals present. These standards are formulated with due regard to risk of product contamination. All staff were noted to be observing the rules and visitors, including this auditor, are briefed before entry to the processing area is permitted.

**F002: Global Standard for Food Safety**  
**Issue 5 : January 2008**  
**Audit Report**

7.3.1	The requirements for personal hygiene shall be documented and communicated to all personnel. Compliance with the requirements shall be checked regularly.	Y	Employees sign to acknowledge receipt of training. The site has a program of documented GMP compliance monitoring on weekly sanitation audit. On the floor supervisors check daily and note results.
7.3.2	Based on risk assessment, the company shall document its jewellery policy.	Y	The site's jewellery policy is included in the hygiene rules which each employee signs prior to commencing work.
7.3.3	Watches shall not be worn. Jewellery shall not be worn, with the exception of a plain wedding ring, a wedding wristband and sleeper earrings (continuous loop). Rings and studs in exposed parts of the body, such as noses, tongues and eyebrows, shall not be worn.	Y	No jewellery is allowed except plain ring band. Medic Alert items are addressed on a case by case basis. All personnel observed during the audit were complying with company jewellery requirements.
7.3.4	Hand cleaning shall be performed at a frequency that is appropriate, based on risk assessment.	Y	Hand washing and sanitation is to be performed at start and after the use of the restroom, and entry into processing areas.
7.3.5	Fingernails shall be kept short, clean and unvarnished. False fingernails shall not be permitted. Where visitors cannot comply, suitable control procedures shall be in place, e.g. non-handling of product, use of gloves.	Y	Long fingernails, false fingernails or nail polish are forbidden in the company hygiene standard.
7.3.6	Excessive perfume or aftershave shall not be worn.	Y	Strong scents are prohibited in the company hygiene policies and none were noted during the audit.
7.3.7	Smoking (where permitted under law), eating and drinking shall only be permitted in designated areas segregated from food-handling and storage areas.	Y	Smoking is only allowed outside the buildings in the designated smoking areas.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 76 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

7.3.8	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster different from the product colour (preferably blue) and containing a metal detectable strip where metal detection/X-ray equipment is in use. These shall be company issued and monitored. Where appropriate, in addition to the plaster, a finger stall shall be worn.	<b>Y</b>	All Band-Aids are blue in color and are company issued.
7.3.9	A sample from each batch of plasters shall be successfully tested through a metal detector and records shall be kept.	<b>Y</b>	The site does not have a high demand for Band-Aids and a shipment may last for years. Each lot of plasters are tested through the company's metal detectors.
7.3.10	Procedures shall be in place to control the use of personal medicines to minimise the risk of contamination.	<b>Y</b>	The site hygiene standards require that all personal medicines must stay in personal lockers.
<b>7.4 Medical Screening</b>			
<b>7.4</b> Statement of Intent	<b>The company shall ensure that medical screening procedures are in place for all employees, contractors or visitors who will be working in or visiting areas where product safety could be compromised.</b>	<b>Y</b>	Medical screening procedures are in place for all employees, with new employees undergoing a company paid drug test. Drug testing is conducted on any employee that has a plant accident and there is random quarterly testing.
7.4.1	The company shall have a procedure for the notification by employees, including temporary employees, of any relevant infections, disease or condition with which they may have been in contact or be suffering from.	<b>Y</b>	Procedures are in place for the notification by employees of any relevant infectious diseases or conditions with which they may be suffering or have had contact, through return to work questionnaires.

7.4.2	Where there may be risk to product safety, visitors and contractors shall be required to complete a health questionnaire prior to entering the raw material, preparation, processing, packing and storage areas. Where appropriate, these persons shall undergo medical screening before permission is granted.	<b>Y</b>	Due to the limits of personal medical questions that can be asked, the site depends on visitors and contractors following the hygiene procedures to minimize risks to finished products.
7.4.3	There shall be documented procedures which are communicated to employees, including temporary employees, contractors and visitors, on action to be taken in the case of infectious disease from which they may be suffering or have been in contact. Particular consideration should be given where product safety may be compromised. Expert medical advice shall be sought where required.	<b>Y</b>	There is a procedure for the management of any person who has entered the premises suffering from an infectious disease, to minimize the risk to product safety. All workers returning from a prolonged illness must present a physician's clearance.
<b>7.5 Protective Clothing – Employees or Visitors to Production Areas</b>			
<b>7.5</b> <b>Statement of Intent</b>	<b>Suitable company issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas.</b>	<b>Y</b>	Employees in all production and warehousing areas were observed wearing company issued protective clothing.
7.5.1	Based on risk assessment, the company shall document and communicate to all employees, contractors or visitors the rules regarding the wearing and changing of protective clothing in specified work areas, e.g. high-risk and low-risk areas. This shall also include policies for wearing of protective clothing away from the production environment, e.g. removal before entering toilets, use of canteen and smoking areas.	<b>Y</b>	All plant employees wear company issued white smocks, in-house shoes and hair nets. All smocks must be removed when leaving either processing area. Smocks are not allowed in break room, toilets, smoking area and other areas outside facility. They do not have any high-risk areas.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 78 of 83	Report No: A-00162263	Auditor: Tom Tucker

7.5.2	Protective clothing shall be available that is: <ul style="list-style-type: none"> <li>provided in sufficient numbers for each employee</li> <li>of suitable design to prevent contamination of the product (as a minimum contain no external pockets or sewn on buttons).</li> </ul>	<b>Y</b>	Suitable protective clothing is issued by the company for staff and visitors entering food handling areas. Protective clothing is donned on site. Shirts have sown pockets.
7.5.3	Clean and dirty clothing shall be segregated and controlled to prevent cross contamination.	<b>Y</b>	Clean and dirty clothing was observed to be kept separate and were controlled.
7.5.4	Laundering of protective clothing shall take place in-house using defined and verified criteria to validate the effectiveness of the laundering process, or by an approved contracted and audited laundry. The effectiveness of cleaning shall be monitored. Washing of work wear by the employee is exceptional but shall be deemed acceptable where, based on a detailed risk assessment, it can be confirmed there is no risk to product safety. Detailed procedures shall be in place to ensure the effectiveness of the laundering process.	<b>Y</b>	Protective clothing is laundered by a contract service. The effectiveness of the process is monitored through visual checks.
7.5.5	Where there is the risk of contamination, smoking and eating while wearing protective clothing shall not be permitted.	<b>Y</b>	Smoking is not allowed while wearing protective clothing.
7.5.6	All scalp hair shall be fully contained to prevent product contamination.	<b>Y</b>	All workers observed had their scalp hair fully contained.
7.5.7	Based on risk assessment, snoods for beards and moustaches shall be worn to prevent product contamination.	<b>Y</b>	Beard nets are required for beards, goatees, and any portion of a mustache below the lip line.
7.5.8	Suitable footwear shall be worn within the production environment.	<b>Y</b>	Company authorized shoes are required in production.

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: foodsafety@saiglobal.com website: www.saiglobal.com			
Issue 6_2007 EFSIS-13.10F	Page 79 of 83	Report No: A-00162263	Auditor: Tom Tucker

**This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd**

**F002: Global Standard for Food Safety  
Issue 5 : January 2008  
Audit Report**

7.5.9	If gloves are used, they shall be replaced regularly. Where appropriate, gloves shall be suitable for food use; of a disposable type; of a distinctive colour (blue where possible) be intact, and not shed loose fibres.	<b>Y</b>	The site uses disposable colored nitrile gloves.
7.5.10	For operations involving <b>high-risk products</b> (refer to glossary) all visibly distinctive protective clothing (including footwear) shall be applied when entering, and removed when leaving, the high risk area and stored in a designated changing area.	<b>N/A</b>	There are no high risk operations.

Note to user: This is the report of a BRC Global Standard for Food Audit, which is based on a sampling exercise, considering the facilities, operations, practices and systems viewed at the site during the Audit. It therefore does not follow that no non-conformances exist where none have been reported. This report shall not be reproduced in part without the permission of SAI Global Assurance Services Ltd.

# Audit Report

## COMPANY PROFILE

<b>Company Name:</b>		<b>Location:</b>	
Coalescence LLC		Columbus OH USA	
<b>Site Ownership/History:</b>			
The property is leased and began operating as Coalescence LLC in September 2008.			
<b>Age of Company:</b>			
The company was founded and began operating in 2005.			
<b>Years at Present Site and Year of Construction:</b>			
The current facility was built in 2001. There has been food manufacturing at this location since 2008.			
<b>Trading Names / Sister Companies / Subsidiaries :</b>			
None			
<b>Plant Size (feet/metres square):</b>			
35,000 sq.ft., 3251 sq.m.			
<b>Number of Workers on Site / Shift Patterns (Please list according to full/part-time workers and contractors):</b>			
43 management and non-management employees between 2 production shifts and 1 sanitation shift per day.			
<b>Turnover (if provided):</b>			
Approx. USD 24,000,000			
<b>Membership of Trade/Research Associations:</b>			
DMSCA (Diverse Manufacturing Supply Chain Alliance)			
<b>Formal Accreditation/Certification (e.g. ISO 9000) and Scope :</b>			
None			
<small>Tel: +44 (0)1906 249974 Fax: +44 (0)1906 009023 email: food.safety@saiglobal.com website: www.saiglobal.com</small>			
Issue 6_2007	Page 81 of 83	Report No: A-00162263	Auditor: Tom Tucker
EFSIS-13.10F			

# Audit Report

<b>EC Licence No/Healthmark:</b>
None. They do not market in EU.
<b>Assured Products or IP Standards:</b>
None
<b>Raw Materials:</b>
Bread, Batter Mix, Breeding, Cinnamon Sprinkle, Vegetable Oil, City Water, Vitamins
<b>Allergens on Site:</b>
Soy Protein, Wheat, Egg, Dairy
<b>Production Processes:</b>
Dry Blend, Mix, Package
<b>Number of Production Lines:</b>
Three production lines under scope of audit.
<b>Number of Product Groups/Categories and Number of Products Per Group:</b>
One category and product group under scope of audit.
<b>Preservation Methods:</b>
Product is shelf stable.
<b>Finished Products:</b>
Dry Blends and Ingredients
<b>Quantity of Finished Products:</b>
2010 – In excess of 6.9 million pounds
<b>Packaging Materials/Types:</b>
Poly Bags (primary) in Kraft bags and lined corrugated boxes
<b>Product Distribution:</b>
Stored and dispatched ambient
<b>Countries Exported To:</b>
None

SAI Global Assurance Services Ltd, Winterhill House, Snowdon Drive, Winterhill, Milton Keynes, MK6 1AX  
Tel: +44 (0)1908 249974 Fax: +44 (0)1908 609825. email: [foodsafety@saiglobal.com](mailto:foodsafety@saiglobal.com) website: [www.saiglobal.com](http://www.saiglobal.com)

Issue 6_2007 EFSIS-13.10F	Page 82 of 83	Report No: A-00162263	Auditor: Tom Tucker
------------------------------	---------------	-----------------------	---------------------

# Audit Report

<b>Customer Type (e.g. Manufacturers, retail):</b>
Food processors
<b>Major Changes Since Last Visit Including Major Investments:</b>
None
<b>Recalls Or Incidents In The Last Year:</b>
None