

Audit Report

Global Standard Packaging and Packaging Materials Issue 5: July 2015

Audit summary			
Company name		BRC site code	
Site name			
Hygiene Category	High Hygiene		

Audit scope	
Scope of audit	The beating, moulding, trimming of disposable paper packaging products for food. Main raw materials include bagasse & bamboo & wood pulp and PLA(Poly lactide) film.
Exclusions from scope	None
Justification for exclusion	N/A

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

Audit results			
Audit result	Certificated	Audit type	Announced
Audit grade	B	Previous audit grade	B

Number of non-conformities	Major against SOI of Fundamental	0
	Critical	0
	Major	1
	Minor	8

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Company details			
Address			
Country	P.R. China	Telephone	
Commercial representative Name	Tian Lili	Email	
Technical representative Name	Tian Lili	Email	

Company profile					
Plant size (square metres)	>25K sq.m	No. of employees	501-1500	No. of key processes	1-3
Subcontracted processes	No				
Other certificates held	ISO9001, ISO14001				
Regions exported to	North America Europe Asia Choose a region Choose a region				
Major changes or auditor observations since last BRC audit	No major changes since previous BRC audit.				
Company description	<p>The facility was found in 2001, producing disposable paper packaging for food contacting directly. Their product is for the markets of EU, Asia and American. Total plant areas, including warehouses, were about 38,000 square meters. There are approx 746 employees in the facility, running in three shifts a day(7:00-15:00; 15:00-23:00; 23:00-7:00). Eight hours a shift and six work days a week in the facility. There are four buildings for production and and a big warehouses for raw pulp and a big warehouse for finished products. Main equipment includes moulding machines and cutting machines. No production processes are outsourced. The output is about 16000 tons in 2017. There were not customer complaints about food safety and no products were recalled or withdrawn since previous BRC audit.</p>				

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Product and process characteristics

Field of Audit (Glass Paper Metal Rigid plastic Flexible plastic Wood and other material Print Chemical processes)	02 - Papermaking Category Category Category
Products in production at the time of the audit	Paper bowls and paper plates

Audit duration details

Finish date	2018-09-14		
Re-audit due date	2019-09-22	Previous audit date	2017-09-19
On-site duration	24 hours	Duration of production facility inspection	12 hours
Reasons for deviation from typical or expected audit duration	N/A due to no deviation		
Next audit type selected	Announced		

Audit duration per day

Audit days	Date	Audit start time	Audit finish time
1 (start date)	2018-09-12	08:30	17:30
2	2018-09-13	08:30	17:30
3	2018-09-14	08:30	17:30

Auditor information

Auditor number	Auditor Name	Role
176177	David Liu	Leader Auditor

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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 1.1.7)	Opening meeting	Site inspection	Procedure review	Closing meeting
Name / Job Title				
Xie Yunsheng/ Management representative	x		x	x
Feng Ying/ Sales manager	x		x	x
He Qixion/ Quality manager	x	x	x	x
He Yunfeng/Warehouse	x		x	x
Tong Xinlian/Production plan	x		x	x
Xu Dan/Purchase manager	x		x	x
Zhu Fengfa/Maintenance	x		x	x
Tian Lili/QA	x	x	x	x
Wei Xiaocui/Admin	x		x	x

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Non-Conformity Summary

Major non-conformity against statement of intent of a fundamental requirement

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

Critical

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

Major

No.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	3.6.1	The supplier of PLA (polylactic acid) film has not been assessed since previous BRC audit. Related COA and a food grade declaration were not provided in 2018.	The supplier was assessed. COA and a food grade declaration were collected and kept. Incoming quality controllers were trained in supplier controls.	Assess the supplier. Collect and keep the up-to-date COA and food grade declaration. Training incoming controllers in supplier controls.	PLA supplier assessment report COA of PLA Food grade declaration of PLA Training records in supplier controls.(Sept.17, 2018)	2018-10-03	David Liu

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Minor

No.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	2.2.4	The flow diagram did not include the reuse of scrap paper.	The flow diagram was reviewed and updated, including the reuse. HACCP team was trained in HACCP principles.	Review and update the flow diagram. Train HACCP team in HACCP principles.	Updated flow diagram Training records in HACCP principles. (Sept.20, 2018)	2018-10-03	David Liu
2	4.4.1	The site security arrangements were not reviewed in 2018.	The site security arrangements were reviewed. Security control team was trained in security controls.	Review the security arrangements Train security control team in security controls.	Security arrangement review report. Training records in security controls.(Sept.17, 2018)	2018-10-03	David Liu
3	4.4.2	During on-site audit, found that there was not a lock for the door of film coating areas.(After production, the door should be locked to ensure only authorized personnel have access to the production areas.)	A lock was provided for the door. Related controllers were trained in security controls.	Provide a lock for the door Train related controllers in site security controls.	Photo showing a lock provided. Training records in site security controls. (Sept.21, 2018)	2018-10-03	David Liu
4	4.8.1	During on-site audit, found that a warehouse near production areas were in bad conditions, with waste plastic bottles and waste materials on the floor.	The warehouse was cleaned, in tidy conditions now. A documented plan was established to check and clean warehouses regularly.	Clean and tidy the warehouse. Establish a documented plan to clean warehouse regularly.	Photo showing the warehouse in tidy conditions. Warehouse cleaning records.(Sept.of 2018)	2018-10-03	David Liu
5	4.11.4	Pest control equipment was not enough in some areas, such as no mouse traps in the warehouse near No.1 plant.	Mouse traps were provided for the areas. Pest controllers were trained in pest controls.	Provide enough pest control equipment for all areas. Train pest controllers in pest controls.	Photo showing mouse traps in place. Training records in pest controls.(Sept.21, 2018)	2018-10-03	David Liu
6	5.7.1	During on-site audit, found that a batch of non-conforming products were not labeled and stored in appointed areas to show their conditions.	The non-conforming products were labeled and stored appointed areas. Warehouse keepers were trained in controls of non-conforming products.	Label the products and store them in the appointed for non - conforming products. Train warehouse keepers in controls of non-conforming products	Photo showing non-conforming products in controls. Training records in non-conforming product controls.(Sept.20, 2018)	2018-10-03	David Liu

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7	5.9.2	During on-site audit, found that some products were not protected well in the warehouse for raw paper boards, such as several bundles of raw paper boards with broken package and some raw paper boards contacting the floor directly.	The raw paper boards were protected correctly. Warehouse keepers were trained to protect products correctly.	Protect the products correctly. Train warehouse keepers to protect products correctly.	Photo showing product in good protection. Training records in product protection.(Sept.18, 2018)	2018-10-03	David Liu
8	6.1.1	Their training plan did not include employees in production areas.	The training plan was reviewed and updated, including the employees in production areas. Quality controllers were trained in training controls.	Review and update the training plan to cover all employees. Train related quality controllers in training controls.	Updated training plan. Training records in training controls.(Sept.20, 2018)	2018-10-03	David Liu

Comments on non-conformities – not tagged, just free text. This is to explain where a large number of NCs have been raised without a major

Detailed Section

1.	Senior management commitment																
1.1	Senior management commitment and continual improvement																
	<p>The safety and quality policy was established and updated on Feb.20, 2017, signed by their general manager XTB. The policy statement was clearly defined in the quality manual, covering legality, quality and safety requirements. The policy has been communicated to all levels of staff by the management team. A plan is in place to review and where necessary update the policy regularly, at least once a year. Last review was done on May.9, 2018.</p> <p>The safety and quality objectives have been established. Key objectives:</p> <p>----Finished Product qualification ratio based on customers testing: more than 99%</p> <p>---- Customer satisfactory ratio: more than 98%</p> <p>-----Finished product qualification rate based on internal testing: more than 98%</p> <p>The objectives have been disassembled to related departments, with detailed objectives, which will be assessed monthly. The KPI is communicated through meeting, e-mail and board displayed in production areas and office. Monthly objective assessment reports are in place. Some quality objective assessment results in 2017 and 2018:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Oct. of 2017</th> <th style="text-align: center;">Mar. Of 2018</th> <th style="text-align: center;">Jul of 2018</th> </tr> </thead> <tbody> <tr> <td>Finished product qualification rate based on internal testing</td> <td style="text-align: center;">98.5%</td> <td style="text-align: center;">98.43%</td> <td style="text-align: center;">99%</td> </tr> <tr> <td>Finished Product qualification ratio based on customers testing</td> <td style="text-align: center;">100%</td> <td style="text-align: center;">99%</td> <td style="text-align: center;">99.02%</td> </tr> <tr> <td>Customer satisfactory ratio</td> <td style="text-align: center;">98%</td> <td style="text-align: center;">100%</td> <td style="text-align: center;">100%</td> </tr> </tbody> </table> <p>Top management provided human resource and financial resource to support BRC standard and maintained product safety and quality management system in 2017 ad 2018.</p> <p>Channels of meetings and e-mails are implemented according to organization structure chart following employees--- shift leaders- department managers--- top management.</p> <p>Communication channels for outside parties are in place, including those for customers and suppliers.</p> <p>Quality department has been appointed to collect and keep relevant legislative requirements.</p> <p>Example for:</p> <p>GB 4806.1-2016 general requirements for food contact materials and food contact products.</p> <p>GB 9685-2016 additives for food contact materials and food contact products.</p> <p>GB 4806.8-2016 general requirements for food contact paper materials</p> <p>FDA CFR 176.170</p> <p>Current and original copy from BRC IoP was found on site.</p> <p>Top management on site attend the opening meeting and closing meeting.</p> <p>This BRC due date was Sep.22, 2018 and actual audit date was Sep.12&13&14, 2018.</p> <p>Corrective evidences were in place for the non conforming items identified during last BRC audit.</p>		Oct. of 2017	Mar. Of 2018	Jul of 2018	Finished product qualification rate based on internal testing	98.5%	98.43%	99%	Finished Product qualification ratio based on customers testing	100%	99%	99.02%	Customer satisfactory ratio	98%	100%	100%
	Oct. of 2017	Mar. Of 2018	Jul of 2018														
Finished product qualification rate based on internal testing	98.5%	98.43%	99%														
Finished Product qualification ratio based on customers testing	100%	99%	99.02%														
Customer satisfactory ratio	98%	100%	100%														
1.2	Management review																
	<p>A management review control procedure is in place, which will be done regularly, at least once a year.</p>																

Last management review was conducted on May.9, 2018, chaired by their general manager, XTB. Related management review reports were in place. Summary of input included customer complaints, monitoring results of main processes, suppliers' performance, product recall and withdrawal, objective and policy reviewed, communications, the performance of food safety management, internal audit results, 2nd party audit and 3rd party audit, previous management review documents, action plans and timeframes

any changes in the management system.

Summary of output: the management review results proved that the product safety and risk management system was suitable and effective including continuous improvements, suitability of food safety policy and food safety objectives, effectiveness of FSMS and resource requirements and improvement decisions.

Improvement items were raised and corrective action plans were established for review. Main improvement decisions include:

1. Controls of foreign bodies, such as pests and hair.
2. Selecting of good suppliers

Weekly meeting about management is also conducted to enable product safety, legality and quality issues to be brought to the attention of senior management and allows for the resolution of issues requiring immediate action.

Examples for weekly meeting record of Feb and Jul, 2018.

1.3	Organisational structure, responsibilities and management authority
	<p>A documented quality manual is available(). Responsibilities have been defined, including those with impacts on product safety, legality and quality. Clear organization structure has been established, covering all business processes, including quality, production, maintenance, sales, purchasing, finance and warehouse.</p> <p>Designated general manager is Xie Taibo. Responsibilities for key members have been established and documented. Documented arrangements were in place for the absence of key staff.</p> <p>Work instructions are available, communicated and in place for staff that responsible for every key activity related to product safety, legality and quality.</p> <p>Communication channel includes Chairman----GM→ management representative and department managers →controllers and shift leaders---operators and versa.</p>
Non-applicable clauses	No

2.	Hazard and risk management system										
2.1	Hazard and risk management team										
	<p>HACCP plan (), updated on May.15,2018, was signed by their general manager(XTB).</p> <p>HACCP team (13 members) have been defined and related responsibilities have been established and documented. Team leader: Xie Yunsheng. All team members have been trained in risk assessment & BRC IoP and related training records were in place.</p> <p><u>Example for team members:</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="border-top: 1px solid black; border-bottom: 1px solid black;"> <th style="text-align: left;">Training content</th> <th style="text-align: left;">Name</th> <th style="text-align: left;">Position</th> <th style="text-align: left;">Training date</th> <th style="text-align: left;">TUTOR</th> </tr> </thead> <tbody> <tr style="background-color: #e1f5fe;"> <td>BRC IOP ISSUE 5</td> <td>He Qixin</td> <td>Quality manager</td> <td>Mar.14, 2018</td> <td>SGS tutor</td> </tr> </tbody> </table>	Training content	Name	Position	Training date	TUTOR	BRC IOP ISSUE 5	He Qixin	Quality manager	Mar.14, 2018	SGS tutor
Training content	Name	Position	Training date	TUTOR							
BRC IOP ISSUE 5	He Qixin	Quality manager	Mar.14, 2018	SGS tutor							

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HACCP/BRC IOP 5	ALL MEMEB ERS	May.22, 2018	Internal tutor
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2.2 Hazard and risk analysis

The product scopes were clearly identified in their HACCP Plan, including all disposable paper products to package food products, such as paper plate, paper dish and paper boxes. Hazard analysis for raw materials and producing steps have been carried out and related control measures have been established and documented based on assessment results. The HACCP plan covers all processing areas and all storage areas for raw materials and finished products.

Historical and known hazards have been identified and considered mainly through regular HACCP team meetings, professional training and information from publications and newspaper. Quality department and sales department have been appointed to pay close attention to relevant codes of practice or recognized guidelines, and legislative requirements.

Raw materials: raw bagasse/bamboo/wood pulp boards, PLA film
 Ingredients: anti-foaming agent, oil-proofing agent, water-proofing agent
 Intended use: direct contact with food

Use temperature: mainly at normal temperature, less than 100 degree

Main parameters: water content---less than 7%; Pb---less than 3 ppm; As---less than 1 ppm; no fluorescent materials, formaldehyde--less than 1 ppm

Main processing steps:

Raw paper boards receiving --- storage----raw paper boards preparation----pulping--- moulding---- lamination with PLA film (if need)---trimming---metal detecting---disinfecting---packaging-- ---finished products.

The flow diagram was verified on May.15, 2018 by HACCP team.

The hazards analysis considered the hazards of physical hazard (metal chips, wood and other foreign bodies), chemical hazard (pesticide residues, fluorescent materials, heavy metal) and microbiological hazard (E. Coli, mould, pathogen).

Based on risk assessment and CCP decision tree, 1 CCP was identified.

The correction and corrective actions taken have been clearly identified. CCP see followings:

		Hazards	CL	Monitoring
CC P	Metal detecting	Metal foreign bodies	Fe≤φ1.2 mm , Non-Fe ≤φ1.55 mm, SUS≤φ2.0	The metal detectors will be checked with probes at start-up, hourly and at the end.

The monitoring system has been established for the CCP, conducted by trained controllers. The correction and corrective actions taken have been clearly identified, including metal detector adjusting and product handling. The corrective action is as followings:
 The products will be re-detected or rejected based on detecting results.

Main verification activities:

CCP monitoring records reviews by quality controllers daily.
 A HACCP review control procedure is in place, which is done at least once a year. Last review was done on May.15, 2018.
 There were not CCP deviations since last BRC audit. No customer complaints due to CCPs' deviations.

2.3 Exemption of requirements based on risk analysis

	Exemptions will be documented and regarded as proposed exemptions for review at audit. No any exemption of requirements based on risk analysis. 2.3.1, 2.3.2 N/A as no exemption of requirements based on risk assessment.
Non-applicable clauses	no

3.	Product safety and quality management system
3.1	Product safety and quality management system
	<p>Their product safety and quality management system has been established, documented and implemented based on ISO90001 and BRC IOP requirements. Main documents for the system include a safety/quality annual, control procedures for processes identified, HACCP system, work instructions and specifications. A quality management team/HACCP team has been appointed to control the documents.</p> <p>The copies of the documents have been distributed to each department and related Key staff could get the up-to-date versions.</p> <p>BRC IoP Standard requirements have been considered by the system.</p> <p>The system is reviewed at planning intervals, at least once every 3 year.</p>
3.2	Documentation control
	<p>A document and record control procedure is in place to define how to control documents and records. The procedure details who will edit documents, who will approve documents, who will keep documents, how to update documents and how to store documents. Based on on-site checking, found that documents were approved by authorized person. A list is in place to indicate the latest version numbers for the documents. The reasons have been recorded for any changes to the documents.</p>
3.3	Record keeping
	<p>A document and record control procedure is in place to define how to control documents and records, including establishing, reviewing, collecting and storage. Quality department has been appointed as the centralized management department.</p> <p>Legible and good justification records were observed from the reviewing of existing maintained records.</p> <p>Records will be kept for long time (over 3 years) according to each kind products.</p>
3.4	Specifications
	<p>Specifications have been established for raw materials, half-finished products and finished products. In general, those are adequate and accurate, which were established based on the results of related hazard analysis, official regulations and customers' requirements.</p> <p>For raw pulp boards, specifications consider:</p> <ol style="list-style-type: none"> 1. control levels of heavy metal 2. Food grade products 3. No fluorescent materials <p>Specificaion of paper products---</p> <p>Raw and finished product specifications have been agreed with relevant parties, customers or suppliers, through oral or documented contracts.</p> <p>The declarations of compliance have been collected and kept from suppliers of raw materials, such</p>

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	<p>as wood pulp boards and bamboo pulp boards. The declarations of finished products have been established and documented for all customers to show food grade products and for food contacting. The declarations of compliance contain contents such as: the nature of the materials, confirmation that materials meet relevant legal requirements, no any post-consumer recycled materials, limitations, no allergens and use information etc.</p> <p>The specificaiton of finished products in place.</p> <p>Trade marks will reviewed with agreement signature by Sales and Customer.</p> <p>Evidence shows that specifications had been regularly reviewed and updated according to relevant requirement. Review frequency is at least once every 3 year.</p> <p>Example for the latest review date is Jan.20, 2018.</p>
3.5	Internal audits
	<p>An internal audit control procedure in place. Based on the risks associated with the activity and previous audit performance, a scheduled plan is in place to ensure internal audits will be carried out throughout the year, including all products and all processing steps. Supplier controls, molding and metal detecting have been identified three important processes for product safety, which will be audited at least twice a year.</p> <p>Internal audit samples in 2017 and 2018 as follows: Dec.21&22, 2017 2 minors Jul. 5&6, 2018 3 minors</p> <p>Details of CARs have been defined and corrective actions have been established and implemented within specific time scales. The corrective actions were verified by HACCP team. The trained internal auditors conducted the internal audits, who didn't audit their own works. Eight trained internal auditors are in place. Training certicates are in place for all internal auditors. A monthly on-site inspection plan is in place, carried out by a team from quality department, production department, maintenance and warehouse keepers. Non conforming items have been identified and documented based on on-site inspections. Based on non conformity, action plans have been established, documented and implemented.</p>
3.6	Supplier approval and performance monitoring
	<p>A purchasing control procedure is in place for approval and monitoring of all suppliers. A list of approval suppliers is in place, which is updated regularly according to supplier assessment results or certificate. The evaluation frequency of supplier is at least once a year.</p> <p>All suppliers of the materials, ingredient, packing products and services have to be approved at the first and then entered into the system before they can be used.</p> <p>For main raw materials, such as raw paper borad and PLA film, related suppliers will be approved and assessed based on certitficates or on-site audits. For other materials with low risks, related suppliers will be approved and assessed based on questionnair.</p> <p>For raw paper board supplier in Tailan, approval and monitoring documents inlcude: 1. HACCP certificate 2. GMP certificate 3. ISO22000 certificate 4. supplier assessment reports.</p> <p>The detailed exception was defined in procedure, no exception happened till now.</p>
3.7	Management of subcontracted processes
	N/A There was no subcontracting of production in place.
3.8	Management of suppliers of services
	<p>A control procedure is in place to approve and monitor service suppliers.</p> <p>The service services and qualified certificates were collected and evaluated its performance annual.</p> <p>The service suppliers included pest control service, waste service, transportation service and lab</p>

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service. Related service contracts were kept on files.

3.9 Traceability

A traceability control procedure is in place. A team is in place for traceability controls. Traceability was based on e-copy records and hard copy records. Traceability records are kept by their quality department, which are retrievable according to on-site tests.

Traceability system demonstrated enough ability based on an on-site test.

Batch number of finished products sampled: 1807042CA16bKE00000000C51409

Order number: 100648-5

Name: 10x6 bowl for an America customer

Quantity: 676 cases (600 bowls/case)

Results:

Batch number of waterproof agent: FS20180621

Batch number of oilproof agent: FY320180622

Batch number of JB2 paperboards: 20180310

Batch number of JB13 paperboards: 20180612

Time spent: 2 hours

Batch number of raw bagasse pulp boards: 20170523

Traceability test frequency is at least once a year and test from Supplier/raw materials to finished products / customer and vice versa.

Example for the traceability test:

Mock time	2018-04-19	2018-04-19
Direction	From finished products to raw materials	From raw materials to finished products
Description of products sampled	Product name: 10X6 bowl Batch number: 1804162AB56bA100000000K41901 Quantity: 77 cases (600)	Raw materials: JB2 pulp boards Batch number: JB220171104 Quantity: 31826.59kg
Production date	Apr. 16, 2018	2018.3.27 A shift --2018.4.16 B shift
Producer	Plant 2, AB, A SHIFT	Plant 2
Result	Batch number of water proofing agent: FS20180409 Batch number of oil proofing agent :170228 FY320180320 Raw pulp board JB1 20180407 Raw pulp board JB 2 20171104 Raw pulp board JB 1920180414	Order numbers of finished products: 4502290109+4502290111+4502290112+4502290113+4502290116+4502290117+4502290118+4502290119+4502290120
Results	effective	effective

3.10 Customer focus and contract review

A procedure is in place for customer communication and contract review procedure. The contracts are reviewed by sales Dept., production Dept. and QA together, and all customer requirements are identified and followed.

No specific customer policies or requirements in place.

3.10.3 N/A as customers did not set particular performance criteria or indicators for monitoring.

3.11	Complaint handling														
	<p>A customer complaint control procedure is in place, Sales department collects complaints from clients, and deliver it to QA and production department. The root of cause was analyzed by QA and production department. Based on cause analysis, corrective actions will be established and implemented.</p> <p>Complaints records in 2017 & 2018 were in place, only two complaints about paper scraps in finished products.</p> <p>Root causes have been identified and correvtive actions have been established and implemented. No any food safety complaints happened till now. Trend analysis will be conducted to ensure continuously improvement if complaints happened.</p>														
3.12	Management of product withdrawals, and incidents and product recalls														
	<p>Incident control procedure defines how to control and manage incidents and potential emergency situations that impact food safety, legality or quality such as:</p> <ul style="list-style-type: none"> - disruption to key services such as water, power, transport, staff availability and communications - events such as fire, wind, flood or natural disaster - malicious contamination or sabotage <p>A control procedure is in place to define how to manage product recall& withdrawal. Procedure defines to inform the certification body within 1 day if actual product recall happened. No product withdrawal or recall in 2017 and 2018.</p> <p>Product recall team has 10 members. Leader: XYS</p> <p>A plan is in place to ensure mock recall tests will be conducted regularly, at least once a year. The current mock tests were conducted based on following path:</p> <table border="1" data-bbox="272 1032 1195 1473"> <tr> <td>Mock time</td> <td>2018-04-19</td> </tr> <tr> <td>Description</td> <td>Batch number of JB2 pulp boards which will be recalled:JB220171104 Quantity:31826.59kg</td> </tr> <tr> <td>Production date</td> <td>2018.3.27 A shift --2018.4.16 B shift</td> </tr> <tr> <td>Delivery date</td> <td></td> </tr> <tr> <td>Order number</td> <td>Order numbers of finished products: 4502290109+4502290111+4502290112+4502290113+4502290116+4502290117+4502290118+4502290119+4502290120</td> </tr> <tr> <td>Mock effectiveness</td> <td>100%</td> </tr> <tr> <td>Customer defined?</td> <td>OK</td> </tr> </table> <p>Recovery is 100% within 2 hours.</p>	Mock time	2018-04-19	Description	Batch number of JB2 pulp boards which will be recalled:JB220171104 Quantity:31826.59kg	Production date	2018.3.27 A shift --2018.4.16 B shift	Delivery date		Order number	Order numbers of finished products: 4502290109+4502290111+4502290112+4502290113+4502290116+4502290117+4502290118+4502290119+4502290120	Mock effectiveness	100%	Customer defined?	OK
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Mock effectiveness	100%														
Customer defined?	OK														
Non-applicable clauses	3.7, 3.10.3														

4.	Site Standards			
4.1	External standards			
	The boundary of factory is clearly defined and there was no pollution around factory. During on-site audit, found that the exteriors were in clean and tidy conditions. All ground within the site were			
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	<p>covered by grass or cement. A clean and unobstructed area was provided along the external walls of the building.</p> <p>Dormitories and canteens located in an isolated areas, without risks of contamination to production areas.</p> <p>4.1.5 N/A due to no external storage of raw materials.</p>
4.2	<p>Building fabric and interiors</p> <p>During on-site audit, found that buildings were suitable for the production of paper products. The building of facility for the product was in well maintained and in good conditions. The fabrication of the site, buildings and facilities are suitable for its products process. The building fabric is maintained to minimize potential for product contamination. Site boundaries are clearly defined and maintained condition in order to prevent potential contamination of product. No any potential contamination observed during assessment. Adequate drainage is observed.</p> <p>The windows were in the closed manner during audit on-site inspection.</p> <p>Glass windows are shielded to prevent breakage, also checked regularly.</p> <p>The lights for lighting in the workshop have been well protected, fly-capturing lamps weren't protected but those were checked, and the check record was provided.</p>
4.3	<p>Utilities</p> <p>Tap water is used for pulp beating, hand-washing and cleaning.</p> <p>The municipal water will be tested by government lab or qualified third party lab at least biannually. A water test report is in place to show safety, including heavy metal, microbiological (TPC, Coliform), Colour, odour, PH, rigidity according to GB5749-2006. The test was done on Nov.7, 2017.</p> <p>High compressing air is not used. Ice is not used.</p>
4.4	<p>Security</p> <p>A security manual has been established and procedures have been defined to control security of storage areas and processing areas and transportation.</p> <p>During on-site audit, found main measures include:</p> <ul style="list-style-type: none"> - Entrance to the facility: safe guards are available all day. - Office: doors will be locked after work - Production areas and storage areas: special controllers have been arranged at entrances to ensure control of these sensitive areas. The unauthorized persons can't enter production and storage areas; Doors shall be locked after production. - Outer visitors and contractors must be accompanied with related responsibility staff; - Computer: password set; - Lab: no need entering for unauthorized persons; - Transportation: before loading container to be checked; <p>Effective measures are taken such sealing, locking and escorting. Some security records were in place, such as: Shipping checking, visitor checking and register records.</p>
4.5	<p>Layout and product flow</p> <p>There is a big incoming material warehouse, three processing buildings and 1 big finished product warehouse. Canteen located in factory but segregated from production and storage area. There is no pollution around factory.</p> <ul style="list-style-type: none"> - Warehouse for raw pulp boards: basic risk areas

	<ul style="list-style-type: none"> - Production areas- basic risk areas; - Packaging areas – basic risk areas; - Warehouse for finished products- close areas. <p>- Working space and storage is sufficient to enable operations to be carried out properly under safe hygienic conditions.</p>
4.6	Equipment
	<p>Equipment has been specified before purchased, tested and commissioned prior to use. Main equipment include molding machines, trimming machines, metal detectors and . Equipment is positioned well to facilitate cleaning and service. Equipment was designed for the intended purpose and was adequately maintained to minimize the risk of product contamination as per a defined control procedure. A plan is in place to maintain the machines routinely and related maintenance records were in place.</p>
4.7	Maintenance
	<p>A preventive maintenance programme is in place, covering equipment and buildings within specified intervals of daily by operators, weekly, monthly and yearly by maintenance. Daily inspection of the equipment is conducted by operator and Eight in-house engineers are in place for maintenance management. The engineering workshop located outside of workshop, without contamination risks to products.</p> <p>No major breakdowns in last 12 months.</p> <p>Maintenance site is protected well to prevent contamination risk to product when maintenance activities happened, production can't continue if maintenance activities not performed and clearance was done, maintenance tools and parts are counted before and after maintenance, hygiene is performed after maintenance, the maintenance record is signed by production and QC and it shows that the production and clearance have been performed.</p> <p>A procedure is in place for temporary repairs/modifications to ensure product safety. Only in case of emergencies, tape, cardboard and other temporary measures can be used. Engineering workshop is sited outside of production workshops.</p> <p>The food grade lubricating oil is used and stored. MSDS and instructions were kept on files.</p>
4.8	Housekeeping and cleaning
	<p>Housekeeping and hygiene systems defined cleaning objects, cleaning methods, frequency, chemicals used, responsibilities and safety requirements. The cleaning plan is in place. The cleaning items are defined and implemented including tools, equipment, surface of the contact product and environment.</p> <p>The systems are performed by internal employees who are trained at least annually. Training plan was established at the start of every year, training was conducted at meeting room at first then on-site operation training. Site operation training result was evaluated by shift team leaders.</p> <p>Verification of the cleaning and disinfection by visually check is demonstrated: daily cleaning visually check by QC.</p> <p>The facility will identify improvement points from result of cleaning verification if non-conformity happened.</p> <p>Cleaning chemical including soft soap, chlorine and alcohol is provided with MSDS and label /instruction. The company doesn't have strongly scented chemical in place. Cleaning chemicals for toilets are segregated from other equipment during on-site audit.</p>
4.9	Product contamination control

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4.9.1	Glass, brittle plastics, ceramics and similar materials control
	<p>Glass and brittle material control procedure is in place. The procedures are for handling glass, brittle or hard plastic, ceramic or other materials include the requirements to monitor and inspect conditions of the materials. The list of the glass and brittle material is available. The inspection records are seen and specify the responsible persons as well as the result and the date. Example for checking record on Jan and Aug of 2018. Checking frequency is at least once every month.</p>
4.9.2	Sharps control
	<p>There is no any staple used in workshop and storage area. No ingredients and packaging which use staples or other foreign-body hazards as part of the packaging material. It is defined clearly in workshop management rule. There is documented policy for the control of the use of sharp metal in place, no snap-off knife was found in the workshop. Knives/sharp objects such as scissors were used in workshop to open packaging of ingredient, it is registered and checked before start-up and at the edge of stopping, product will be segregated and evaluated once breakage happened, but till now not any breakage happened.</p>
4.9.3	Chemical and biological control
	<p>Documented chemical control procedure with a reference of SSOP is in place, the approved chemical list and relative MSDS are in place, for example, MSDS and food grade testing report of lubricant is reviewed. Cleaning chemicals stored in a locked room, restricted access. Risk and risk analysis for microbiological hazard is conducted in risk management risk analysis sheet. It is used to identify biological risk and allergen and control these risks. Such as extruding step can eliminate biological risk based on risk analysis.</p>
4.10	Waste and waste disposal
	<p>A waste control procedure is in place. Procedures of collection, collation and disposal are in place. Waste is moved from the facility and disposed of by local government. External waste is stored in container bins with covers and plastic drum with lids. A control procedure is in place to direct staff to handle unsafe products or substandard trademarked materials correctly, which should be destroyed by own staffs at first with control records and then confirm with contractor. 4.10.6 N/A due to no external storage of refuse.</p>
4.11	Pest control
	<p>The pest control system is in place. A third party company, Nanxiong pest control center, has been contracted valid to Dec of 2018. At the same time, two internal employees have been appointed and trained for pest controls. The outside company inspects the facility once a month and related service records are in place. Procedures are in place to define how to control pest activities. Responsibilities for site management and instructions are kept on files. The control pests include mice, fly, cockroach, mosquitoes, etc. Pest control devices include traps, pest killers and glue boards, etc. EFKs were available on site with the appropriate locations. Lighting lumps are changed every half one year or when needed. Pest activities monitored with records, these records were analyzed with its trend at least once a year.</p>

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	An in-depth, documented pest control survey is undertaken regularly, at least once a year. During on-site audit, found that no pest activity evidences were found in warehouses and production areas.
Non-applicable clauses	4.1.5, 4.10.6

5.	Product and process control
5.1	<p>Product development</p> <p>A documented product design and development procedure is in place to ensure product safety, quality and legality. No changes to manufacturing processes or new product categories in 2017 and 2018. Only changes to product sizes 2017. For the changes, trails have been carried out and related records were available. The trail samples, including label information, have been approved by related customers. HACCP team and HACCP team leader have assessed and approved the changes to packaging and products sizes. Assessment reports are in place.</p>
5.2	<p>Graphic design and artwork control</p> <p>A procedure is in place for graphic design and artwork controls. All artwork files were provided by their customers provided artwork files. Trail records and related testing reports were in place. The formal acceptance and approval of final product concepts and artworks by the specifier were in place, it was validated that the agreed product quality and safety standards at start up and regularly. The site has a documented procedure for managing changes to artwork. Customer-approved reference materials, including samples, were stored and segregated/controlled well.</p>
5.3	<p>Packaging print control</p> <p>N/A due to no printing in the facility.</p>
5.4	<p>Process control</p> <p>The facility has identified manufacturing control points that could affect the quality of the products produced, including beating, moulding and trimming. Processing specifications have been established and documented for the control points. Critical manufacturing process controls: Beating recipe, beating time, concentration Moulding moulding temperature, sensory checking Sealing Size , sensory checking Checks were performed at start up, regularly, following adjustments and others required in process checking schedules. Operating procedures were implemented and monitored. Related checking records have been kept. A control procedure is in place for changes to product composition, processing methods or equipment. The facility will re-establish process characteristics and validate product data with special report once changes happen.No any changes in processing steps in 2017 and 2018.</p>
5.5	Calibration and control of measuring devices

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A calibration control procedure is in place for the testing and measuring devices control procedure, covering:

- a list of measuring and monitoring devices
- checking frequency
- checking methods
- trained staff to carry out the checks when the device shall be internal calibrated

Main devices include rulers, scales, weights and thermometers

During on-site audit, found that related operators were aware of the procedures to be undertaken. Mandatory calibration once per year for scales and weights, which were calibrated on Jul.23, 2018 and Apr.1, 2018, with calibration certificates. At the same time, an internal checking plan is in place for all devices.

5.6 Product inspection, testing and measuring

A plan is in place for product inspection, testing and measuring, covering on-line inspections, internal laboratory tests and outer contractor tests.

----Incoming raw pulp boards: label, color, size, foreign bodies, water content, fluorescent materials and COA: once/ each batch;

----Semi-finished product: appearance, color, size and water content test: once/ batch;

----Finished product: 1) Sensory, 2) size, 3) oil and water resistance ability, 4) weight, 5) 365nm and 254nm fluorescent materials 6) Microbe (coliform, mold) 7) Water content

A sample of test report of finished product:

Products	standard	Main parameters	results
36oz treesaver single compartment tray-PLA laminated	EU AP (2002) 1	Migration of colorants; preserving effect; specific migration of Benzophenone and 4-methylbenzophe none; PCB content, extractable heavy metals	pass

Outer contractor tests:

- Outer contractor includes SGS/ITS laboratory.
- Heavy metal, fluorescent materials, Migration as EU/FDA requirement: at least once a year.

The internal laboratory is not accredited, but some methods were taken:

- comparison testing with the third party: at least once/ a year to take;
- calibration of equipment at least once a year;
- methods need to be accredited and approved, GB methods were taken;
- all lab tester must be trained in testing at least once a year.

5.7 Control of non-conforming product

A non-conforming product control procedure is defined and implemented.

Clear process well understood by staffs that are interviewed during the audit. Special container in special area for non-conforming products were provided and stored separately.

- For incoming material: rejection in time, responsibility is QC receiver;
- For semi-finished product: production operator must isolate and label non-conforming product, QC responsible for assess and evaluation;
- For finished product: test finished products and isolate/evaluate the non-conformity, QC responsible for evaluation and handling and making a loss.

Procedure defines how to handle and conduct potential trend analysis.
 The statistic of non-conformity product was conducted by QA operator, any potential trend was performed in corrective action report based on each quality levels such as size, appearance, colour etc.
 The potential trends were reviewed in monthly management meeting and corrective action will be followed in next circle.

5.8 Incoming goods

A receiving control procedure is in place. Incoming quality controllers will check purchase order/ deliver sheet, COA, label and packing condition at first according to receiving standard, then raw materials will be sampled to check appearance, size, water content and other parameters in internal lab based on receiving standard. Raw materials will be rejected if non-conformity happened. The received materials were verified by authorized person such as QA prior receiving. Materials then are stored in incoming materials warehouse and labeled and used by FIFO rule. During on-site audit, found that internal testing reports of raw paper boards include size, sensory checking, water content and fluorescent materials.

During on-site audit, below reports were reviewed:

materials	Tested by	Main parameters	Standard
Bagasse pulp from Thailan supplier	SGS	Chloroform extractive residues	FDA 21 CFR 176.170
Bamboo pulp from sister company	SGS	Chloroform extractive residues	FDA 21 CFR 176.170

For waterproof & oilproof agent, statements are in place to meet 176.120 of FDA

5.9 Storage of all materials and intermediate and finished products

During on-site audit, found that all materials were separately stored and clearly identified. The materials were stored on the pallets and away from floor. The stock rotation is based on FIFO rule. Chemicals are handled in such a way that risk to product safety, quality and legality is minimized. Material intended for recycling was segregated and labeled.

5.10 Dispatch and transport

A document transportation control procedure is in place and during the audit, the loading area is clean and the condition was followed the transportation requirements.
 The warehouse keepers will inspect the container before loading. The inspection items: cleanness,

pest activity and dilapidation. The container is not passed until inspection results is OK.
 Raw material and packaging transport arranged by suppliers.
 Finished products are shipped with the third party company.
 All facilities used for the transportation of product, movement around the site, and dispatch of finished product are suitable for the purpose, maintained in good repair and in a hygienic condition.

Non-applicable clauses	5.3
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6. Personnel

6.1 Training and competence

A training control procedure is in place.
 A training plan is in place for employees, including CCP/HACCP, GMP, BRC packaging and site security.
 Training methods include meeting room courses and on-site training. For CCP training, each CCP controllers were trained at first in meeting course with questionnaire and then on-site operation training. Training results were assessed based on paper examinations and on-site performance. Operators can't engage in production if training assessment not passed.

Example for training records:

Training content	trainee	date	Tutor
Quality awareness training	All operators in production areas	May.15, 2018	Ms. He
Quality controls	Quality controllers	Jul.9, 2018	LCB

6.2 Personal hygiene

Documented personal hygiene control procedure is developed and implemented. Hand cleaning was performed on entering to production areas and at a reasonable frequency. Controllers have been appointed to monitor the effectiveness of hygiene procedures periodically.
 During on-site audit found that no watch, jewellery, rings were worn by the employees and managements. And it was checked and monitored by the appointed employee before into production areas and hourly.
 No drinking, eating and smoking in production and storage areas.

6.3 Staff facilities

Sufficient hand-washing facilities are provided at the entrances to production areas.

- Taps are hand-free in the hand washing stations;
- Running water;
- Liquid soap;
- Hand washing policy is defined and posted.

Man and woman toilets are adequately segregated and do not open directly into storage and also provided with hand-washing facilities.
 Catering facilities are in a special isolated area, segregated from production and storage areas.
 Personal items are stored in small closet in changing- room, no food is permitted in production and store areas.
 Changing room locates at entrances before entering into production areas. Employees must change personal things inside changing room and wear protective clothing. Personal things and working protective clothing are segregated in changing room.

6.4	Medical screening
	<p>The medical screening procedure is in place for all employees or visitors who will VISIT areas where product safety could be compromised.</p> <p>The physical examination for employees was carried out by local hospital at least once per year and the health licenses were in place for all employees. During on-site audit, four employees were sampled to review their health certificates. DXJ, ZXL, WHD and CTJ. Health certificates were in place and valid.</p>
6.5	Protective clothing
	<p>Each employee has at least 2 work uniforms including caps or hairnets and coats according to different risk grade.</p> <p>Completed protective clothing should be put on before entering production areas, also for visitors and contractors.</p> <p>Protective clothing must be changed in changing room before to toilet and use of canteen and smoking areas outside workshop.</p> <p>Protective clothing is cleaned by a contracted laundry. During on-site audit, found that protective clothing was in clean conditions.</p>
Non-applicable clauses	no