



5.Product Characteristics			
High care	No	High risk	No
Allergens handled on site	No allergen in product areas and storages, in dining room: wheat, peanut, soybeans and eggs		
Product claims made e.g. IP, organic	Kosher, Halal		
Product recalls in last 12 Months	No		
Products in production at the time of the audit	Food additive-CMC		

盛德化工有限公司  
Sidley Chemical Limited



Tel:+86-539-8328803

<http://celluloseether.com>

Address: Linyi City ,China

## Global Standard for Food Safety Issue

*Sodium Carboxymethylcellulose*

*E. Code: E466*

### Section 1 - Chemical Product and Company Identification

Material name: Sodium Carboxymethylcellulose

Synonyms: [Cellulose](#) Sodium Glycolate

Supplier:

Sidley Chemical Limited.

Linyi city , SHANDONG,CHINA

Tel: 0086 539 8328803

### Section 2 - Composition /Information on Ingredients

CAS#	Chemical Name	Percent	EINECS/ELINCS
<a href="#">9004-32-4</a>	<a href="#">Sodium Carboxymethylcellulose</a>	ca 100	unlisted



6.Audit Duration Details			
On-site duration	16 man hours	Duration of production facility inspection	8 man hours
Reasons for deviation from typical or expected audit duration	Time as per BRC Audit calculator		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2013-05-15	1330	1730
2	2013-05-16	0830	1730
3(finish date)	2013-05-17	0830	1230

7.Key Personnel			
Auditor Number	176342	Auditor Names and roles	Felix Wang-Leader auditor Gavin Cha- Trainee auditor

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9)				
Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Zhou Zhiqiang/ General Manager	x			x
Zhu Hui/ Technical manager	x	x		x
Yan Zhenxing/ Production manager	x	x	x	x
Sha Wenqian/ Office department	x		x	x
Yao Dong/ warehouse department	x		x	x
Ma Tonggui/ workshop chief	x	x		x
Dong Yeshengli/ operator	x			x
Zheng Haiyan/ Lab	x		x	x

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## Non-Conformity Summary Sheet

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

Critical			
No.	Requirement ref.	Details of non-conformity	Anticipated re-audit date

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Major							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	2.10.2	CCP2: metal detection, calibration frequency was before and after production per day, but on site found the metal detector calibration record after production was not in place for review from 2013-05-13 to 2013-05-15.	1- We had trained the CCP operators. 2- QA would review the CCP monitor record per day.	Root cause- the CCP operator did not fill in the record accordingly and the QA did not review it in time.  Actions taken- train the CCP operators and fill in the record accordingly and review the record by QA per day strictly.	Metal detector monitoring record and training record dated 2013-05-17.	2013-06-07	Felix Wang

Minor							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

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Minor							
1	3.9.1	The Food grade NaOH stored in temporary storage area of workshop had no batch number for traceability purpose.	<ul style="list-style-type: none"> <li>1- We had labelled the NaOH.</li> <li>2- We had trained relevant operators about the identification and traceability control procedure.</li> </ul>	<p>Root cause- the operator did not label it in time.</p> <p>Actions taken- train relevant operators about the identification and traceability control procedure and label the NaOH at once.</p>	Pictures of before and after the NaOH being labelled and training record dated 2013-05-18.	2013-06-07	Felix Wang
2	4.2.2	The security measures for NaClO storage area was not adequate and anyone could open the value of the NaClO container without enter into the iron fence.	<ul style="list-style-type: none"> <li>1-We had added damper for NaClO storage area which could play a good protective effect.</li> <li>2-We had trained relevant employees about security plan.</li> </ul>	<p>Root cause- The security team did not find this problem.</p> <p>Actions taken- Adding damper for NaClO storage area, it can play a good protective effect. Train relevant employees about security plan.</p>	Training record dated 2013-05-20 and pictures before and after adding damper for NaClO storage area.	2013-06-07	Felix Wang
3	4.4.1	There was a hole in the wall of the second floor of the workshop.	<ul style="list-style-type: none"> <li>1- We had sealed the hole with cement.</li> <li>2- We had trained relevant employee about the GMP.</li> </ul>	<p>Root cause-the hole was not sealed in time while place the pipelines into the workshop.</p> <p>Actions taken- seal the hole immediately with cement and train the relevant employee about the GMP.</p>	Pictures before and after the hole being sealed and training record dated 2013-05-20.	2013-06-07	Felix Wang
4	4.5.1	The water test report done by Linyi City Lanshan District CDC was in place for review but Pb,	<ul style="list-style-type: none"> <li>1- We had required updated water test report dated 2013-05-22.</li> </ul>	<p>Root cause- the QA did not check the water test report strictly according to GB5749-</p>	Water test report dated 2013-05-22	2013-06-07	Felix Wang

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Minor							
		Hg, PH items was not included in it according to GB5749-2006.	2- We had trained relevant QA about GB5749-2006.	2006. Actions taken- send water sample to Lanshan CDC and re-test it, train relevant QA about GB5749-2006.	and training record dated 2013-05-21.		
5	5.3.1	The refined cotton supplied by Zouping Yizhong Industrial Limited Co., Ltd was Non-GMO resourced, but the Non-GMO report was not available for review.	1- We had trained relevant QA about Non-GMO control procedure. 2- We had required Non-GMO report from Zouping Yizhong Industrial Limited Co., Ltd.	Root cause- the QA ignored the refined cotton supplied by Zouping Yizhong Industrial Limited Co., Ltd. Actions taken-require Non-GMO report from Zouping Yizhong Industrial Limited Co., Ltd and train relevant QA about Non-GMO control procedure.	Non-GMO report with No. LR119082 and training record dated 2013-05-20.	2013-06-07	Felix Wang
6	6.1.2	On site found the etherificate process monitor record was filled out in advance by the operator.	1- We had trained relevant operators about the record control procedure. 2- We would enhance monitor by QA and monitor.	Root cause-the operator did not obey the record control procedure and the monitor did not find it in time. Actions taken- train the relevant operators about the record control procedure and enhance monitor by QA and monitor.	Training record dated 2013-05-21.	2013-06-07	Felix Wang

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# Detailed Audit Report

## 1. Senior Management Commitment

### 1.1 Senior management commitment and continual improvement

The Quality Policy dated 2013-02-18 was signed by GM Zhou Zhiqiang and documented in the food safety and quality management manual (SDYL-A) including: Ensure customer satisfaction, ensure safety and hygiene, and obey regulation, ongoing improvement. The quality policy was displayed on the wall of the plant and was trained to all staff.

Food safety and Quality Objectives were as following: customer satisfactory rate: over 95%; safety customer complaints: 0, product manufactured pass rate of 100%. These objects were monitored on a quarterly basis, discussed at management meetings and also were reviewed during the previous management review.

Monthly meeting was conducted and record was in place.

Management review was conducted once a year and the last one was happened on 2012-07-20 and 2 decisions were output including gain BRC certificate.

It was the initial BRC audit.

Requirement No	REQUIREMENT	Conforms
<b>FUNDAMENTAL</b> Statement of Intent	The company's senior management shall demonstrate they are fully committed to the implementation of the requirements of the <i>Global Standard for Food Safety</i> and to processes which facilitate continual improvement of food safety and quality management.	Y
1.1.1	The company shall have a documented policy which states 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 be: <ul style="list-style-type: none"> <li>signed by the person with overall responsibility for the site</li> <li>communicated to all staff.</li> </ul>	Y
1.1.2	The company's senior management shall ensure that clear objectives are defined to maintain and improve the safety, legality and quality of products manufactured, in accordance with the quality policy and this Standard. These objectives shall be: <ul style="list-style-type: none"> <li>documented and include targets or clear measures of success</li> <li>clearly communicated to relevant staff</li> <li>monitored and results reported at least quarterly to site senior</li> </ul>	Y

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	management.	
1.1.3	<p>Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, annually as a minimum, to review the site performance against the Standard and objectives set in 1.1.2. The review process shall include the evaluation of:</p> <ul style="list-style-type: none"> <li>• previous management review action plans and time frames</li> <li>• results of internal, second party and/or third party audits</li> <li>• customer complaints and results of any customer performance reviews</li> <li>• incidents, corrective actions, out of specification results and non-conforming materials</li> <li>• review of the management of the HACCP system</li> <li>• resource requirements.</li> </ul> <p>Records of the meeting shall be documented and used to revise the objectives.</p> <p>The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed time scale</p>	Y
1.1.4	The company shall have a demonstrable meeting programme which enables food safety, legality and quality issues to be brought to the attention of senior management at least monthly and allows for the resolution of issues requiring immediate action.	Y
1.1.5	The company's senior management shall provide the human and financial resources required to produce food safely in compliance with the requirements of this Standard and for the implementation of the HACCP-based food safety plan.	Y
1.1.6	The company's senior management shall have a system in place to ensure that the company is kept informed of scientific and technical developments, industry codes of practice and all relevant legislation applicable in the country of raw material supply, production and, where known, the country where the product will be sold.	Y
1.1.7	The company shall have a genuine, original hard copy or electronic version of the current Standard available.	Y
1.1.8	Where the company is certificated to the Standard it shall ensure that announced recertification audits occur on or before the audit due date indicated on the certificate.	N/A
1.1.9	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. Relevant departmental managers or their deputies shall be available as required during the audit process.	Y

1.1.10		The company's senior management shall ensure that the root causes of non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence.	N/A
1.2	<b>Organisational structure, responsibilities and management authority</b>		
<p>The management structure was documented as a tree within the food safety and quality manual, covering senior management team, production, purchasing, QA, QC, office, Lab, trade, maintenance. All report to the GM. Job descriptions was available for all managers and supervisors and a responsibility matrix has been documented.</p> <p>Document arrangement of absence of key staff was showed to auditor.</p> <p>6 lab report to 1 technical manager; 2 workshop chief, 1 purchase employee report to production manager, 4 sales report to sales manager, all report to General manager.</p>			
Statement of Intent	The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality and quality.		Y
1.2.1	The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, legality and quality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.		Y
1.2.2	The company's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instruction.		Y

## 2 The Food Safety Plan – HACCP

FUNDAMENTAL Statement of Intent	The company shall have a fully implemented and effective food safety plan based on Codex Alimentarius HACCP principles.	Y
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HACCP (SDYL/JH-A) plan was established and maintained based on the codex Alimentarius HACCP principles.

The multi-disciplinary team comprises members main from the following departments: Production Dept, Quality Dept, Maintenance Dept, Purchase Dept, Sales Dept, total 10 members were included. Mr. Yan Zhenxing was appointed to HACCP team leader. He had many years experience in manufacturing of sucralose products and better understanding of HACCP principles and their application. Other HACCP team members had received HACCP principle training.

A full description of the product developed include: Raw materials including refined cotton/chloroactic acid /NaOH/Alcohol/ HCl; the described items including Flow chart/ Using method/ storage and distribution conditions / Physical or chemical properties ./ Labelling base on legal requirements.

Product descriptions were adequate. For the finished products: Raw materials and package materials characters are considered./CMC/ Inner: PE bag/ Outer: Kraft paper bag /ambient temperature / Shelf life: 24 months. / Heavy metal follow FCC VI/ GB/ TPC  $\leq 1 \times 1000$  cfu/g, E. coli  $\leq 30$  MPN/100g, salmonella: not detected.

The intended use has been described as “Normally consumer used as food additives.”

Process flow diagram of food additive-CMC: Raw material receiving—Storing—dosing—alkalize—etherificate—neutralize and deterge—rake dry—drying—grinding—packaging —metal detection—storage—transportation.

Hazard analysis has been completed from raw material, processing to final products, including of biological, chemical, and physical hazards. Likely occurrence of hazard and severability of the effects considered fully during the hazard analysis. Suitable control measures for each kind of hidden hazard were documented.

All control points were reviewed to identify those that were critical. A decision tree has been used to assess the hazard controls at each process step and the results are documented.

HACCP plan of CMC: CCP1: Raw materials receiving, CCP2: Metal detecting.

Critical limit for each CCP is scientific. For its products: CL1: chemical hazard cover heavy metal follows relevant regulations, every batch. CL2: physical hazard:  $Fe\phi \leq 1.5$ mm,  $Sus\phi \leq 2.5$ mm,  $Non-Fe\phi \leq 2.0$ mm start and end of production, every batch.

Critical limits were based on subjective or science data: CL1 based on Notional regulation/ CL2 based on USA FDA report and requirements of customers.

Monitoring system for each CCP is established and implemented, SOPs for CCPs monitoring was available.

The procedures for each CCP identify the corrective action to be taken when the limits are exceeded.

The corrective action plan was detailed specified in HACCP plan by HACCP team. For each CCP, it was identified the corrective action to be taken when a failed to meet the limit. CCP1: raw materials receiving, rejection and inform supplier/ CCP2: metal detector, re-pass and reject if it does not pass.

Procedures of validation and verification to confirm that the HACCP system working effectively was in place.

Last verification and validation carried out on 2013-03-21. Verification reports of other products were maintained. **A Major NC was raised: CCP2: metal detection, calibration frequency was before and after production per day, but on site found the metal detector calibration record after production was not in place for review from 2013-05-13 to 2013-05-15.**

2.1	The HACCP food safety team – Codex Alimentarius Step 1	
2.1.1	The HACCP plan shall be developed and managed by a multi-disciplinary	Y

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	<p>food safety team that includes those responsible for quality/technical, production operations, engineering and other relevant functions.</p> <p>The team leader shall have an in-depth knowledge of HACCP and be able to demonstrate competence and experience.</p> <p>The team members shall have specific knowledge of HACCP and relevant knowledge of product, process and associated hazards.</p> <p>In the event of the company not having appropriate in-house knowledge, external expertise may be used, but day-to-day management of the food safety system shall remain the responsibility of the company.</p>	
<b>2.2</b>	<b>Prerequisite programmes</b>	
<b>2.2.1</b>	<p>The company shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> <li>• cleaning and sanitising</li> <li>• pest control</li> <li>• maintenance programmes for equipment and buildings</li> <li>• personal hygiene requirements</li> <li>• staff training</li> <li>• purchasing</li> <li>• transportation arrangements</li> <li>• processes to prevent cross-contamination</li> <li>• allergen controls.</li> </ul> <p>The control measures and monitoring procedures for the prerequisite programmes must be clearly documented and shall be included within the development and reviews of the HACCP</p>	Y
<b>2.3</b>	<b>Describe the product – Codex Alimentarius Step 2</b>	
<b>2.3.1</b>	<p>The scope of each HACCP plan, including the products and processes covered, shall be defined. For each product or group of products a full description 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, allergens, recipe</li> <li>• origin of ingredients</li> <li>• physical or chemical properties that impact food safety, e.g. pH, aw</li> <li>• treatment and processing, e.g. cooking, cooling</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, and potential for known customer misuse, e.g. storage, preparation.</li> </ul>	Y

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2.3.2	<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 this mayinclude 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 relevant for the production and sale of products</li> <li>• customer requirements</li> </ul>	Y
<b>2.4 Identify intended use – Codex Alimentarius Step 3</b>		
2.4.1	<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>	Y
<b>2.5 Construct a process flow diagram – Codex Alimentarius Step 4</b>		
2.5.1	<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 material receipt through to processing, storage and distribution. As a guide, this should 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-care/high-risk area segregation</li> <li>• finished products, intermediate/semi-processed products, by-products and waste.</li> </ul>	Y
<b>2.6 Verify flow diagram – Codex Alimentarius Step 5</b>		
2.6.1	<p>The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit and challenge at least annually. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.</p>	Y
<b>2.7 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>		
2.7.1	<p>The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps,</p>	Y

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	and allergen risks (refer to clause 5.2). It shall also take account of the preceding and following steps in the process chain.	
2.7.2	<p>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:</p> <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 specific concern to the product</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> </ul> <p>Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.</p>	Y
2.7.3	The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Where the control is achieved through existing prerequisite programmes, this shall be stated and the adequacy of the programme to control the hazard validated. Consideration may be given to using more than one control measure.	Y
2.8	<b>Determine the critical control points (CCP) – Codex Alimentarius Step 7, Principle 2</b>	
2.8.1	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 or eliminate a food safety hazard or reduce it to an acceptable level. 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.	Y
2.9	<b>Establish critical limits for each CCP – Codex Alimentarius Step 8, Principle 3</b>	
2.9.1	<p>For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be:</p> <ul style="list-style-type: none"> <li>measurable wherever possible, e.g. time, temperature, pH</li> <li>supported by clear guidance or examples where measures are subjective, e.g.</li> <li>photographs</li> </ul>	Y
2.9.2	The HACCP food safety team shall validate each CCP. Documented evidence shall show that the control measures selected and critical limits identified are capable of consistently controlling the hazard to the specified	Y

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	acceptable level.	
<b>2.10</b>	<b>Establish a monitoring system for each CCP – Codex Alimentarius Step 9, Principle 4</b>	
<b>2.10.1</b>	<p>A monitoring procedure shall be established for each CCP to ensure compliance with critical limits. 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>• offlinemeasurement</li> <li>• continuous measurement, e.g.</li> <li>• thermographs, pH meters etc.</li> <li>• where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product.</li> </ul>	Y
<b>2.10.2</b>	<p>Records associated with the monitoring of each CCP shall include the date, time and result of measurement and shall be signed by the person responsible for the monitoring and verified, as appropriate, by an authorised person. Where records are in electronic form there shall be evidence that records have been checked and verified.</p>	N
<b>2.11</b>	<b>Establish a corrective action plan – Codex Alimentarius Step 10, Principle 5</b>	
<b>2.11.1</b>	<p>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.</p>	Y
<b>2.12</b>	<b>Establish verification procedures – Codex Alimentarius Step 11, Principle 6</b>	
<b>2.12.1</b>	<p>Procedures of verification shall be established to confirm that the HACCP plan, including controls managed by prerequisite programmes, are effective. Examples of verification activities include:</p> <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> <p>Results of verification shall be recorded and communicated to the HACCP food safety team.</p>	Y
<b>2.13</b>	<b>HACCP documentation and record keeping – Codex Alimentarius Step 12, Principle 7</b>	

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2.13.1	Documentation and record keeping shall be sufficient to enable the company to verify that the HACCP controls, including controls managed by prerequisite programmes, are in place and maintained.	Y
2.14	<b>Review the HACCP plan</b>	
2.14.1	<p>The HACCP food safety team shall review the HACCP plan and prerequisite programmes at least annually and 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 consumer use</li> <li>• emergence of a new risk, for example adulteration of an ingredient</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 and/or prerequisite programmes, fully documented and validation recorded.</p>	Y

### 3. Food safety and quality management system

3.1	<b>Food safety and quality manual</b>	
<p>The company had in place a food safety and quality management manual which met the requirement of standard including outline of working methods and practices and department specific work instruction.</p> <p>Food safety and quality management manual was distributed to each department. Key staff could access the up-to-date version of the manual.</p> <p>Shelf life of all products was 24 months, and the period of retention for records was at least 3 years.</p>		
Statement of Intent	The company's processes and procedures to meet the requirements of this Standard shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe product.	Y
3.1.1	The company's documented procedures, working methods and practices shall be collated in the form of a printed or electronic quality manual.	Y
3.1.2	The food safety and quality manual shall be fully implemented and the manual or relevant components shall be readily available to key staff.	Y
3.1.3	All procedures and work instructions shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. This shall include the use of photographs,	Y

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		diagrams or other pictorial instructions where written communication alone is not sufficient (e.g. there are issues of literacy or foreign language).	
<b>3.2</b>	<b>Documentation control</b>		
Statement of Intent	The company shall operate an effective document control system to ensure that only the correct versions of documents, including recording forms, are available and in use.		Y
<b>3.2.1</b>	<p>The company shall have a procedure to manage documents which form part of the food safety and quality system. This shall include:</p> <ul style="list-style-type: none"> <li>• a list of all controlled documents indicating the latest version number</li> <li>• the method for the identification and authorisation of controlled documents</li> <li>• a record of the reason for any changes or amendments to documents</li> <li>• the system for the replacement of existing documents when these are updated.</li> </ul>		Y
<b>3.3</b>	<b>Record completion and maintenance</b>		
Statement of Intent	The company shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.		Y
<b>3.3.1</b>	Records shall be legible, retained in good condition and retrievable. Any alterations to records shall be authorised and justification for alteration shall be recorded. Where records are in electronic form these shall be suitably backed up to prevent loss.		Y
<b>3.3.2</b>	Records shall be retained for a defined period with consideration given to any legal or customer requirements and to the shelf life of the product. This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g. by freezing). As a minimum, records shall be retained for the shelf life of the product plus 12 months.		Y
<b>3.4</b>	<b>Internal audit</b>		
<p>The company had in place an internal audit control procedure (CX8.2.2-06) to specify internal audit. Internal audits planned and conducted yearly. The latest in-house audit happened on 2012-07-22/23.</p> <p>Trained Inner auditors: A: Zhu Hui, B: Chen Tao, C: Yan Zhenxing. Team leader: Yan Zhenxing, They attended ISO training courses.</p> <p>Internal audit plan and internal audit report including conformities as well as non-conformities could be provided by the factory. 1 non conformity was raised.</p> <p>The internal audit records as following: Internal audit plan, Internal audit checklist, non conformities report, open/close meeting attendance record.</p> <p>Hygiene inspection to ensure that the factory environment and processing equipment is maintained in a suitable condition for food production was in place for monthly basis.</p>			

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<b>FUNDAMENTAL</b> Statement of Intent	The company shall be able to demonstrate it verifies the effective application of the food safety plan and the implementation of the requirements of the Global Standard for Food Safety.	Y
<b>3.4.1</b>	There shall be a planned programme of internal audits with a scope which covers the implementation of the HACCP programme, prerequisite programmes and procedures implemented to achieve this Standard. The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance; all activities shall be covered at least annually.	Y
<b>3.4.2</b>	Internal audits shall be carried out by appropriately trained competent auditors, who are independent from the audited department.	Y
<b>3.4.3</b>	The internal audit programme shall be fully implemented. Internal audit reports shall identify conformity as well as non-conformity and the results shall be reported to the personnel responsible for the activity audited. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.	Y
<b>3.4.4</b>	In addition to the internal audit programme there shall be a programme of documented inspections to ensure that the factory environment and processing equipment is maintained in a suitable condition for food production. These inspections shall include: <ul style="list-style-type: none"> <li>• hygiene inspections to assess cleaning and housekeeping performance</li> <li>• fabrication inspections to identify risks to the product from the building or equipment</li> </ul> <p>The frequency of these inspections shall be based on risk but will be no less than once per month in open product areas.</p>	Y
<b>3.5</b>	<b>Supplier and raw material approval and performance monitoring</b>	
<b>3.5.1</b>	<b>Management of suppliers of raw materials and packaging</b>	
<p>Documented supplier approval procedure and continual assessment programme based on risk assessment was in place.</p> <p>There was a qualified supplier list in place including packaging material, raw material, ingredients and other materials.</p> <p>The criteria for initial approval of suppliers was in place including suppliers legality evaluation such as certificates of QS, business license; supplier questionnaire; test report according to the specification. All suppliers were categorised to A, B, C levels based on risk assessment and had to be approved by the QA Department before they could be used.</p> <p>Supplier's performance evaluation for all suppliers was conducted by the factory taking into account of product conformity, delivering timely, quality system.</p>		

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Detail raw materials acceptance standards were in place and raw materials were assessed on receipt by COA inspection or in house checks.

Refined cotton supplier Sheyang County Fuli refined cotton Co., Ltd, its QS certificate, Business license, tax registration certificate, test report with No.QC052105-2012 according to GB/T 9107-1999, supplier performance evaluation report (YL/JL-031) was available for review.

Food grade NaOH supplier Yantai Hengbang Chemical Co., Ltd, its QS certificate, Business license, tax registration certificate, test report with No. 2012 F0240 according to GB5175-2008, supplier performance evaluation report was available for review.

Edible Alcohol supplier Shandong Fulaichun Alcohol Co., Ltd, its QS certificate, Business license, tax registration certificate, test report with No. SP120371 according to GB10343-2008, COA dated 2013-04-14; supplier performance evaluation report was available for review.

No outsource processes.

Statement of Intent	The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials (including packaging) to the safety, legality and quality of the final product are understood and managed.	Y
3.5.1.1	<p>The company shall undertake a documented risk assessment of each raw material or group of raw materials to identify potential risks to product safety, legality and quality. This shall take into account the potential for:</p> <ul style="list-style-type: none"> <li>● allergen contamination</li> <li>● foreign body risks</li> <li>● microbiological contamination</li> <li>● chemical contamination.</li> </ul> <p>Consideration shall also be given to the significance of a raw material to the quality of the final product.</p> <p>The risk assessment shall form the basis for the raw material acceptance and testing procedure and for the processes adopted for supplier approval and monitoring.</p>	Y
3.5.1.2	<p>The company shall have a documented supplier approval and ongoing monitoring procedure to ensure that suppliers are manufacturing products under hygienic conditions, effectively manage risks to raw material quality and safety and are operating effective traceability processes. The approval and monitoring procedure shall be based on one or a combination of:</p> <ul style="list-style-type: none"> <li>● supplier audits</li> <li>● third party audits or certification, e.g. to BRC Global Standards</li> <li>● supplier questionnaires.</li> </ul> <p>Where approval is based on questionnaires, these shall be reissued at least every three years and suppliers required to notify the site of any significant changes in the interim.</p>	Y



3.5.1.3	The procedures shall define how exceptions are handled (e.g. where raw material suppliers are prescribed by a customer or where products are purchased from agents and direct audit or monitoring has not been undertaken).	Y
3.5.2	<b>Raw material and packaging acceptance and monitoring procedures</b>	
Statement of Intent	Controls on the acceptance of raw materials shall ensure that raw materials do not compromise the safety, legality or quality of products.	Y
3.5.2.1	<p>The company shall have a documented procedure for the acceptance of raw materials and packaging on receipt based upon the risk assessment (3.5.1). Raw material acceptance and its release for use shall be based on one or a combination of:</p> <ul style="list-style-type: none"> <li>• visual inspection on receipt</li> <li>• certificates of conformance – specific to each consignment</li> <li>• certificates of analysis</li> <li>• product sampling and testing.</li> </ul> <p>A list of raw materials and the requirements to be met for acceptance shall be available. The parameters for acceptance and frequency of testing shall be clearly defined.</p>	Y
3.5.2.2	The procedures shall be fully implemented and records maintained to demonstrate the basis for acceptance of each batch of raw materials.	Y
3.5.3	<b>Management of suppliers of services</b>	
Statement of Intent	The company shall be able to demonstrate that where services are outsourced, the service is appropriate and any risks presented to food safety have been evaluated to ensure effective controls are in place.	Y
3.5.3.1	<p>There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services shall include as appropriate:</p> <ul style="list-style-type: none"> <li>• pest control</li> <li>• laundry services</li> <li>• contracted cleaning</li> <li>• contracted servicing and maintenance of equipment</li> <li>• transport and distribution</li> <li>• off-site storage of ingredients, packaging or products</li> <li>• laboratory testing</li> <li>• catering services</li> <li>• waste management.</li> </ul>	Y
3.5.3.2	Contracts or formal agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential food safety risks associated with the service have been addressed.	Y
3.5.4	<b>Management of outsourced processing</b>	

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No processes were outsourced.		
Statement of Intent	Where any intermediate process steps in the manufacture of a product which is included within the scope of certification is subcontracted to a third party or undertaken at another company site, this shall be managed to ensure this does not compromise the safety, legality or quality of the product.	N/A
3.5.4.1	The company shall be able to demonstrate that where part of the production process is outsourced and undertaken off site, this has been declared to the brand owner and, where required, approval granted.	N/A
3.5.4.2	The company shall ensure that subcontractors are approved and monitored by successful completion of either a documented site audit or third-party certification to the BRC Global Standard for Food Safety or other GFSI-recognised Standard (see Glossary).	N/A
3.5.4.3	Any outsourced processing operations shall: <ul style="list-style-type: none"> <li>be undertaken in accordance with established contracts which clearly define any processing requirements and product specification</li> <li>maintain product traceability.</li> </ul>	N/A
3.5.4.4	The company shall establish inspection and test procedures for outsourced product on return, including visual, chemical and/or microbiological testing, dependent on risk assessment.	N/A
3.6	<b>Specifications</b>	
<p>The following specifications were sampled and reviewed including the following.</p> <p>Raw materials: Refined cotton(GB/T 9107-1999)/chloroacetic acid (HG/T 3271-2000)/NaOH/Alcohol(GB10343-2008)</p> <p>Packaging: PE bag (GB9687)</p> <p>Finished products: CMC(GB1904-2005)</p> <p>The final specifications are referred as FCC VI, GB1904-2005 and requirements from local CIQ/customers/USA and others.</p> <p>The specifications were adequate and accurate and ensure compliance with relevant safety and legislative requirements. The company reviews its specifications regularly, at least yearly.</p> <p>Corrective actions procedure has been established and implemented. Quality department was responsible for this issue. Records review found that the company takes corrective actions in a timely manner for non-conformities.</p>		
Statement of Intent	Specifications shall exist for raw materials including packaging, finished products and any product or service which could affect the integrity of the finished product.	Y
3.6.1	Specifications for raw materials and packaging shall be adequate and accurate and ensure compliance with relevant safety and legislative requirements. The specifications shall include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological or physical standards).	Y

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3.6.2		Manufacturing instructions and process specifications shall comply with recipes and quality criteria as detailed in agreed customer specifications.	Y
3.6.3		Specifications shall be available for all finished products. These shall either be in the agreed format of the customer or, in the case of branded products, include key data to meet legal requirements and assist the customer in the safe usage of the product.	Y
3.6.4		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 it has taken steps to ensure formal agreement is in place.	Y
3.6.5		Specifications shall be reviewed whenever products change (e.g. ingredients, processing method) or at least every three years. The date of review and the approval of any changes shall be recorded.	Y
3.7		<b>Corrective action</b>	
FUNDAMENTAL Statement of Intent		The company shall be able to demonstrate that they use the information from identified failures in the food safety and quality management system to make necessary corrections and prevent recurrence.	Y
3.7.1		<p>The company shall have a documented procedure for handling non-conformances identified within the scope of this Standard to include:</p> <ul style="list-style-type: none"> <li>• clear documentation of the non-conformity</li> <li>• assessment of consequences by a suitably competent and authorised person</li> <li>• identification of the corrective action to address the immediate issue</li> <li>• identification of an appropriate timescale for correction</li> <li>• identification of personnel with appropriate authority responsible for corrective action</li> <li>• verification that the corrective action has been implemented and is effective</li> <li>• identification of the root cause of the non-conformity and implementation of any necessary corrective action.</li> </ul>	Y
3.8		<b>Control of non-conforming product</b>	
<p>Non-conforming product control procedure was in place.</p> <p>All out-of-specification products were clearly identified in red colour plastic container, labelled and quarantined. All non-conforming products were handled or disposed of according to the requirement.</p> <p>Clear process well understood by staffs that were interviewed during the audit. Specified 'on hold' areas with yellow marking.</p> <p>Corrective actions were implemented to avoid recurrence of non-conformance. The list of non-conforming products has been reviewed, No major trends.</p>			

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Statement of Intent	The company shall ensure that any out-of-specification product is effectively managed to prevent release.	Y
3.8.1	<p>There shall be documented procedures for managing non-conforming products which include:</p> <ul style="list-style-type: none"> <li>the requirement for staff to identify and report potentially non-conforming product</li> <li>clear identification of non-conforming product, e.g. direct labelling or the use of IT systems</li> <li>secure storage to prevent accidental release, e.g. isolation areas</li> <li>referral to the brand owner where required</li> <li>defined responsibilities for decision making on the use or disposal of products appropriate to the issue, e.g. destruction, reworking, downgrading to an alternative label or acceptance by concession</li> <li>records of the decision on the use or disposal of the product</li> <li>records of destruction where product is destroyed for food safety reasons.</li> </ul>	Y
3.9	<b>Traceability</b>	
<p>The company had in place an identification and traceability control procedure which made the company able to trace materials from raw material source to finished product and vice versa.</p> <p>The company ensured the traceability of all materials used for its products, such as: batch number of raw material, ingredient and packaging materials: raw material code; for ingredient and packaging materials: receiving date; Finished products: 3(year) +05(month) +06(date) +07(serial number).</p> <p>Traceability test carried out at least twice per year to cover both directions (raw material to finished product and vice versa).</p> <p>The most recent traceability testing from raw material-refined cotton- product conducted (CMC) on 2013-02-22(15:00-16:35), the duration was within 4 hours, and the traceability testing records are maintained on files. Raw material: refined cotton batch number was 1311, quantity: 21101 kgs; finished product batch number is 30113, and Quantity: 35168kg. Quantity check and mass balance considered in its traceability testing.</p> <p>A test (for 30503 CMC) initiated by the auditor on the day of the audit involved the following: from ingredient to finished products, which was completed within 3 hours and mass balance, quantities were accurate to 100%.</p> <p><b>A Minor NC was raised: The Food grade NaOH stored in temporary storage area of workshop had no batch number for traceability purpose.</b></p>		
FUNDAMENTAL Statement of Intent	The company shall be able to trace all raw material product lots (including packaging) from their supplier through all stages of processing and despatch to their customer and vice versa.	Y
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.	N

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3.9.2	The company shall test the traceability system across the range of product groups to ensure traceability can be determined from raw material to finished product and vice versa, including quantity check/mass balance. This shall occur at a predetermined frequency and results shall be retained for inspection. The test shall take place at least annually. Full traceability should be achievable within four hours.	Y
3.9.3	Where rework or any reworking operation is performed, traceability shall be maintained.	Y
<b>3.10 Complaint handling</b>		
<p>Trade department collected the customer complaint, Trade department delivered it to production manager and Quality manager and GM. Quality manager hold meeting and make analysis of complaint. GM made corrective action according to the decision. The Quality department was responsible for the verification work.</p> <p>No complaint was raised in 2012-2013.</p>		
Statement of Intent	Customer complaints shall be handled effectively and information used to reduce recurring complaint levels.	Y
3.10.1	All complaints shall be recorded, investigated and the results of the investigation and root cause of the issue recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.	Y
3.10.2	Complaint data shall be analysed for significant trends and used to implement on-going improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.	Y
<b>3.11 Management of incidents, product withdrawal and product recall</b>		
<p>The suspected product definition as: Class I: Death health, carried out when there was a reasonable probability that the use of product would cause serious adverse health consequences or death.</p> <p>Class II: Carried out when the product may cause temporary or medically reversible adverse health consequences and the probability of serious adverse health consequence was remote.</p> <p>Class III: Carried out when the product is not likely to cause health consequence, but violates some specific food regulation.</p> <p>No recalls to date.</p> <p>The product recall &amp; withdrawal procedure was tested annually. Mock recall report dated 2013-03-20 with final product with batch number 2122210 was in place including timing of key activities. Mock recall finished within 2 hours and mock recall rate was 100%.</p> <p>A documented procedure had been established to manage incidents and potential emergency situations. Special work instructions were defined, including fire, flood, disaster, food safety incident, malicious contamination or sabotage.</p>		

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It was defined in the procedure that in the event of a product recall, SGS shall be informed within three working days of the decision to issue a recall.		
Statement of Intent	The company shall have a plan and system in place to effectively manage incidents and enable the effective withdrawal and recall of products should this be required.	Y
3.11.1	<p>The company shall have documented procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality. This shall include consideration of contingency plans to maintain business continuity. Incidents may include:</p> <ul style="list-style-type: none"> <li>• disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications</li> <li>• events such as fire, flood or natural disaster</li> <li>• malicious contamination or sabotage.</li> </ul> <p>Where products which have been released from the site may be affected by an incident, consideration shall be given to the need to withdraw or recall products.</p>	Y
3.11.2	<p>The company shall have a documented product withdrawal and recall procedure. This shall include as a minimum:</p> <ul style="list-style-type: none"> <li>• identification of key personnel constituting the recall management team, with clearly identified responsibilities</li> <li>• guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained</li> <li>• an up-to-date list of key contacts or reference to the location of such a list, e.g. recall 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>• a plan to handle the logistics of product traceability, recovery or disposal of affected product and stock reconciliation.</li> </ul> <p>The procedure shall be capable of being operated at any time.</p>	Y
3.11.3	The product recall and withdrawal procedures shall be 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. The results of the test and of any actual recall shall be used to review the procedure and implement improvements as necessary.	Y
3.11.4	In the event of a product recall, the Certification Body issuing the current certificate for the site against this Standard shall be informed within three working days of the decision to issue a recall.	Y

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4. Site Standards		
4.1	External standards	
<p>Modern building (2009).</p> <p>In good repair and well maintained with investments regularly planned. Located in an industrial park. No local activities that would risk product contamination.</p>		
Statement of Intent	The production site shall be of suitable size, location, construction and design to reduce the risk of contamination and facilitate the production of safe and legal finished products.	Y
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 potential contaminants, flooding etc.), they shall be reviewed in response to any changes.	Y
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. External traffic routes under site control shall be suitably surfaced and maintained in good repair to avoid contamination of the product.	Y
4.1.3	The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).	Y
4.2	Security	
<p>No FDA registers number.</p> <p>Plant security control procedure was established, enclosed site with 24 hour security.</p> <p>Production areas and warehouses were restricted areas, visitors were not permitted enter except accompanying person presence.</p> <p>Gatekeeper was responsible to control entrance of employees, contractors and visitors and persons would not be permitted to enter the factory without authorization.</p> <p>Plant security plan was reviewed once a year and the previous review was conducted on 2012-12-21.</p> <p>All employees of the factory was trained about plant security on 2013-04-09.</p> <p><b>A minor NC was raised: The security measures for NaClO storage area was not adequate and anyone could open the value of the NaClO container without enter into the iron fence.</b></p>		
Statement of Intent	Security systems shall ensure that products are protected from theft or malicious contamination whilst under the control of the site.	Y
4.2.1	The company shall undertake a documented assessment of the security arrangements and potential risks to the products from any deliberate attempt	Y

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	to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled. Identified security arrangements shall be implemented and reviewed at least annually.	
4.2.2	Measures shall be in place to ensure only authorised personnel have access to production and storage areas and access to the site by employees, contractors and visitors shall be controlled. A visitor reporting system shall be in place. Staff shall be trained in site security procedures and encouraged to report unidentified or unknown visitors.	N
4.2.3	Where required by legislation, the site shall be registered with, or be approved by, the appropriate authority.	Y
4.3	<b>Layout, Product Flow and Segregation</b>	
<p>CMC product was low risk product; separate packaging room, drying room, kneading area, centrifuging area in place.</p> <p>No high risk and high care products.</p> <p>Detailed plan of the site including access points for personnel and travel routes, location of staff facilities and routes to the facilities from places of work, production process flow, routes for the removal of waste was in place.</p>		
<b>FUNDAMENTAL</b> Statement of Intent	The factory layout, flow of processes and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with relevant legislation.	Y
4.3.1	<p>There shall be a plan of the site which designates areas where product is at different levels of risk from contamination; that is:</p> <ul style="list-style-type: none"> <li>enclosed product areas</li> <li>low-risk areas</li> <li>high-care areas</li> <li>high-risk areas.</li> </ul> <p>See Appendix 2 for guidance.</p> <p>This shall be taken into account when determining the prerequisite programmes for the particular areas of the site.</p>	Y
4.3.2	<p>The site plan shall define:</p> <ul style="list-style-type: none"> <li>access points for personnel and travel routes</li> <li>location of staff facilities and routes to the facilities from places of work</li> <li>production process flow</li> <li>routes for the removal of waste</li> <li>routes for the movement of rework.</li> </ul> <p>If it is necessary to allow access through production areas, designated</p>	Y

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	walkways shall be provided that ensure there is adequate segregation from materials. All facilities shall be designed and positioned, where possible, so that movement of personnel is by simple, logical routes. The movement of waste and rework shall not compromise the safety of products.	
4.3.3	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. Contractors involved in maintenance or repair activities shall be under the supervision of a nominated person.	Y
4.3.4	In low-risk areas the process flow together with the use of 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.	Y
4.3.5	Where <b>high-care areas</b> are part of the manufacturing site there should be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials, equipment, personnel, waste, airflow, air quality and utilities provision. Where physical barriers are not in place, the site shall have undertaken a full evaluation of the risks of cross-contamination and alternative effective processes shall be in place to protect products from contamination.	N/A
4.3.6	Where <b>high-risk areas</b> are part of the manufacturing site, there shall be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials, equipment, personnel, waste, airflow, air quality and utilities provision. The location of transfer points shall not compromise the segregation between high-risk areas and other areas of the factory. Practices shall be in place to minimise risk of product contamination (e.g. the disinfection of materials on entry).	N/A
4.3.7	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.	Y
4.3.8	Temporary structures constructed during building work or refurbishment, etc. shall be designed and located to avoid pest harbourage and ensure the safety and quality of products.	N/A
4.4	<p><b>Building fabric</b> Raw material handling, preparation, processing, packing and storage areas</p> <p>Modern building fabric – continual modernised since 2009. Good facilities.</p> <p>Floors, drainages, windows, doors, ceiling and overheads were well designed and maintained.</p> <p>Existing glass windows fitted with shatter retaining plastic film.</p> <p>Air was filtered in packaging room.</p>	

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There was no high risk and high care area.		
<b>A minor NC was raised: There was a hole in the wall of the second floor of the workshop.</b>		
Statement of Intent	The fabrication of the site, buildings and facilities shall be suitable for the intended purpose.	Y
4.4.1	<b>Walls</b> shall be constructed, finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.	N
4.4.2	<b>Floors</b> shall be suitably hard wearing to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious and maintained in good repair.	Y
4.4.3	<b>Drainage</b> , 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. 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.	Y
4.4.4	Where sites include <b>high-care</b> or <b>high-risk</b> facilities, there shall be a plan of the drains for these areas which shows the direction of flow and location of any equipment fitted to prevent the back up of waste water. The flow of drains shall not present a risk of contamination of the high-care/risk area.	N/A
4.4.5	<b>Ceilings and overheads</b> shall be constructed, finished and maintained to prevent the risk of product contamination.	Y
4.4.6	Where <b>suspended ceilings</b> or roof voids are present, adequate access to the void shall be provided to facilitate inspection for pest activity, unless the void is fully sealed.	Y
4.4.7	Where there is a risk to product, <b>windows</b> , and roof glazing which is designed to be opened for ventilation purposes, shall be adequately screened to prevent the ingress of pests.	Y
4.4.8	Where they pose a risk to product, glass windows shall be protected against breakage.	Y
4.4.9	<b>Doors</b> shall be maintained in good condition. External doors and dock levellers shall be close fitting or adequately proofed. External doors to open product areas shall not be opened during production periods except in emergencies. Where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress.	Y
4.4.10	Suitable and sufficient <b>lighting</b> shall be provided for correct operation of processes, inspection of product and effective cleaning.	Y
4.4.11	Where they constitute a risk to product, bulbs and strip lights – including those on electric fly-killer devices – shall be adequately protected. Where full	Y

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	protection cannot be provided, alternative management such as wire mesh screens or monitoring procedures shall be in place.	
4.4.12	Adequate <b>ventilation</b> and <b>extraction</b> shall be provided in product storage and processing environments to prevent condensation or excessive dust.	Y
4.4.13	<b>High-risk areas</b> shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented. This shall be based on a risk assessment, taking into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.	N/A
4.5	<b>Utilities – water, ice, air and other gases</b>	
<p>City Potable water was used for processing and cleaning, and was tested by authorized department once a year. Test report with No. 2013-000410 was available for review, 21 items were included.</p> <p>Water distribution plan was in place for review including water treatment and water recycling.</p> <p><b>A minor NC was raised: The water test report done by Linyi City Lanshan District CDC was in place for review but Pb, Hg, PH items was not included in it according to GB5749-2006.</b></p>		
Statement of Intent	Utilities used within the production and storage areas shall be monitored to effectively control the risk of product contamination.	Y
4.5.1	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 at point of use or pose no risk of contamination according to applicable legislation. The microbiological and chemical quality of water shall be analysed at least annually. The sampling points and frequency of analysis shall be based on risk, taking into account the source of the water, on-site storage and distribution facilities, previous sample history and usage.	N
4.5.2	An up-to-date plan shall be available of the water distribution system on site, including holding tanks, water treatment and water recycling as appropriate. The plan shall be used as a basis for water sampling and the management of water quality.	Y
4.5.3	Where legislation specifically permits the use of water which may not be potable for initial product cleaning (e.g. for the storage/washing of fish), the water shall meet the designated legal requirement for this operation.	N/A
4.5.4	Air, other gases and steam used directly in contact with or as an ingredient in products shall be monitored to ensure this does not represent a contamination risk. Compressed air used directly in contact with the product shall be filtered.	N/A
4.6	<b>Equipment</b>	
<p>Most equipment such as pipes, centrifugal machine, drying machine, SUS retorts, mixing machine, centrifuging machine, sieving machine and Metal detector, Metal detectors, around 4 years old and well</p>		

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maintained under routine maintenance systems.

Most of its equipment and tools are made of stainless (304#) the others were made of food grade materials too. Relevant certificates base on GB16798 (Food machine hygienic standard) can be available.

Equipments were positioned well to facilitate cleaning and service.

Statement of Intent	All food processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.	Y
4.6.1	All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.	Y
4.6.2	Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.	Y
4.7	<b>Maintenance</b>	

6 in-house engineers reported to production manager who operated documented maintenance plan.

If temporary repairs were necessary, safety of product would be protected. Tools and parts into workshop were count and collected at beginning and finishing, relevant records were in place.

Lubricating oil used was food grade registered in NSF H1 grade.

No major breakdowns in last 12 months.

Documented hygiene inspection on start up completed by production supervisors.

Statement of Intent	An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns.	Y
4.7.1	There shall be a documented planned maintenance schedule or condition monitoring system which includes all plant and processing equipment. The maintenance requirements shall be defined when commissioning new equipment.	Y
4.7.2	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment damage, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.	Y
4.7.3	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.	Y
4.7.4	The company shall ensure that the safety or legality of product is not jeopardised during maintenance and subsequent cleaning operations.	Y

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	Maintenance work shall be followed by a documented hygiene clearance procedure, which records that product contamination hazards have been removed from machinery and equipment.	
4.7.5	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, shall be food grade.	Y
4.7.6	Engineering workshops shall be kept clean and tidy and controls shall be in place to prevent contamination risks to the product (e.g. provision of swarf mats at the entrance/exit of workshops).	Y
<b>4.8</b>	<b>Staff facilities</b>	
	<p>Designated changing facilities were provided for all personnel, whether staff, visitor or contractor, prior to entry to production or packing areas.</p> <p>Outdoor clothing and other personal items stored in special cabinets. The uniforms were hung on the specifically shelf's in changing room.</p> <p>Sufficient hand-washing facilities were provided in the front of workshops. Taps were also hand-free; The disinfectant was alcohol and the detergent was in the place.</p> <p>Canteen facilities were well controlled and were inspected per month about hygiene and contamination, and relevant inspection record was in place for review.</p>	
Statement of Intent	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. The facilities shall be maintained in good and clean condition.	Y
4.8.1	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).	Y
4.8.2	Storage facilities of sufficient size to accommodate personal items shall be provided for all personnel who work in raw material handling, preparation, processing, packing and storage areas.	Y
4.8.3	Outdoor clothing and other personal items shall be stored separately from workwear within the changing facilities. Facilities shall be available to separate clean and dirty workwear.	Y

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4.8.4	<p>Where an operation includes a <b>high-care area</b>, personnel shall enter via a specially designated changing facility with arrangements to ensure that protective clothing will not be contaminated before entry to the high-care area. The changing facilities shall incorporate the following requirements:</p> <ul style="list-style-type: none"> <li>• clear instructions for the order of changing into dedicated protective clothes to prevent the contamination of clean clothing</li> <li>• dedicated footwear, by exception shoe coverings shall be provided for visitors only to be worn in the high-care area</li> <li>• an effective system shall be provided to segregate areas for wearing high-care from other footwear (e.g. a barrier or bench system) or there shall be an effective boot wash on entrance to the high-care area</li> <li>• protective clothing shall be visually distinctive from that worn in lower risk areas and shall not be worn outside of the high-care area</li> <li>• hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing</li> <li>• on entry to high-care areas, hand-washing and disinfection shall be provided.</li> </ul>	N/A
4.8.5	<p>Where an operation includes a <b>high-risk area</b>, personnel shall enter via a specially designated changing facility at the entrance to the high-risk area. The changing facilities shall include the following requirements:</p> <ul style="list-style-type: none"> <li>• clear instructions for the order of changing into dedicated protective clothes to prevent the contamination of clean clothing</li> <li>• dedicated footwear shall be provided to be worn in the high-risk area</li> <li>• an effective system shall be provided to segregate areas for wearing high-risk and other footwear, e.g. a barrier or bench system</li> <li>• protective clothing shall be visually distinctive from that worn in other areas and shall not be worn outside of the high-risk area</li> <li>• hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing</li> <li>• on entry to high-risk areas, hand-washing and disinfection shall be provided.</li> </ul>	N/A
4.8.6	<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 a suitable temperature</li> <li>• liquid soap</li> <li>• single use towels or suitably designed and located air driers</li> <li>• water taps with hand-free operation</li> <li>• advisory signs to prompt hand-washing.</li> </ul>	Y
4.8.7	<p>Toilets shall be adequately segregated and shall not open directly into production, packing and storage 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> </ul>	Y

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	<ul style="list-style-type: none"> <li>advisory signs to prompt hand-washing.</li> </ul> <p>Where hand-washing facilities within toilet facilities are the only facilities provided before re-entering production, the requirements of 4.8.6 shall apply and signs shall be in place to direct people to hand-wash facilities before entering production.</p>	
4.8.8	Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations.	Y
4.8.9	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. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.	Y
4.8.10	Where catering facilities are provided on the premises, they shall be suitably controlled to prevent contamination of product (e.g. as a source of food poisoning or introduction of allergenic material to the site).	Y
<b>4.9</b>	<b>Chemical and physical product contamination control</b> <b>Raw material handling, preparation, processing, packing and storage areas</b>	
<p>Knives were checked per shift and relevant record was in place.</p> <p>A chemical control procedure was in place in PRP managing the using, storage and handling of chemicals, and the chemicals were stored in separated room, relevant MSDSs, testing reports was in place, the relevant staffs was trained and training record was available for review.</p> <p>Glass and brittle material control procedure was available. Glass and brittle material items list and weekly checking records were available for exposed processing area.</p> <p>Staples were not allowed in the production area.</p> <p>No wooden tools used except wooden pallet in final product warehouse, which were checked in fixed frequency.</p>		
Statement of Intent	Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product.	Y
<b>4.9.1</b>	<b>Chemical control</b>	
4.9.1.1	Processes shall be in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination. These shall include as a minimum:	Y

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	<ul style="list-style-type: none"> <li>an approved list of chemicals for purchase</li> <li>availability of material safety data sheets and specifications</li> <li>confirmation of suitability for use in a food processing environment</li> <li>avoidance of strongly scented products</li> <li>the labelling and/or identification of containers 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>	
4.9.1.2	Where strongly scented or taint-forming materials have to be used, for instance for building work, procedures shall be in place to prevent the risk of taint contamination of products.	Y
4.9.2	<b>Metal control</b>	
4.9.2.1	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 a record of inspection for damage and the investigation of any lost items. Snap-off blade knives shall not be used.	Y
4.9.2.2	The purchase of ingredients and packaging which use staples or other foreign-body hazards as part of the packaging materials shall be avoided. Staples and paper clips shall not be used in open product areas. Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination.	Y
4.9.3	<b>Glass, brittle plastic, ceramics and similar materials</b>	
4.9.3.1	Glass or other brittle materials shall be excluded or protected against breakage in areas where open products are handled or there is a risk of product contamination.	Y
4.9.3.2	Documented procedures for handling glass and other brittle materials shall be in place and implemented to ensure that necessary precautions are taken. Procedures shall include as a minimum: <ul style="list-style-type: none"> <li>a list of items detailing location, number, type and condition</li> <li>recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product</li> <li>details on cleaning or replacing items to minimise potential for product contamination.</li> </ul>	Y
4.9.3.3	Documented procedures detailing the action to be taken in case of breakage of glass or other brittle items shall be implemented and include the following: <ul style="list-style-type: none"> <li>quarantining the products and production area that were potentially affected</li> <li>cleaning the production area</li> </ul>	Y

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	<ul style="list-style-type: none"> <li>inspecting the production area and authorising to continue production</li> <li>changing of workwear 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>4.9.3.4</b>	<b>Products packed into glass or other brittle containers</b>	
<b>4.9.3.4.1</b>	The storage of the containers shall be segregated from the storage of raw materials, product or other packaging.	N/A
<b>4.9.3.4.2</b>	<p>Systems shall be in place to manage container breakages between the container cleaning/inspection point and container closure. This shall include, as a minimum, documented instructions which ensure:</p> <ul style="list-style-type: none"> <li>the removal and disposal of at-risk products in the vicinity of the breakage; this may be specific for different equipment or areas of the production line.</li> <li>the effective cleaning of the line or equipment which may be contaminated by fragments of the container. Cleaning shall not result in the further dispersal of fragments, for instance by the use of high pressure water or air.</li> <li>the use of dedicated, clearly identifiable cleaning equipment (e.g. colour coded) for removal of container breakages. Such equipment shall be stored separately from other cleaning equipment.</li> <li>the use of dedicated, accessible lidded waste containers for the collection of damaged containers and fragments.</li> <li>a documented inspection of production equipment is undertaken following the cleaning of a breakage to ensure cleaning has effectively removed any risk of further contamination.</li> <li>authorisation is given for production to re-start following cleaning.</li> <li>the area around the line is kept clear of broken glass.</li> </ul>	N/A
<b>4.9.3.4.3</b>	Records shall be maintained of all container breakages on the line. Where no breakages have occurred during a production period, this shall also be recorded. This record shall be reviewed to identify trends and potential line or container improvements.	N/A
<b>4.9.4</b>	<b>Wood</b>	
<b>4.9.4.1</b>	Wood should not be used in open product areas except where this is a process requirement (e.g. maturation of products in wood). Where the use of wood cannot be avoided, the condition of wood shall be continually monitored to ensure it is in good condition and free from damage or splinters which could contaminate products.	Y
<b>4.10</b>	<b>Foreign body detection and removal equipment</b>	
<p>All products were filtered with 40/80/100/120 meshes filter according to different technical requirements or customer requirements. Filters were checked about integrity and meshes and foreign matter per shift.</p> <p>Magnets were used for all products with 6000 gauss and all were calibrated once a year and were</p>		

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cleaned per shifts by operator and relevant checking record was in place.

All products metal detected after packing process.

Detectors tested Fe $\phi$ ≤1.5mm, Sus $\phi$ ≤2.5mm, and Non-Fe $\phi$ ≤2.0mm.

Tests included single products and consecutive products and allowed detected product to be rejected into a locked bin with belt stop, audible alarm.

No historical failed test. Metal detector demonstrated effectively by staffs that were well aware of failure process – isolation of stock and retesting.

Statement of Intent	The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies.	Y
<b>4.10.1</b>	<b>Foreign body detection and removal equipment</b>	
<b>4.10.1.1</b>	<p>A documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign body contamination. Typical equipment to be considered may include:</p> <ul style="list-style-type: none"> <li>• filters</li> <li>• sieves</li> <li>• metal detection</li> <li>• magnets</li> <li>• optical sorting equipment</li> <li>• X-ray detection equipment</li> <li>• other physical separation equipment e.g. gravity separation, fluid bed technology.</li> </ul>	Y
<b>4.10.1.2</b>	The type, location and sensitivity of the detection and/or removal method shall be specified as part of the company's documented system. Industry best practice shall be applied with regard to the nature of the ingredient, material, product and/or the packed product. The location of the equipment or any other factors influencing the sensitivity of the equipment shall be validated and justified.	Y
<b>4.10.1.3</b>	<p>The company shall ensure that the frequency of the testing of the foreign body detection and/or removal equipment is defined and takes into consideration:</p> <ul style="list-style-type: none"> <li>• specific customer requirements</li> <li>• the company's ability to identify, hold and prevent the release of any affected materials, should the equipment fail.</li> </ul>	Y
<b>4.10.1.4</b>	Where foreign material is detected or removed by the equipment, the source of any unexpected material shall be investigated. Information on rejected materials shall be used to identify trends and where possible instigate preventive action to reduce the occurrence of contamination by the foreign material.	Y

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4.10.2		Filters and sieves
4.10.2.1	Filters and sieves used for foreign body control shall be of a specified mesh size or gauge and designed to provide the maximum practical protection for the product. Material retained or removed by the system shall be examined and recorded to identify contamination risks.	Y
4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage on a documented frequency based on risk. Records shall be maintained of the checks. Where defective filters or sieves are identified this shall be recorded and the potential for contamination of products investigated and appropriate action taken.	Y
4.10.3		Metal detectors and X-ray equipment
4.10.3.1	Metal detection equipment shall be in place unless risk assessment demonstrates that this does not improve the protection of final products from metal contamination. Where metal detectors are not used justification shall be documented. The absence of metal detection would only normally be based on the use of an alternative, more effective, method of protection (e.g. use of X-ray, fine sieves or filtration of products).	Y
4.10.3.2	Where metal detectors or X-ray equipment is used, this shall be situated at the latest practical step in the process flow and, wherever possible, after the product has been packaged.	Y
4.10.3.3	The metal detector or X-ray equipment shall incorporate one of the following: <ul style="list-style-type: none"> <li>an automatic rejection device, for continuous in-line systems, which shall either divert contaminated product out of the product flow or to a secure unit accessible only to authorised personnel</li> <li>a belt stop system with an alarm where the product cannot be automatically rejected, e.g. for very large packs</li> <li>in-line detectors which identify the location of the contaminant shall be operated to allow effective segregation of the affected product.</li> </ul>	Y
4.10.3.4	The company shall establish and implement documented procedures for the operation and testing of the metal or X-ray equipment. This shall include as a minimum: <ul style="list-style-type: none"> <li>responsibilities for the testing of equipment</li> <li>the operating effectiveness and sensitivity of the equipment and any variation to this for particular products</li> <li>the methods and frequency of checking the detector</li> <li>recording of the results of checks.</li> </ul>	Y

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4.10.3.5	<p>Metal detector checking procedures shall be based on best practice and shall as a minimum include:</p> <ul style="list-style-type: none"> <li>• use of test pieces incorporating a sphere of metal of a known diameter. The test pieces shall be marked with the size and type of test material contained.</li> <li>• tests carried out using separate test pieces containing ferrous metal, stainless steel and typically non-ferrous metal, unless the product is within a foil container.</li> <li>• a test that both the detection and rejection mechanisms are working effectively under normal working conditions.</li> <li>• checks that test the memory/reset function of the metal detector by passing successive test packs through the unit.</li> </ul> <p>In addition, where metal detectors are incorporated on conveyors:</p> <ul style="list-style-type: none"> <li>• the test piece shall be passed as close as possible to the centre of the metal detector aperture and wherever possible be carried out by inserting the test piece within a clearly identified sample pack of the food being produced at the time of the test.</li> </ul> <p>Where in-line metal detectors are used the test piece shall be placed in the product flow wherever this is possible.</p>	Y
4.10.3.6	<p>The company shall establish and implement corrective action and reporting procedures in the event of the testing procedure identifying any failure of the foreign body detector. Action shall include a combination of isolation, quarantining and re-inspection of all product produced since the last successful test.</p>	Y
<b>4.10.4 Magnets</b>		
4.10.4.1	<p>The type, location and the strength of magnets shall be fully documented. Documented procedures shall be in place for the inspection, cleaning, strength testing and integrity checks. Records of all checks shall be maintained.</p>	Y
<b>4.10.5 Optical sorting equipment</b>		
4.10.5.1	<p>Each unit shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.</p>	N/A
<b>4.10.6 Container cleanliness – glass jars, cans and other rigid containers</b>		
4.10.6.1	<p>Based on risk assessment, procedures shall be implemented to minimise foreign body contamination originating with the packaging container (e.g. jars, cans and other preformed rigid containers). This may include the use of covered conveyors, container inversion and foreign body removal through rinsing with water or air jets.</p>	N/A

4.10.6.2	The effectiveness of the container cleaning equipment shall be checked and recorded during each production. Where the system incorporates a rejection system for dirty or damaged containers, the check shall incorporate a test of both the detection and effective rejection of the test container.	N/A
<b>4.11 Housekeeping and hygiene</b>		
<p>The cleaning and disinfection plan was available for review including responsible employee, cleaning items, cleaning frequency, cleaning method, cleaning criteria.</p> <p>Cleaning and housekeeping was conducted with records describing the method, equipment and area.</p> <p>The training record of cleaning and housekeeping dated 2013-03-8/10 was available.</p> <p>Cleaning and disinfection chemicals were suitably labelled, secured in the designated area and used in accordance with chemical work instructions.</p> <p>Visual check daily and checking records were available for review and the results were considered satisfactory.</p> <p>No CIP.</p>		
<b>FUNDAMENTAL</b> Statement of Intent	Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised.	Y
4.11.1	<p>Documented cleaning procedures shall be in place and maintained for the building, plant and all equipment. Cleaning procedures shall as a minimum include the:</p> <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, including dismantling equipment for cleaning purposes where required</li> <li>• cleaning chemicals and concentrations</li> <li>• cleaning materials to be used</li> <li>• cleaning records and responsibility for verification.</li> </ul> <p>The frequency and methods of cleaning shall be based on risk.</p> <p>The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.</p>	Y
4.11.2	Limits of acceptable and unacceptable cleaning performance shall be defined, based on the potential hazards (e.g. microbiological, allergen or foreign body contamination). Acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see Glossary), microbiological testing or chemical testing as appropriate. The cleaning and disinfection procedures and frequency shall be validated and records maintained.	Y

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4.11.3	The resources for undertaking cleaning shall be available. Where it is necessary to dismantle equipment for cleaning purposes or to enter large equipment for cleaning, this shall be appropriately scheduled and, where necessary, planned for non-production periods. Cleaning staff shall be adequately trained or engineering support provided where access within equipment is required for cleaning.	Y
4.11.4	The cleanliness of equipment shall be checked before equipment is released back into full production. The results of checks on cleaning, including visual, analytical and microbiological checks, shall be recorded and used to identify trends in cleaning performance and instigate improvements where required.	Y
4.11.5	<p>Cleaning equipment shall be:</p> <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>• cleaned and stored in a hygienic manner to prevent contamination.</li> </ul> <p>Equipment used for cleaning in high-care and high-risk areas shall be dedicated for use in that area.</p>	Y
4.11.6	<b>Cleaning in place (CIP)</b>	
4.11.6.1	Cleaning-in-place (CIP) facilities, where used, shall be monitored and maintained to ensure their effective operation.	N/A
4.11.6.2	<p>A schematic plan of the layout of the CIP system shall be available. There shall be an inspection report or other verification that:</p> <ul style="list-style-type: none"> <li>• systems are hygienically designed with no dead areas, limited interruptions to flow streams and good system drain ability.</li> <li>• scavenge pumps are operated to ensure that there is no build-up of cleaning fluids in the vessels.</li> <li>• spray balls effectively clean vessels by providing full surface coverage and are periodically inspected for blockages. Rotating spray devices should have a defined operational time.</li> <li>• CIP equipment has adequate separation from active product lines, e.g. through the use of double seat valves, manually controlled links or blanks in pipework.</li> </ul> <p>The system shall be revalidated following alterations or additions to the CIP equipment. A log of changes to the CIP system shall be maintained.</p>	N/A
4.11.6.3	<p>The CIP equipment shall be operated to ensure effective cleaning is carried out:</p> <ul style="list-style-type: none"> <li>• The process parameters, time, detergent concentrations, flow rate and temperatures shall be defined to ensure removal of the appropriate target hazard, e.g. soil, allergens, vegetative microorganisms, spores. This shall be validated and records of the validation maintained.</li> <li>• Detergent concentrations shall be checked routinely.</li> </ul>	N/A

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	<ul style="list-style-type: none"> <li>Process verification shall be undertaken by analysis of rinse waters and/or first product through the line for the presence of cleaning fluids or by tests of ATP (bioluminescence techniques) allergens or micro-organisms as appropriate.</li> <li>Detergent tanks shall be kept stocked up and a log maintained of when these are filled and emptied. Recovered pre-rinse solutions shall be monitored for a build-up of carry-over from the detergent tanks.</li> <li>Filters, where fitted, shall be cleaned and inspected at a defined frequency.</li> </ul>	
<b>4.12</b>	<b>Waste/waste disposal</b>	
<p>No food products were supplied for animal feed in the factory.</p> <p>Waste was collected and removed by local official department.</p> <p>External waste collection containers were managed well to minimise risk.</p> <p>The factory would handle unsafe products or substandard trademarked materials their self.</p>		
Statement of Intent	Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.	Y
4.12.1	Where licensing is required for the disposal of categorised waste, it shall be removed by licensed contractors and records of disposal shall be maintained and available for audit.	Y
4.12.2	Food products intended to be supplied for animal feed shall be segregated from waste and managed in accordance with relevant legislative requirements.	N/A
4.12.3	<p>External waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be:</p> <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>	Y
4.12.4	If unsafe products or 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 which includes the quantity of waste collected for destruction or disposal.	N/A
<b>4.13</b>	<b>Pest control</b>	
<p>The regular inspection and treatment of the site to deter eradicate infestation was conducted by inner PCO. And the factory could provide PCOs' certificate issued by Qingdao Yongli Pest Control Co., Ltd, pest control plan, and inspection frequency was weekly, target organisms including: flies, mice, mosquitoes, moths and other pest.</p>		

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<p>There was a pest control procedure covering all area of the site and a map of pest control facilities which identified the location of pest control facilities in place.</p> <p>Flying killers and traps were used for pest control.</p> <p>6 EFKs, 15 traps.</p> <p>Tube of EFKs was changed at least once a year.</p> <p>Trend was conducted once a month.</p> <p>The in-depth, documented pest control survey was undertaken quarterly, by inner PCO.</p>		
Statement of Intent	The whole site shall have an effective preventive pest control programme in place to minimise the risk of infestation and there shall be the resources available to rapidly respond to any issues which occur to prevent risk to products.	Y
4.13.1	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.	Y
4.13.2	Where a company undertakes its own pest control, it shall be able to effectively demonstrate that: <ul style="list-style-type: none"> <li>• pest control operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site</li> <li>• sufficient resources are available to respond to any infestation issues</li> <li>• there is ready access to specialist technical knowledge when required</li> <li>• legislation governing the use of pest control products is understood</li> <li>• dedicated locked facilities are used for the storage of pesticides.</li> </ul>	Y
4.13.3	Pest control documentation and records shall be maintained. This shall include as a minimum: <ul style="list-style-type: none"> <li>• an up-to-date plan of the full site 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 for the contractor</li> <li>• details of pest control products used, including instructions for their effective use and action to be taken in case of emergencies</li> <li>• any observed pest activity</li> <li>• details of pest control treatments undertaken.</li> </ul>	Y

4.13.4	Bait stations shall be robust, of tamper resistant construction, secured in place and appropriately located to prevent contamination risk to product. Missing bait boxes shall be recorded, reviewed and investigated. Toxic rodent baits shall not be used within production areas or storage areas where open product is present except when treating an active infestation.	Y
4.13.5	Fly-killing devices and/or pheromone traps shall be correctly sited and operational. If there is a danger of insects being expelled from a fly-killing extermination device and contaminating the product, alternative systems and equipment shall be used.	Y
4.13.6	In the event of infestation, or evidence of pest activity, immediate action shall be taken to eliminate the hazard. Any potentially affected products should be subject to the non-conforming product procedure.	Y
4.13.7	Records of pest control inspections, pest proofing and hygiene 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 in a timely manner.	Y
4.13.8	An in-depth, documented pest control survey shall be undertaken at a frequency based on risk, but typically quarterly, by a pest control expert to review the pest control measures in place. The timing of the survey shall be such as to allow access to equipment for inspection where a risk of stored product insect infestation exists.	Y
4.13.9	Results of pest control inspections shall be assessed and analysed for trends on a regular basis, 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. The analysis shall be used as a basis for improving the pest control procedures.	Y
4.14	<b>Storage facilities</b>	
<p>The products were stored on the pallets and away from the wall in warehouses.</p> <p>All materials storage temperature was ambient temperature.</p>		
Statement of Intent	All facilities used for the storage of ingredients, in-process product and finished products shall be suitable for its purpose.	Y

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4.14.1	<p>Documented procedures to maintain product safety and quality during storage shall be developed on the basis of risk assessment, understood by relevant staff and implemented accordingly. These may include as appropriate:</p> <ul style="list-style-type: none"> <li>managing chilled and frozen product transfer between temperature controlled areas</li> <li>segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake</li> <li>storing materials off the floor and away from walls</li> <li>specific handling or stacking requirements to prevent product damage.</li> </ul>	Y
4.14.2	<p>Where temperature control is required, the storage area shall be capable of maintaining product temperature within specification and operated to ensure specified temperatures are maintained. Temperature recording equipment with suitable temperature alarms shall be fitted to all storage facilities <b>or</b> there shall be a system of recorded manual temperature checks, typically on at least a four-hourly basis or at a frequency which allows for intervention before product temperatures exceed defined limits for the safety, legality or quality of products.</p>	N/A
4.14.3	<p>Where controlled atmosphere storage is required, the storage conditions shall be specified and effectively controlled. Records shall be maintained of the storage conditions.</p>	N/A
4.14.4	<p>Where storage outside is necessary, items shall be protected from contamination and deterioration.</p>	N/A
4.14.5	<p>Receipt documents and/or product identification shall facilitate correct stock rotation of raw materials, intermediate products and finished products in storage and ensure materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life.</p>	Y
4.15	<b>Dispatch and transport</b>	
<p>Transport requirements with the logistics company named Yishui Desheng Logistic Co., Ltd were clearly defined in the contract.</p> <p>Products deliver check records were available. The items, such as batch of finished products, sanitation condition, pest activities, and sealing number were checked and recorded.</p>		
Statement of Intent	<p>Procedures shall be in place to ensure that the management of dispatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety or quality of the products.</p>	Y
4.15.1	<p>Documented procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include as appropriate:</p>	Y

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	<ul style="list-style-type: none"> <li>controlling temperature of loading dock areas</li> <li>the use of covered bays for vehicle loading or unloading</li> <li>securing loads on pallets to prevent movement during transit</li> <li>inspection of loads prior to dispatch.</li> </ul>	
4.15.2	Traceability shall be ensured during 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.	Y
4.15.3	<p>All vehicles or containers used for the dispatch of products shall be inspected prior to loading to ensure that they are fit for purpose. This shall ensure that they are:</p> <ul style="list-style-type: none"> <li>in a suitably clean condition</li> <li>free from strong odours which may cause taint to products</li> <li>suitably maintained to prevent damage to products during transit</li> <li>equipped to ensure any temperature requirements can be maintained.</li> </ul> <p>Records of inspections shall be maintained.</p>	Y
4.15.4	Where temperature control is required, the transport shall be capable of maintaining product temperature within specification, under minimum and maximum load. Temperature data-logging devices which can be interrogated to confirm time/temperature conditions or a system to verify and record at predetermined frequencies the correct operation of refrigeration equipment shall be used and records maintained.	N/A
4.15.5	Maintenance systems and documented cleaning procedures shall be maintained for all vehicles and equipment used for loading/unloading (e.g. hoses connecting to silo installations). There shall be records of the measures taken.	Y
4.15.6	<p>The company shall have documented procedures for the transport of products, which shall include:</p> <ul style="list-style-type: none"> <li>any restrictions on the use of mixed loads</li> <li>requirements for the security of products during transit, particularly when vehicles are parked and unattended</li> <li>clear instructions in the case of vehicle breakdown, accident or failure of refrigeration systems which ensure the safety of the products is assessed and records maintained.</li> </ul>	Y
4.15.7	Where the company employs third-party contractors, all the requirements specified in this section shall be clearly defined in the contract and verified or the contracted company shall be certificated to the Global Standard for Storage and Distribution or similar internationally recognised Standard.	Y





5. Product control		
5.1	Product design/development	
<p>Little new product variations other than change of raw materials. Full development procedure documented.</p> <p>For its products, shelf life test procedure was established and implemented. A shelf life trails record with batch number 0090709 in ambient temperature for CMC was retained on files. The test items: Sensory, stickiness, moisture and taste. All results were still within specification.</p> <p>The product formulation and production process is fully validated to meet the stated claim.</p>		
Statement of Intent	Product design and development procedures shall be in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products are produced.	Y
5.1.1	The company shall provide clear guidelines on any restrictions to the scope of new product developments to control the introduction of hazards which would be unacceptable to the company or customers (e.g. the introduction of allergens, glass packaging or microbiological risks).	Y
5.1.2	All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or authorised HACCP committee member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment.	Y
5.1.3	Trials using production equipment shall be carried out where it is necessary to validate that product formulation and manufacturing processes are capable of producing a safe product of the required quality.	Y
5.1.4	Shelf-life trials shall be undertaken using documented protocols reflecting conditions experienced during storage and handling. Results shall be recorded and retained and shall confirm compliance with relevant microbiological, chemical and organoleptic criteria. Where shelf-life trials prior to production are impractical, for instance for some long-life products, a documented science-based justification for the assigned shelf life shall be produced.	Y
5.1.5	All products shall be labelled to meet legal requirements for the designated country of use and shall include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer. There shall be a process to verify that ingredient and allergen labelling is correct based on the product recipe.	Y

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5.1.6	Where a product is designed to enable a claim to be made to satisfy a consumer group (e.g. a nutritional claim, reduced sugar), the company shall ensure that the product formulation and production process is fully validated to meet the stated claim.	Y
5.2	<b>Management of allergens</b>	
<p>The company had in place allergen control procedure to avoid the risk of cross contamination of products containing allergen.</p> <p>The company identified allergen items based on 2003/89/EC, 2005/26/EC and 2006/142/EC and risk analysis for allergens had been carried out and No allergen was in production line and warehouse, only wheat, peanut, soybeans and eggs in dining room.</p> <p>Final product was not allergen.</p> <p>All employees were trained about allergen on 2013-03-12 and records were available for review.</p>		
<b>FUNDAMENTAL</b> Statement of Intent	The company shall have a developed system for the management of allergenic materials which minimises the risk of allergen contamination of products and meets legal requirements for labelling.	Y
5.2.1	The company shall carry out an assessment of raw materials to establish the presence and likelihood of contamination by allergens (refer to glossary). This shall include review of raw material specifications and, where required, obtain additional information from suppliers, for example through questionnaires to understand the allergen status of the raw material, its ingredients and the factory in which it is produced.	Y
5.2.2	The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products and any new product development ingredients or products.	Y
5.2.3	<p>A documented 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:</p> <ul style="list-style-type: none"> <li>• consideration of the physical state of the allergenic material, i.e. powder, liquid, particulate</li> <li>• identification of potential points of cross-contamination through the process flow</li> <li>• assessment of the risk of allergen cross-contamination at each process step</li> <li>• identification of suitable controls to reduce or eliminate the risk of cross-contamination.</li> </ul>	Y
5.2.4	Documented procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination into	Y

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	<p>products not containing the allergen. 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>• the use of separate or additional protective over clothing when handling allergenic materials</li> <li>• use of identified, dedicated equipment and utensils for processing</li> <li>• scheduling of production to reduce changes between products containing an allergen and products not containing the allergen</li> <li>• systems to restrict the movement of airborne dust containing allergenic material</li> <li>• waste handling and spillage controls</li> <li>• restrictions on food brought onto site by staff, visitors, contractors and for catering purposes.</li> </ul>	
5.2.5	Where rework is used, or reworking operations carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen.	N/A
5.2.6	Where the nature of the production process is such that cross-contamination from an allergen cannot be prevented, a warning shall be included on the label. National guidelines or codes of practice shall be used when making such a warning statement.	N/A
5.2.7	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.	N/A
5.2.8	Equipment or area cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination by allergens. The cleaning methods shall be validated to ensure they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be identifiable and specific for allergen use, single use, or effectively cleaned after use.	N/A
5.2.9	All relevant personnel, including engineers, temporary staff and contractors, shall have received general allergen awareness training and be trained in the company's allergen-handling procedures.	Y
5.2.10	An effective system of documented checks shall be in place at line start-up, following product changeover and changes in batches of packaging to ensure that the labels applied are correct for the products packed.	N/A
5.3	<b>Provenance, assured status and claims of identity preserved materials</b>	
<p>GMO control system was in place. No GMO products.</p> <p>The factory gained HALAL and Kosher certificates for its products and well maintained. The mass balance was tested very half a year and the last one was conducted on 2013-02-22.</p>		

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The No GMO certificate for refined cotton supplied by Sheyang Fuli refined cotton Co., Ltd with No. Ir116100 was in place.

**A minor NC was raised: The refined cotton supplied by Zouping Yizhong Industrial Limited Co., Ltd was Non-GMO resourced, but the Non-GMO report was not available for review.**

Statement of Intent	Systems of traceability, identification and segregation of raw materials, intermediate and finished products shall be in place to ensure that all claims relating to provenance or assured status can be substantiated.	Y
5.3.1	Where claims are to be made on finished packs about the provenance, assured or 'identity preserved' status (see Glossary) of raw materials used, the status of each batch of the raw material shall be verified and records maintained.	N
5.3.2	Where a claim is made relating to the provenance, assured or identity preserved status of a product or ingredient, the facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. The company shall undertake documented mass balance tests at least every six months and at a frequency to meet the particular scheme requirements.	Y
5.3.3	The process flow for the production of products where claims are made shall be documented and potential areas for contamination or loss of identity identified. Appropriate controls shall be established to ensure the integrity of the product claims.	Y
<b>5.4 Product Packaging</b>		
<p>The relative package materials kept in special storage, the inner package materials and out package materials were also kept separately. Those were stored on the plate and with good protection.</p> <p>Food grade certificates were in place for packaging materials, such as for inner PE bag test report with No. 12QGW-453 was available for review.</p>		
Statement of Intent	Product packaging shall be appropriate for the intended use and shall be stored under conditions to minimise contamination and deterioration.	Y
5.4.1	When purchasing or specifying food contact packaging the supplier of packaging materials shall be made aware of any particular characteristics of the food (e.g. high fat content, pH or usage conditions such as microwaving) which may affect packaging suitability. Certificates of conformity or other evidence shall be available for product packaging to confirm it conforms to relevant food safety legislation and is suitable for its intended use.	Y
5.4.2	Where appropriate, packaging shall be stored away from raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified before being returned to an appropriate storage area. Obsolete packaging shall be stored	Y

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	in a separate area and systems shall be in place to prevent accidental use.	
5.4.3	Product contact liners (or raw material/work-in-progress contact liners) purchased by the company shall be appropriately coloured and resistant to tearing to prevent accidental contamination.	Y
5.5	<b>Product inspection and laboratory testing</b>	
<p>Documented inspection and analysis standard and sampling plan were in place.</p> <p>Testing and inspection schedules have been established to ensure specified product requirements could be met.</p> <p>The schedules included inspection method, standard, test items, frequency. Incoming raw materials, semi-processing products, finished products, food contacted surface; packaging material had been defined in it.</p> <p>The system of ongoing shelf life assessment was in place.</p> <p>The external labs were including Jining Institute of Supervision &amp; Inspection on product quality and CIQ.</p> <p>The main test items of products: Pesticide residue/ Heavy metal/ microbe items.</p> <p>CNAS lab and internal lab used for finished product testing, raw materials testing.</p> <p>COA sampled:</p> <p>COA of CMC dated on 2013-5-16 including PH, chloride, Moisture, Pb, Fe, As, results OK.</p> <p>Test report by Jining Institute of Supervision &amp; Inspection on product quality including PH, chloride, Moisture, Pb, Fe, As, results OK.</p> <p>Total 4 lab technicians in its lab.</p> <p>All of them were suitable trained, and training certificates are maintained on file.</p>		
Statement of Intent	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.	Y
5.5.1	<b>Product inspection and testing</b>	
5.5.1.1	There shall be a scheduled programme of testing covering products and the processing environment which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, frequency and specified limits shall be documented.	Y
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	Y

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	any unsatisfactory results or trends.	
5.5.1.3	The company shall ensure that a system of on-going 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 aw. Records and results from shelf life tests shall validate the shelf life period indicated on the product.	Y
5.5.2	<b>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 fully segregated from the manufacturing site and have operating procedures to prevent any risk of product contamination.	Y
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>	Y
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.	Y
5.5.2.4	Procedures shall be in place to ensure reliability of laboratory results, other than those critical to safety and legality 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>	Y
5.6	<b>Product release</b>	
Finished product was not released unless all agreed procedures have been followed.		

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Statement of Intent	The company shall ensure that finished product is not released unless all agreed procedures have been followed.	Y
5.6.1	Where products require positive release, procedures shall be in place to ensure that release does not occur until all release criteria have been completed and release authorised.	Y

6. Process Control		
6.1	Controls of operations	
<p>Operation procedure was in place to verify that the processes and equipment employed were capable of producing consistently safe and legal product with the desired quality characteristics. Packaging and labels need to be inspected and validated before releasing and packing. Product was also inspected before loading. Records were retained in place.</p> <p><b>A minor NC was raised: On site found the etherificate process monitor record was filled out in advance by the operator.</b></p>		
FUNDAMENTAL Statement of Intent	The company shall operate to documented procedures and/or work instructions that ensure the production of consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan.	Y
6.1.1	<p>Documented process specifications and work instructions shall be available for the key processes in the production of products to ensure product safety, legality and quality. The specifications as appropriate shall include:</p> <ul style="list-style-type: none"> <li>● recipes – including identification of any allergens</li> <li>● mixing instructions, speed, time</li> <li>● equipment process settings</li> <li>● cooking times and temperatures</li> <li>● cooling times and temperatures</li> <li>● labelling instructions</li> <li>● coding and shelf life marking</li> <li>● any additional critical control points identified in the HACCP plan.</li> </ul>	Y
6.1.2	Process monitoring, such as of temperature, time, pressure and chemical properties, shall be implemented, adequately controlled and recorded to ensure that product is produced within the required process specification.	N
6.1.3	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.	Y



6.1.4	Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores).	Y
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 and quality of the product to determine the action to be taken.	Y
6.1.6	Documented checks of the production line shall be carried out before commencing production and following changes of product. These shall ensure that lines have been suitably cleaned and are ready for production. Documented checks shall be carried out at product changes to ensure all products and packaging from the previous production have been removed from the line before changing to the next production.	Y
6.1.7	Documented procedures shall be in place to ensure that products are packed into the correct packaging and correctly labelled. These shall include checks at the start of packing, during the packaging run, following packaging changes and when changing batches of packaging materials, in order to ensure that correct packaging materials are used. The procedures shall also include verification of any code information or other printing carried out at the packing stage.	Y
<b>6.2</b>	<b>Quantity-weight, volume and number control</b>	
In the packing workshop, the net weight of the finished product was checked by one designed employee on site. Packed to minimum weight which met customers and legal requirement.		
Statement of Intent	The company shall operate a quantity control system which conforms to legal requirements in the country where the product is sold and any additional industry sector codes or specified customer requirement.	Y
6.2.1	The frequency and methodology of quantity checking shall meet the requirements of appropriate legislation governing quantity verification, and records of checks shall be maintained.	Y
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 and records shall be maintained.	Y
<b>6.3</b>	<b>Calibration and control of measuring and monitoring devices</b>	
All the measuring equipment used to monitor CCPs and product safety and legality were identified properly.		
Measuring equipment list was in place.		

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The thermometers and pressures in workshop were calibrated by official dept twice a year. Such as pressure certificate with No. F10-20130585 would expire on 2013-11-07; thermometer with No. XMTD-3002 would expire on 2014-05-28.

The electronic balances were calibrated by local official dept twice a year and by inner staff per day.

Statement of Intent	The company shall be able to demonstrate that measuring and monitoring equipment is sufficiently accurate and reliable to provide confidence in measurement results.	Y
6.3.1	The company shall identify and control measuring equipment used to monitor CCPs, product safety and legality. This shall include as a minimum: <ul style="list-style-type: none"> <li>a documented list of equipment and its location</li> <li>an identification code and calibration due date</li> <li>prevention from adjustment by unauthorised staff</li> <li>protection from damage, deterioration or misuse.</li> </ul>	Y
6.3.2	All identified measuring devices, including new equipment, shall be checked and where necessary adjusted: <ul style="list-style-type: none"> <li>at a predetermined frequency, based on risk assessment</li> <li>to a defined method traceable to a recognised national or international Standard where possible.</li> </ul> <p>Results shall be documented. Equipment shall be readable and be of a suitable accuracy for the measurements it is required to perform.</p>	Y
6.3.3	Reference measuring equipment shall be calibrated and traceable to a recognised national or international Standard and records maintained.	Y
6.3.4	Procedures shall be in place to record actions to be taken when the prescribed measuring and monitoring devices are found not to be operating within specified limits. Where the safety or legality of products is based on equipment found to be inaccurate, action shall to be taken to ensure at-risk product is not offered for sale.	Y

## 7. Personnel

**7.1** Training  
Raw material handling, preparation, processing, packing and storage areas

The company has a comprehensive training programme for staff before induction and annual and annual refreshment as appropriate.

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Training plan of 2013 was available including HACCP knowledge, CCP control, food safety, pest control, WI, allergen, cleaning and disinfection, chemical control, quality policy and quality target, other aspect. The company evaluated the effectiveness of the training through orally or writing examination or on-site operation.

For example, CCPs operators were trained on 2013-01-08 and training effectiveness were verified by writing examination and on-site operation.

<b>FUNDAMENTAL</b> Statement of Intent	The company shall ensure that all personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.	Y
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.	Y
7.1.2	Where personnel are engaged in activities relating to critical control points, relevant training and competency assessment shall be in place.	Y
7.1.3	The company shall put in place documented programmes covering the training needs of relevant personnel. These shall include as a minimum: <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 the effectiveness of training</li> <li>the delivery of training in the appropriate language of trainees.</li> </ul>	Y
7.1.4	Records of all training shall be available. This shall include as a minimum: <ul style="list-style-type: none"> <li>the name of the trainee and confirmation of attendance</li> <li>the date and duration of the training</li> <li>the title or course contents, as appropriate</li> <li>the training provider.</li> </ul> <p>Where training is undertaken by agencies on behalf of the company, records of the training shall be available.</p>	Y
7.1.5	The company shall routinely review the competencies of its staff. As appropriate, it shall provide relevant training. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.	Y
<b>7.2</b>	<b>Personal hygiene</b> <b>Raw material handling, preparation, processing, packing and storage areas</b>	

Documented detailed personnel procedure in place.

No issues seen regarding compliance to documented hygiene policies.



Statement of Intent	The company's personal hygiene standards shall be appropriate to the products produced, documented, and adopted by all personnel, including agency staff, contractors and visitors to the production facility.	Y
7.2.1	<p>The requirements for personal hygiene shall be documented and communicated to all personnel. This shall include as a minimum the following requirements:</p> <ul style="list-style-type: none"> <li>• Watches shall not be worn.</li> <li>• Jewellery shall not be worn, with the exception of a plain wedding ring or wedding wristband.</li> <li>• Rings and studs in exposed parts of the body, such as ears, noses, tongues and eyebrows, shall not be worn.</li> <li>• Fingernails shall be kept short, clean and unvarnished. False fingernails shall not be permitted.</li> <li>• Excessive perfume or aftershave shall not be worn.</li> </ul> <p>Compliance with the requirements shall be checked routinely.</p>	Y
7.2.2	Hand cleaning shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination.	Y
7.2.3	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue) and containing a metal detectable strip. These shall be company issued and monitored. Where appropriate, in addition to the plaster, a glove shall be worn.	N/A
7.2.4	Where metal detection equipment is used, a sample from each batch of plasters shall be successfully tested through the equipment and records shall be kept.	N/A
7.2.5	Processes and written instructions for staff shall be in place to control the use and storage of personal medicines, so as to minimise the risk of product contamination.	Y
<b>7.3</b>	<b>Medical screening</b>	
<p>Employees would be medically examined, prior to employment and yearly during employment. Visitor would be required to answer health questionnaire.</p> <p>Visitors and contractors would be required to answer health questions before entering production area and warehouse.</p>		
Statement of Intent	The company shall ensure that procedures are in place to ensure that employees, agency staff, contractors or visitors are not a source of transmission of food-borne diseases to products.	Y

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7.3.1	The company shall have a procedure which enables notification by employees, including temporary employees, of any relevant infection, disease or condition with which they may have been in contact or be suffering from.	Y
7.3.2	Where there may be a risk to product safety, visitors and contractors shall be required to complete a health questionnaire or otherwise confirm that they are not suffering from a condition which may put product safety at risk, prior to entering the raw material, preparation, processing, packing and storage areas.	Y
7.3.3	There shall be documented procedures for employees, contractors and visitors, relating to action to be taken where they may be suffering from or have been in contact with an infectious disease. Expert medical advice shall be sought where required.	Y
7.4	<b>Protective clothing Employees or visitors to production areas</b>	
<p>Each employee had 2 work uniforms including caps, hairnets, coats, trousers and footwear in GMP workshop.</p> <p>Hands washed and sanitised.</p> <p>Uniform cleaning and disinfection WI was in place. Uniform was cleaned by employees themselves, the washed working clothes were disinfected by UV light. Frequency was twice a week.</p>		
Statement of Intent	Suitable company-issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas.	Y
7.4.1	The company shall document and communicate to all employees, contractors or visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. <b>high-care</b> or low-risk areas). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, use of canteen and smoking areas).	Y
7.4.2	<p>Protective clothing shall be available that:</p> <ul style="list-style-type: none"> <li>is provided in sufficient numbers for each employee</li> <li>is of suitable design to prevent contamination of the product (as a minimum containing no external pockets above the waist or sewn on buttons)</li> <li>fully contains all scalp hair to prevent product contamination</li> <li>includes snoods for beards and moustaches where required to prevent product contamination.</li> </ul>	Y
7.4.3	Laundering of protective clothing shall take place by an approved contracted or in-house laundry using defined and verified criteria to validate the effectiveness of the laundering process. Washing of workwear by the employee is exceptional but shall be acceptable where the protective clothing	Y

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	is to protect the employee from the products handled and the clothing is worn in enclosed product or low-risk areas only.	
7.4.4	<p>Where protective clothing for <b>high-care or high-risk areas</b> is provided by a contracted laundry, this shall be audited either directly or by a third party, or should have a relevant certification. The laundry must operate procedures which ensure:</p> <ul style="list-style-type: none"> <li>• effective cleaning of the protective clothing</li> <li>• clothes are commercially sterile following the washing and drying process</li> <li>• adequate segregation between dirty and cleaned clothes</li> <li>• cleaned clothes are protected from contamination until delivered to the site, e.g. by the use of covers or bags.</li> </ul>	N/A
7.4.5	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.	Y
7.4.6	Where items of personal protective clothing that are not suitable for laundering are provided (such as chain mail, gloves and aprons), these shall be cleaned and sanitised at a frequency based on risk.	Y