



# **Audit Report**

Global Standard Packaging Materials Issue 6: August 2019

1.Audit summary				
Company name	Foshan Chuangweilai Packaging Materials Co., L	.td.	BRCGS site code	10006532
Site name	Foshan Chuangweilai Packaging Materials Co., Ltd.			
Scope of audit	Gravure printing, lamination, curing, slitting of flexible plastic film in material of BOPP, TOPP, POPP, PET, KPET, KOPP, VMCPP, VMPET, VMOPP, AL, BOPA, RCPP, CPP, PE, or further converting into bags for primary food contact.			
Scope exclusions	none			
Justification for exclusion	NA			
Start date	2023-10-19	Finish	date	2023-10-20
Re-audit due date	2024-10-20	Previo	ous audit date	2022-10-20

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose an item	Choose an item		
Choose an item	Choose an item		

2.Audit results				
Audit result	Certificat	ted	Audit Programme	Announced
Audit grade	В		Previous audit grade	В
Certificate issue date	2023-11	-20	Certificate expiry date	2024-12-01
Number of non-conformiti	es	Major against SOI of Fundamental		0
		Critical		0
Major			0	
		Minor		13

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3.Company details			
Address	No.8, Eighth Road, Changjiao Industrial Zone, Xingtan Town, Shunde District, Foshan city, Guangdong province 528325,		
Country	P.R. China	Telephone	008613923168276
Commercial representative Name	Wang Donlin	Email	sales@rijing88.com
Technical representative Name	Yang Dapeng	Email	1511316211@qq.com

4.Company prof	ile				
Plant size (square metres)	<10K sq.m	No. of employees	51-500	No. HARA Plans	1-3
Subcontracted ac	ctivities	No			
Outsourced proce	esses	No			
Other certificates	held	ISO9001			
Regions exported	d to	North America Europe Asia Oceania Choose an item.			
Major changes or observations since audit		Added 1 composite machine and 1 bag making machine which were installing since last BRCGS audit.			
Company descrip	otion	The company was established in 2020 and was put into operation in year 2022. The company was a producer of plastic package. The product was exported to EU, USA, Australia, Middle East and domestic client.  It's brother company got its system certified against BRCGS PM, the two company share the same main management team.  Total production area including warehouse on the site was of approx. 5000 square meters. There were approx. 55 employees in the plant running in two shifts at the moment. It composed of 2 production building and 1 main warehouse.  No production processes were outsourced.  The main equipment were 1 printing machines, 2 lamination machines, 1 slicing machines, 1 doctor machines, 7 bag making machines.			

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4.Company profile	
	No production processes were outsourced. The company had been certified against with ISO9001 and local authority approval. The output in 2022 was about 75000000PCS finished plastic products and had a turnover of 60 million RMB. No major changes in raw materials and processing steps since previous BRCGS audit. There were not customer complaints about food safety and no products were recalled or withdrawn in 2022 and 2023.

5.Product and process characteristics		
Manufacturing Categories	05 - Flexible plastics 07 - Print processes Please select Please select Please select Please select	
Products in production at the time of the audit	Plastic bags	

6.Audit duration details				
Total audit duration	12 hours	Duration of production facility inspection	6 hours	
Reasons for deviation	No deviation			
Next audit type selected	Unannounced			

Audit Duration p	er day		
Audit Day	Date	Start Time	Finish time
1	2023-10-19	09:00	17:30
2	2023-10-20	08:30	12:30

Auditor information			
Auditor number	Auditor Name	Role	
33194	Judy Chen	Lead Auditor	
Click or tap here to enter text.		Please select	

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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

Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Mr. Wang Donglin / General Manager	Onsite		Onsite	Onsite
Mr. Yang Dapeng/ QA Manager	Onsite	Onsite	Onsite	Onsite
Mr. Guo Haibang / Production Manager	Onsite	Onsite	Onsite	Onsite
Ms. Li Chuqi/Admi supervisor	Onsite		Onsite	Onsite
Ms. Chen Xiaonan /Purchase supervisor	Onsite		Onsite	Onsite
Mr. Chen Ping/ Sales manager	Onsite	Onsite	Onsite	Onsite
Mr. Li Jinjun/Manager supervisor	Onsite	Onsite	Onsite	Onsite
Ms. Qian Xiao'e/warehouse supervisor	Onsite	Onsite	Onsite	Onsite

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced
2022-10-20	BRCGS PM ISSUE 6	Announced

Document control						
CB Report number	AF/ CAN256128					
Template Name	P609 Packaging Ma	terials	Audit Report	Template v11		
Standard Issue		Template is	sue date	2022-02-15		
Directory allocation	PackMat	Vers	sion	1.0		

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# **Non-Conformity Summary Sheet**

Major	Major non-conformity against statement of intent of a fundamental requirement								
No.	Clause	Detail	Critical or Major	Re-audit date					

Critic	al		
No.	Clause	Detail	Re-audit date

Majo	or						
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

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Mino	or						
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	1.1.2	The product safety and quality culture plan was established, but the review of the effectiveness of completed and ongoing activities wasn't implemented.	We have reviewed the effectiveness of the product safety and quality cultural plan completed and ongoing activities.	Provide training on food safety and quality culture management requirements for administrative department management personnel.	The administrative department members were negligent in management of product safety and quality cultural activity plans.	2023-11-10	Judy Chen
2	1.1.5	The products were exported to Europe and America without collecting relevant regulations and standards of Europe and America.	We have collected relevant regulations and standards of Europe and America.	Provide training on document control requirements to the administrative department.	The administrative department staff was not aware of product export requirements and didn't update the standard list in time.	2023-11-10	Judy Chen
3	1.2.2	The management review in 2023 did not cover their product safety & quality culture plan and food safety defence review results.	Supplemented relevant items on management review.	We will train the management personnel on management review procedure.	Management personnel were negligent in management review.	2023-11-10	Judy Chen
4	2.2.4	The process flow diagram did not cover the process breathing valve sealing.	Updated the process of flow diagram and covered the process breathing valve sealing.	Provide training on process flow chart confirmation requirements for process technicians and HARA team members.	The process technicians was negligent to draw the relevant process.     The HARA team was negligent to confirm the process flowchart.	2023-11-10	Judy Chen
5	3.8.2	The vulnerability assessment records for	Conducted a vulnerability assessment again.	We will train the purchase department and quality	The purchase department and quality inspection	2023-11-10	Judy Chen

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Mino	or						
		2023 did not include coffee valves, AL foil, glue, solvents etc.		inspection personnel on vulnerability assessment requirements.	personnel were negligent and did not evaluate all raw materials.		
6	3.10.1	Sampled three services suppliers, one service supplier FSDD was not evaluated according to service supplier management requirements.	Evaluated the supplier of service FSDD according to service supplier management requirements.	We will train the administrative department staff on service supplier management requirements.	The administrative department member neglected to evaluate the service provider as required.	2023-11-10	Judy Chen
7	3.11.2	During on-site audit found that two rollers of plastic film were not labelled timely to show their batch numbers in buffer room of curing workshop.	Immediately tracked and labelled the plastic films in the buffer room of curing workshop.	We will train the production staff, workshop management personnel and QC on identification and traceability.	The production staff were negligent to post labels in time.	2023-11-10	Judy Chen
8	3.11.4	Failure to implement forward traceability as planned.	Have implemented forward traceability as planned.	Provide training on traceability procedures for quality inspection department personnel.	The quality inspection department members were insufficient understanding of standard requirements.	2023-11-10	Judy Chen
9	4.4.1	The annual food safety defence assessment was not provided, although some defence measures were taken.	Conducted an annual product defence assessment.	We will train the food defence team members on product defence requirements.	The food defence team members were negligent.	2023-11-10	Judy Chen

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Mine	or						
10	4.9.2.3	A nap-off blade knife was found on the work bench in the enclosed area of new machine installation in lamination workshop, although the new machine has not been installed yet and cannot be used.	Have replaced the unbreakable blade knife.	Will train the operators.     Will require administrator to check if the edge tools need to be used.	The workshop staff was not familiar with the management requirements for cutting tools.      The management did not check edge tools.	2023-11-10	Judy Chen
11	5.1.2	The evaluation for the new product, plastic bag A04283, was not complete for the records of production testing and the verification of quality parameters achieved were not provided.	Have evaluated completely the new product, plastic bag A04283 and recorded the production testing and the verification of quality parameters achieved.	Provide training on design and development programs for design and development personnel.	The design and development personnel were not familiar with the design and development program and didn't keep complete design and development records.	2023-11-10	Judy Chen
12	6.3.9	The used cigarette butts, beverage bottles and cookie bags were found in the garbage bin at the hand-washing disinfection area in workshop.	Have cleared the garbage bin.	Provide training on hygiene requirements for production staff.	The production staff were weak of hygiene awareness.	2023-11-10	Judy Chen
13	6.4.2	The auditor wasn't required to fill in a health questionnaire.	Have required people on the outside enter the workshop to fill in a health questionnaire.	Will train the workshop administrators.     Will make a health questionnaire and ask external personnel to fill in a	1.The administrative department supervisor did not train workshop management personnel on	2023-11-10	Judy Chen

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Minor			
	health questionnaire, when they enter workshop before.	the control requirements for external personnel.  2. No health questionnaire.	

Comment		

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# **Additional Modules/Head Office Non-Conformity Summary Sheet**

Critic	Critical					
No Clause Detail Re-audit date						

Majo	Major Control of the										
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by				

Minc	Minor									
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by			

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# **Detailed Section**

# 1. Senior management commitment

# 1.1 Senior management commitment and continual improvement

A safety/quality manual was in place, QM-01, approved by their general manager.

The policy statement was clearly defined in the safety/quality manual, covering legality, quality, safety and customer requirements. The policy has been communicated to all levels of staff by the management team. A plan was in place to review (covered by management review) and where necessary update the policy regularly.

The document food safety and quality culture plan has been established to address the activities impact on product safety for development and improvement of the food safety and quality culture. Main activities include 1) Communication on product safety and quality by setting up bulletin board in the public area, product safety and quality meetings regularly; 2) Training in product safety & quality management; 3) Team establishments in product safety & quality culture; 4) Employee performance assessment in product safety & quality culture etc.

A plan was in place to monitor and assess the effectiveness of product safety and quality culture activities. The effectiveness review wasn't implemented.

The safety and quality objectives have been established, documented, communicated, monitored and updated to maintain and improve the quality, safety and legality of products manufactured, in accordance with the product safety and quality policy and the BRCGS PM standard.

The general objective: Customer satisfactory rate: more than 95%.

Main objectives for related departments, as below:

- 1) Third party test pass rate: 100%,
- 2) Customer satisfaction: higher than 90,
- 3) Finished product pass rate: 95%,
- 4) food safety incident: 0

The objectives have been disassembled to each department with detailed objectives and measures of success for each department, which will be assessed monthly. Objective assessment records were in place, showing the objectives achieved after last audit.

Top management provided human resource and financial resource to support BRCGS PM standard and maintained product safety and quality management system in the last year.

Administration Department and sales had been appointed to collect and keep relevant legislative requirements, such as scientific and technical developments, industry codes of practice, all relevant legislation applicable in the country of manufacture and the country where the product will be used. Legislative requirements were collected from customer, certification body and Internet. The list was updated on Sep.12,2023. Main legislative documents collected and kept as below:

(EU) No. 10/2011 plastic materials and articles intended to come into contacting with food.

GB 4806.1-2016 general requirements for food contact materials and food contact products.

GB 4806.6-2016 general requirements for food contact resins.

GB 4806.7-2016 general requirements for food contact plastic materials and food contact plastic products.

GB 9685-2016 additives for food contact materials and food contact products.

Products test reports shew that they met the legal requirements in the country of manufacture and of use.

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The genuine, original hard copy and electronic version of the current BRCGS package standard issue 6 were in place. The quality department will collect any changes to the standard or protocol that are published on the BRCGS website.

This BRCGS due date was Oct.20, 2023, and actual audit date was Oct.19,2023.

Top management and department managers on site attend the opening meeting and closing meeting. Relevant departmental managers and/or their deputies were available during the audit.

1 major and 6 minor CARs were identified in the last BRCGS PM audit. During this audit, related corrective evidence were reviewed and found the non-conforming items had been corrected.

A BRCGS logo using policy was in place based on BRCGS requirements, which cannot be showed on their product packaging. The policy was respected after last audit.

The product safety and quality culture plan was established, but the review of the effectiveness of completed and ongoing activities wasn't implemented.

A minor CAR was raised.

The products were exported to Europe and America without collecting relevant regulations and standards of Europe and America.

A minor CAR was raised.

# 1.2 Management review

The document Management Review Procedure was in place, which will be done regularly, at least once a vear.

Last management review was conducted on Aug.18,2023, charged by their top manager. Related management review reports were in place. Summary of input included previous management review document, action plans and timeframes, the results of internal, second-party and third-party audits, customer performance indicators, complaints and feedback, the effectiveness of the HARM, the impact of applicable legislative and certification scheme changes, incidents, corrective actions, out-of-specification results and non-conforming materials, resource requirements, the effectiveness of the product defence and product fraud prevention plans, monitoring results of main processes, suppliers' performance, product recall and withdrawal, objective and policy reviewed, communications, any changes in the management system etc. 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. The management review report was sent to general manager and relevant department managers to follow up the improvement decisions.

Monthly quality team meeting was conducted to enables product safety, legality, and quality issues to be brought to the attention of senior management and allows for the resolution of issues requiring immediate actions.

Monthly meeting records were sampled and reviewed, such as records in Jun and Aug of 2023.

The management review in 2023 did not cover their product safety & quality culture plan and food safety defence review results.

A minor CAR was raised.

# 1.3 Organisational structure, responsibilities, and management authority

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A documented quality manual is available. The clear organisational structure, responsibilities, management authority and lines of communication were defined in the manual to manage the product safety, legality and quality. Clear organization structure was in place, covering:

General manager---HACCP team Leader---H. R; finance; production operation; sales, purchase—Department (technology and new product development, logistic, purchase, admin, quality, production, and sales.)

Responsibilities for key members have been established and documented, and documented arrangements were in place for the absence of key staff. For example, quality manager will take the place of HACCP team leader if he was absence.

Work instructions were in place for staff whose activities related to product safety, legality, and quality, such as quality manager and production manager.

Non-applicable clauses

None

# 2. Hazard and risk management

# 2.1 Hazard and risk management team

The HACCP plan CWL-WI-HACCP-01 was in place for all food contacting plastic products. HACCP team had 8 members from top management, production department, quality department, technology,

admin, sales etc.

No external expert.

Team leader: Mr. Wang DH. HACCP team member had more than 20-year work experience in relevant area. They attended the training of HACCP plan and BRCGS PM standard. The team demonstrated competence in hazard and risk analysis principles and was kept up to date with factory changes and customer requirements as they occur.

# 2.2 Hazard analysis and risk assessment

The up-to-date HACCP plan CWL-WI-HACCP-01 was in place. The potential hazards for steps had been assessed and identified, and control measures had been established and implemented.

The intended scope of certification has been clearly identified in the HARA Plan, including all plastic bags for food contacting. Hazard analysis for all raw materials and all producing steps have been carried out and related control measures have been established and documented.

Raw materials for plastic bags: BOPP/ TOPP/ POPP/ PET/ KPET/ KOPP/ VMCPP/ VMPET/ VMOPP/ AL/BOPA/ RCPP/ CPP/ PE film

Other raw materials: ink, adhesive, solvent Intended use: direct contact with food.

Packaging: plastic bags inside and carton outside

Main safety parameter: solvent residues less than 5 mg/cm<sup>2</sup>, no plasticizer etc.

Safety standard: GB4806.7

The flow diagrams were verified by HACCP team once a year or any significant incidents or process changed. The last flow diagram was verified on May.30,2023.

The hazards analysis considered the hazards of physical hazard (metal chips, plastic chips, and other foreign bodies), chemical hazard (taint, odour, allergen, migrations, solvent residues, heavy metal, lubricant etc.), microbiological hazard (E. Coli, mould, pathogen), potential problems arising from the use of recycled

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materials, consumer foreseeable misuse, quality defects, potential for malicious intervention and raw material fraud and other necessary hazards.

Based on risk assessment, 2 CCPs were identified. HACCP plan as follows:

CCP 1----Curing----hazard: Solvent residues

Limited levels: temperature, time. Curing duration shall be more than defined limited levels.

Monitoring: The curing duration will be monitored for every batch of laminated film.

Correction: 1: Rejected, 2: Processing Adjustment

CCP 2----bag making----hazard: bad sealing.

Limited levels: Sealing temperature shall be controlled. Work instructions were in place for every bag. Monitoring: In-line temperature system for continuous monitoring. On-site controllers will check the system once every 2h.

Correction: 1: Rejected, 2: Processing Adjustment

The monitoring system has been established for the CCPs, conducted by trained controllers. The correction and corrective actions taken have been clearly identified in CCP monitoring table both of process and product handling to before the deviation will be met to specification. The corrective actions defined.

A HACCP review control procedure is in place, which is done at least once a year. The review included any product composition and process changes, complaints, product failures, finished product recalls, product withdrawals, internal audits of PRP and external and third-party audits results, new developments etc. Last review was done on May.30,2023.

The process flow diagram did not cover the process breathing valve sealing. A minor CAR was raised.

Non-applicable clauses

None

# 3. Product safety and quality management

#### 3.1 Product safety and quality management system

The product safety and quality management system has been established, documented, and implemented based on BRCGS package requirements. Main documents for the system include a safety/quality manual, control procedures for processes identified, HACCP plans, work instructions and specifications. A quality staff has been appointed to control the documents. Documents were publicized in the document system. The copies of the documents have been distributed to related department and related Key staff could get the up-to-date versions.

The document system was reviewed every year.

The factory operated independently.

#### 3.2 Document control

The document control procedure CWL-QP-PK-01 is in place to define how to control documents.

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The procedure details who will edit documents, who will approve documents, who will keep documents, how to identify and authorize documents, how to update documents, how to store documents and how to manage existing documents.

The organization documentation system including 4 different levels. The provided documents included manual, HARA plan, relevant procedures, operation instructions and records.

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.

For electronic documents, passports were used to protected them. At the same time, the documents will be backed up to avoid loss.

### 3.3 Record keeping

A record control procedure CWL-QP-PK-02 is in place to define how to control records, including establishing, reviewing, collecting and storage.

Quality department has been appointed as the centralized management department.

Legible and good justification records were observed from the reviewing of existing maintained records. Records will be kept for long time (quality guarantee period +1 years) according to each kind products.

# 3.4 Specifications

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.

The specification of plastic film was based on GB4806.7-2016 and GB 9685-2016, mainly including control levels of overall migrations. The specification of Al foil was based on GB 4806. 9-2016, mainly including control levels of heavy metal and overall migrations.

The specifications of finished products were based on GB 4806.7-2016 and GB 9685-2016.

Specifications for finished bags was sampled and reviewed:

- -----Main legislation considered: GB 4806.7-2016 and GB 9685-2016.
- ----Recipe
- -----Design and draft
- ----Functional requirements (such as sealing strength and high temperature resistance ability)
- -----Limited levels of quality defects
- -----Safety parameters, such as migrations and solvent residues.

Raw and finished product specifications have been agreed with relevant parties, customers, or suppliers through documented contracts.

The declarations of finished products have been established and documented for all customers to show food grade products and for food contacting.

Raw and finished product specifications have been agreed with relevant parties, customers or suppliers through documented contracts or documented specifications.

The declarations of compliance have been collected and kept from suppliers of glue and raw film and raw Al foil. 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 post-consumer recycled materials, limitations, no allergens and use information etc.

The declarations of compliance contain main contents:

1) confirmation that the materials used meet relevant legal requirements, not any post-consumer recycled materials.

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- 2) Intend use: food contacting
- 3) Confirmation that the finished products meet relevant legal requirements, such as GB 4806.7-2016 and US FDA 21 CFR 177.1520,

Company also qualified each material to the third party to confirm to its conformity.

Trademarks will be reviewed with agreement signature by Sales and Customer.

The specifications had been regularly reviewed and updated according to relevant requirement when product composition or characteristics change or at least once every 3 years.

Any changes to existing agreements or contract, the relevant department will review, document and communicate to appropriate departments.

Last review was done on Dec. 20, 2021. Evidence shows that specifications had been reviewed and updated when the product composition or characteristics change.

#### 3.5 Internal audits

An internal audit control procedure CWL-QP-PK-08 was 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 twice a year, including all products and all processing steps. During on-site audit, below internal audit reports were reviewed:

Internal audit on Aug.11-12, 2023---- 5 deviations

Main documents and records for the internal audits included:

1. Audit plan 2. audit checklist (the checklist was based on BRCGS requirements) 3. Deviations identified and related corrective/corrective actions.

The internal audit items included HARA plan, PRP, product defence and product fraud prevention plans, performance of procedures implemented etc.

Audit records showed that auditors were independent from their own department. All internal auditors had received BRCGS PM training. They didn't audit their own department during auditing.

The deviation and related corrective actions were sampled and reviewed.

Details of deviations have been defined and corrective/corrective actions have been established and implemented within specific time scales. The corrective/corrective actions were verified by HACCP team.

A monthly on-site inspection plan is in place, carried out by their quality team, including hygiene inspections, environment and processing equipment inspections. Checked the inspection records in Aug and Sep of 2023. Non-conforming items have been identified and documented based on on-site inspections. Based on root cause analysis for the non-conformities, action plans have been established, documented, and implemented.

# 3.6 Corrective and preventive action

The corrective and preventive control procedure CWL-QP-PK-12 was in place for correct any failures or non-conforming.

Main steps include:

- 1. Take corrective actions.
- 2. Analysis and determine the root causes.
- 3. Identify and determine the preventive actions.
- Carry out preventive actions.
- 5. Verification of actions.

Any out of controls in specifications would be regarded as non-conformity and reported to QA. The non-conformity would be identified, assessment of consequence, correction and root cause analysis and verification of corrective action effectiveness as well as the trend analysis.

During on-site audit, some corrective and preventive actions were sampled and reviewed.

Such as customer complaints, CARs of internal audit, non-conformities of processes and products etc.

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The root cause was analysed and used to avoid the reoccurrence. The corrective action records were available for review during the audit.

# 3.7 Supplier approval and performance monitoring

A Purchase Control Procedure CWL-QP-PK-20 is in place for approval and monitoring of all suppliers. The supplier list was updated on Aug.14,2023.

Based on risk assessment of raw materials, suppliers were identified as low risks.

Supplier approval assessment based on supplier audit or questionnaire which including process control, product safety, traceability, HACCP review, GMP.

Below supplier approval records were reviewed:

- 1. PE film---from GDHL ---- supplier audit on Apr.26,2023.
- 2. PET film----from GDZY---- supplier audit on Jul.16,2023.

At the same time, necessary information, such as testing reports, business license, production license and statement of compliance were collected.

Traceability was included in the supplier approval. Some supplier was evaluated by questionnaire with traceability verified.

If raw materials are purchased from companies that are not the manufacturer or packer, the site identified and list the last manufacturers or packers, which were showed on the list of approved suppliers. At the same time, necessary information, such as testing reports, business license and statement of compliance, were collected. The raw materials are purchased from the manufacturers.

The exception control rule in place and will be followed once any exception occurs. If the raw materials are exceptions to the supplier approval processes. Label information, testing reports and agents' declarations will be used for their approval.

# 3.8 Product authenticity, claims and chain of custody

The fraud and substitution vulnerability assessment was documented to access information on historical and developing threats to the supply chain which may present a risk of adulteration or substitution of raw materials.

The SOP defined the assessment shall be conducted once a year for all raw materials to assess the potential risk of fraud and substitution. Main raw materials: PE film, PET film, ink etc. The risk assessment was reviewed on Jun.2,2023.

Based on the risk assessment, found no high risk of fraud and substitution. All raw materials were identified middle or low risk of fraud and substitution.

Control measures were defined to avoid risk of fraud and substitution. The risk is controlled by supplier controls, transportation controls and incoming controls (Raw materials will be also identified by visual checks, declarations, lab test and receiving inspection).

3.8.3 N/A as no raw materials are identified as being at particular risk of adulteration or substitution.

The vulnerability assessment records for 2023 did not include coffee valves, AL foil, glue, solvents etc.

# A minor CAR was raised.

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# 3.9 Management of subcontracted activities and outsourced processes

# N/A. No subcontracted activities and outsourced processes.

# 3.10 Management of suppliers of services

The service supplier control procedure CWL-QP-PK-30 has been established and been included in the purchase control procedures.

The procedure defined how to approve, monitor, and assess the service suppliers regularly. A list of approved service suppliers is in place based on risk assessment results and supplier performance monitoring results. The service suppliers in the site include those of transportation, product testing, pest controls and waste disposal. During on-site audit, three service suppliers were sampled.

- 1. Transportation service----JYM Transportation.
- 2. Pest control service----FSJB

The evaluation of service supplier FSDD wasn't provided.

At the same time, related suppliers' licenses and contracts were reviewed.

Sampled three services suppliers, one service supplier FSDD was not evaluated according to service supplier management requirements.

A minor CAR was raised.

#### 3.11 Traceability

A traceability control procedure CWL-QP-PK-06 is in place.

A team is in place for traceability controls. Traceability records were collected and kept by their quality department, which were retrievable according to on-site tests. Hard copies (paper records) and e-copies were used for traceability controls.

Traceability system demonstrated enough ability based on an on-site test. During on-site audit, a batch of finished products were sampled for a traceability test:

Product name: A03225 BAG

Customer: K02

Production No.: 23060311 Quantity: 59825 PCS Shipping:2023-07-17. Time spent: 2 hours.

Related production records were in place. Results were acceptable.

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

- 1. Traceability test from finished products to raw materials:
- ---Testing date: Sep.28,2023
- ---Finished products sampled: plastic bags A01490
- ---Lot. No.: CWL23070704-2 ---Quantity: 21273PCS

Delivery:2023-08-05.

Results: Related raw materials can be traced, such as related suppliers and batch numbers. Related process checking records were in place.

Finished in 4 hours(3h30min), effective test.

During on-site audit found that two rollers of plastic film were not labelled timely to show their batch numbers in buffer room of curing workshop.

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#### A minor CAR was raised.

Failure to implement forward traceability as planned. A minor CAR was raised.

# 3.12 Complaint handling

The customer complaint control procedure CWL-QP-PK-22 was in place.

Sales department collects complaints from clients and deliver it to QA and production departments. The root causes were analysed by QA and production department. And related persons will take corrective actions. Complaint records were in place. No food safety complaints happened till now.

Total 17 complaints in the last year.

During on-site audit, the complaint about leakage was sampled. See below:

2023-03-11 bad printing

2023-09-06 bad sealing

2023-08-13 folds

The root analysis, corrective and corrective actions were taken.

The complaint record and result of investigation were reviewed regularly. Related corrective action and verified record was defined clearly. Complaint data was analysed to identify significant trends.

# 3.13 Management of product withdrawals, and incidents and product recalls

The document Withdrawal Management Procedure CWL-QP-PK-13 was in place to define how to manage product recall& withdrawal.

Product recall team in place and related responsibilities were defined.

Recall procedure defines that factory will inform supply chain, regulator and CB (SGS China) within three working days of the decision to issue a recall. The recall procedure takes into account of the stock return, logistics for recovery, storage of recovered product and disposal.

Incident control procedure defines how to control and manage incidents and potential emergency situations that impact food safety, legality, or quality such as:

- 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
- failure of or attacks against, digital cyber-security

No product actual recall or withdrawal in the last year.

A plan is in place to ensure mock recall will be conducted regularly, at least once a year. Last mock test as below:

Mock recall date---- Apr.23,2023

Assumed reason---- material PET12\*395, lot. 7570010200320 were bad quality.

Total---- 106.1kg

For product ---- Film B808, lot. RJKC20230416-05, total: 57360m

Shipping ---2023-04-29 Time spent---- 2 hours.

Product status: rejected if appropriate.

Handled by QA Manager. The recall test was valid.

#### Non-applicable clauses

3.8.3 N/A. No raw materials are identified as being at particular risk of adulteration or substitution.

3.9 NA. No subcontracted activities and outsourced processes

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### 4. Site Standards

#### 4.1 External standards

The site located in an industrial park. Local neighbouring activities were industrial area. The boundary of factory is clearly defined and there was no pollution around the factory. During on-site audit, found that the exteriors were in clean and tidy conditions. All ground within the site were covered by grass or cement. Main buildings in the site

Main buildings in the site

- 1. A 5-story building: 2<sup>nd</sup> floor for bag making and packaging, 1<sup>st</sup> floor for printing, lamination, slicing.
- 2. 3<sup>rd</sup> floor for warehouse areas.
- 3. 4<sup>th</sup> floor for cylinder storage.
- 4. A three-story building for office, catering and dormitory.

There were dormitory and catering hall within the factory at the separated area.

# 4.1.5 N/A as no products stored on exteriors.

4.2 Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas

The internal site, buildings and facilities were suitable for the type of production.

The building fabric was maintained to minimize potential for product contamination. Site boundaries were clearly defined and maintained condition to prevent potential contamination of product.

For production areas and storage areas, main materials used in buildings as below:

Floor in production areas---cement floor, coated with epoxy resin.

Floor in storage areas---terrazzo floor

Wall----coated with white cement or colour plate.

Ceiling---- colour plate

During on-site audit, found that buildings were suitable for the produce of plastic products.

The buildings for production and storage were in good maintenance conditions. The building fabric is maintained to minimize potential for product contamination. Site boundaries are clearly defined and maintained condition to prevent potential contamination of product. No potential contamination observed during on-site inspection.

The windows were in the closed manner during audit on-site inspection. No entrances for pests.

Glass windows are shielded to prevent breakage, also checked regularly.

Suitable and sufficient lighting was provided to ensure a safe working environment, correct operation of processes, effective inspection of the product and cleaning. The lights for lighting in the workshop had been checked regularly, and the check record was provided.

Wall, floor, ceiling, door, window, Light and central ventilation were acceptable.

Exhaust fans were used with screen.

# 4.2.3 N/A. No internal drainage in the workshop.

4.2.6 N/A as elevated walkways were not used in the site.

#### 4.3 Utilities

Utilities to and within the production and storage areas were designed, constructed, maintained and monitored to effectively control the risk of product contamination.

Water is supplied from the municipal water supply system and used for equipment cleaning and hand washing. No water was used in production as a raw material.

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During on-site audit, found that no water was contact products directly.

No steam was used.

Ice is not used.

High compressing air is not used.

### 4.3.2 N/A as no water, ice, compressed air or other gases come into direct contact with package.

# 4.4 Site security and product defence

A Security control procedure CWL-WI-CPFL-03 was in place for security system.

Security control procedures have been established and implemented for production areas, storage areas and exteriors and transportation. Main measures:

Entrance of factory: Security officers are at main entrance, safeguards are available.

Exterior: monitoring cameras, routine inspection by safeguards.

Production areas and storage areas: monitoring cameras. Locked after production. The unauthorized persons can't enter production and storage areas.

Outer visitors and contractors must be accompanied with related responsibility managers.

Computer: password set.

Transportation: before loading container to be checked.

A team is in place for security controls.

Security risk assessment was in place, which was reviewed yearly. Last review of the assessment was done on Jun.23,2023.

CCTV system was used for critical areas.

Training in site security procedure was provided in orientation program for related function, such as new staff, store and warehouse, production staff, including security guard.

The visitor who accesses to production and storage area for all materials must be checked at the entrance.

# 4.4.3 N/A. No external storage tanks, silos and any intake pipes with an external opening. The annual food safety defence assessment was not provided, although some defence measures were taken.

A minor CAR was raised.

### 4.5 Layout, product flow and segregation

The factory layout, process flow and personnel movement flow were provided. Site plans were available. Premises and plant had been well designed to control risk of product contamination and to comply with all relevant legislations. Verified on process flow diagram and lay out, segregation considers the flow of product, waste, raw materials, equipment, personnel, and utilities.

Process flow was clearly segregated for raw material, semi-product, and finished product. All areas were prepared and constructed to minimise the risk of the contamination.

Working space and storage were enough to enable operations to be carried out properly under safe hygienic conditions.

The warehouse of finished products was close areas and other areas were low risk areas.

Removal of outer packaging was carried out in a designated room.

The routes were suitable, without cross-contamination risks. Personnel access and movement were acceptable.

# 4.6 Equipment

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Equipment has been specified before purchased, tested, and commissioned prior to use. Lubrication points and application methods of any lubricant was not able to contaminate the product.

Main equipment included printing machines, laminating machines, and bag making machines.

Equipment was designed for the intended purpose and was adequately maintained to minimize the risk of product contamination as per a defined control procedure. Equipment is positioned well to facilitate cleaning and service. Notices on equipment was cleanable and secure.

Equipment had been specified before purchase and tested and commissioned prior to use. The maintenance and cleaning plan was in place.

# 4.6.3 N/A. No wooden equipment was used in workshop.

#### 4.7 Maintenance

A preventive maintenance procedure is in place, covering equipment and buildings, to prevent contamination and reduce the risk of breakdown.

A plan is in place to maintain the machines routinely and related maintenance records were in place. For main equipment, maintained daily by operators, weekly, monthly, and yearly by maintenance controllers.

During on-site audit, below maintenance records were sampled and reviewed:

----maintenance records for printing machines, lamination machines and bag making machines in 2023. Found their maintenance plans were respected.

No major breakdowns since previous audit.

Maintenance sites were protected well to prevent contamination risk to product when maintenance activities happened. Production can't continue if maintenance activities performed. After maintenance, the site: 1) Clean related equipment and areas; 2) maintenance tools and parts counted and checked before and after maintenance to avoid contamination from foreign bodies. Maintenance records were in place to show that the checking and clearance have been performed.

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.

The lubricating oil is used and stored. MSDS and instructions were kept on files.

Maintenance logs shall be maintained for all off-line testing equipment. This included, as a minimum: any adjustments and the re-calibration date of any interventions.

### 4.8 Housekeeping and cleaning

Cleaning control procedure is in place.

Housekeeping and hygiene systems defined cleaning objects, cleaning methods, frequency, chemicals used, operators and safety requirements. The cleaning plan is in place. Cleaning method for product contacting surfaces: water cleaning---75% alcohol

The systems are performed by internal employees who are trained at least annually.

Verification of the cleaning and disinfection by visually check was demonstrated. Cleaning checking records were sampled and reviewed, including those in May to Sept. of 2023.

During audit on site, found that most machines, tools, floor, wall in cleaning conditions.

Based on their risk assessment, it's low risk in microbiological contamination due to low water content of finished products. Last review was done on May.11,2023.

# 4.8.5 NA. Based on their risk assessment, it's low risk in microbiological contamination due to low water content of finished products. No microbiological environmental monitoring plan.

### 4.9 Product contamination control

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# 4.9.1 Glass, brittle plastics, ceramics, and similar materials control

Glass and brittle material control procedure is in place.

The procedures are for handling glass, brittle, or hard plastic, ceramic, or other materials.

The list of the glass and brittle material is available for all production areas and warehouses. The inspection records on Sept.1-19, 2023 are seen and specify the responsible persons as well as the result and the date. Frequency of checking: daily.

During on-site inspection, found that glass in production areas were in good conditions, without broken glass.

# 4.9.2 | Sharps and metal control

There were no staples used in production and storage areas. 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. 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.

A nap-off blade knife was found on the work bench in the enclosed area of new machine installation in lamination workshop, although the new machine has not been installed yet and cannot be used. A minor CAR was raised.

# 4.9.3 Chemical and biological control

A chemical control procedure is in place. Chemicals used in production areas mainly include: alcohol 2) hand-washing liquid 3) lubricating oil 4) ink 5) solvent 6) glue.

Other chemicals: pest control chemicals (controlled by contracted pest service)

The list of approved chemicals is in place. Chemicals were kept with clear identification card in segregated storage room and lock system. Only authorized and trained person could access to this area.

Chemical's label, MSDS and instruction was viewed and kept in controlled condition. Food grade lubricant was with NSF registration.

Cleaning chemicals stored in a locked room, restricted access.

MSDS for chemicals are on the wall.

Risk analysis was conducted to identify and control potential risks from microbiological contamination and any potential allergens. No allergens were used in the production areas and storage areas. At the same time, a rule was in place to ensure employees not to bring any allergens into production and storage areas. In the site, raw materials, half-finished products and finished products had a low water content to avoid biological risks.

# 4.10 Waste and waste disposal

A waste control procedure is in place. Procedures of collection, collation and disposal are in place. Waste was sorted and collected in appropriate designated waste containers according to legislative requirements with categorized labels.

Paper and plastic waste materials will be treated by an outside service (Yulin JH). Process waste was managed to minimise release to the environment. Other living waste is moved from the facility and disposed of by local government. Hazardous waste was disposed by licensed third party. Contracted with Foshan JK (Contract No. JK820230015). The removal records were maintained and available.

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External waste is stored in container bins with covers and plastic drum with lids. Frequency of removal: Daily. No waste accumulation was found on site.

A control procedure is in place to direct staff to handle unsafe products or substandard trademarked materials correctly, which should be destroyed by their own staffs.

Trademarked materials were destructed at the prescribed station.

External storage of refuse was placed in designated areas and designed or maintained to minimise the risk of pest harbourage.

# 4.10.6 N/A as no substandard trademarked materials are transferred to a third party for destruction or disposal.

### 4.11 Pest management

A pest control procedure is in place.

A third-party company (Foshan JB) has been contracted for pest controls. The outside service visited the facility at least twice a month. Pest Control was implemented covering all potential areas. A Pest device map was provided onsite. The controlled pests include mice, flies, cockroach, mosquitoes, and other pests. Pest control devices include traps, pest killers and glue boards.

At the same time, internal controllers have been appointed for routine pest controls.

Fly-capturing lamp and mouse trap were checked by internal pest controllers.

Some checking records from Aug. to Sept. in 2023 were reviewed.

The records from outside service in 2023 were sampled and reviewed.

Operator certificate was checked; Pesticide Registration Certificates and MSDS were available.

Sampled three employees in production and warehouse departments and they knew how to report pest activity to designated person.

Pest control training on Dec.5,2023.

Pest checking and control records were analysed with its trend semi-Annually. Reviewed the pest analysis reports on Aug.1,2023. Action plans were in place for improvement decisions.

During on-site audit, found that no pest activity evidence found in warehouses and production areas.

# 4.11.3 N/A outside pest control service was contracted for pest controls.

# Non-applicable clauses

- 4.1.5: N/A. No external storage.
- 4.2.3 N/A. No internal drainage in the workshop.
- 4.2.6 N/A as elevated walkways were not used in the site.
- 4.3.2 N/A as no water, ice, compressed air or other gases come into direct contact with package.
- 4.4.3 N/A. No external storage tanks, silos and any intake pipes with an external opening.
- 4.10.6 N/A as no substandard trademarked materials are transferred to a third party for destruction or disposal.
- 4.11.3 N/A outside pest control service was contracted for pest controls.

# 5. Product and process control

#### 5.1 Product development

A documented product design and development procedure CWL-QP-PK-25 is in place to ensure new product safety, quality, and legality.

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For new products, main design and development steps include:

- 1) Customers' requirements identification
- 2) New product design and review
- 3) Moulding design and development
- 4) Production trials
- 5) Product testing and review
- 6) Customer review and approval
- 7) Retaining samples and parameters outputs (including mould assessment, quality controls, process parameter and specification).

Based on their procedure, for any changes, trails will be carried out. The trail samples, including graphic design, will be approved by related customers. For new products, HACCP team will review and approve them.

The main product changes were product size, material, shape.

A Project: plastic bag A04283 was reviewed.

The documented procedure was in be in place to address the transfer of customer specifications or requirements to the site's own systems.

During on-site audit, the internal specification of plastic bag A03709 transferred from customers' specification was reviewed.

The specification included raw material requirements, process parameters, finished product parameters etc.

The evaluation for the new product, plastic bag A04283, was not complete for the records of production testing and the verification of quality parameters achieved were not provided. A minor CAR was raised.

# 5.2 Graphic design and artwork control

A procedure is in place for graphic design and artwork controls to manage artwork and all pre-press processed conducted, including information collation into artwork, artwork files receipt from customer, completed artwork verification and approval by customer etc.

The process of formal acceptance and approval of final product concepts and artworks was defined. Artwork files were provided by their customers or designed by themselves. For their products, main artwork included size, raw materials used, functional parameters, printing standards. For new products, production 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.

The site has a documented procedure for managing changes to artwork and print specifications to manage obsolete artwork and printing materials.

Customer-approved reference materials were stored and segregated/controlled well based on on-site inspections. Quality controllers were appointed for controls of artwork masters and electronic artworks. During on-site audit, a product was sampled to review related artwork controls.

Product sampled: plastic bag D00170.

Customer's approval document in place.

Signed artwork masters in place.

Hard copy and e-copy artwork files in place.

# 5.3 Packaging print control

The step has been identified as a control point and a printing control procedure has been established to manage the print control process. In the site, plastic bags or film may be printed. Gravure printing was used in the site.

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Risk assessment was done for pre-press activities (approval of artwork and printing plate development), printing and handle of printed products. Control measures were in place based on the risk assessment. Printing was started after first checking by on-site controllers to ensure raw film, colour standards, printing plates and approved samples will be prepared correctly. A plan is in place to sample printed products for printing information checking.

- 1. The visual checks were undertaken routinely by printing controllers, at least hourly, to ensure correct essential information.
- 2. In-line automated inspection equipment (vision systems) is used to check printing information. On-site controllers will adjust printing system or mark the printed products if printing defects identified. During on site audit, found that printing plates were stored in designated locker with clear traceable identification to customer's approved materials. No composite printing was used. Printing operators have been well trained and annual competency evaluation has been performed. Samples together with production records have been retained in archive room with 3 years.

Records were in place for unused printed products.

Lighting in print inspection cabinets was controlled based on national industry standards.

### 5.3.5 N/A as no composite printing

#### 5.4 Process control

Documented process and product control procedure was in place.

The facility has identified manufacturing process control points that could affect the quality of the products produced, such as printing, lamination, curing, bag making. Processing specifications have been established and documented for major process steps.

The hazard and risk management team had identified and recorded all potential product defects that were reasonably expected to occur at each step.

The company had established process control parameters related to food safety and quality as defined to procedures. Operating procedures had been established and implemented in order to control all parameters.

Key controls were determined in the process review and detailed in specifications.

The following critical manufacturing process control points were defined after reviewed.

Process parameter and control limited was established and inspected to QC Team. Quality check was performed as the requirement of HACCP plan, quality performance and SOP of each process control point with sampling plan. Checks were performed at start up, regularly, following adjustments and others required in process checking schedules.

During on-site audit, some process checking records were sampled and review.

For example:

Printing control for D00170, curing control for A03709 and 27750, bag making for A04283.

Operating procedure was implemented.

Equipment settings are critical to the safety or legality of the product, changes to the equipment settings were completed by trained and authorised staff. Controls was password-protected or otherwise restricted. No previous material was found kept in current production.

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 changes in processing steps since previous audit.

A documented line clearance procedure during production change was in place.

Line clearance was evidence for the on-going packaging process during plant tour of this audit.

#### 5.5 Calibration and control of measuring and monitoring devices

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The measuring and monitoring devices control procedure CWL-QP-PK-07 was established for the testing and measuring devices to define how to control monitoring equipment. The calibration list of measuring and monitoring devices was in place, covering:

- a list of measuring and monitoring devices with locations
- devices code, calibration date and calibration due date
- checking methods, adjusting methods and protection measure
- authorise and train staff to carry out the checks when the device shall be internal calibrated or subcontract to third parties for calibration.

Main devices include rulers (such as thickness tester, digital rulers), scales, weight, pull strength testers, friction index tester, sealing tester, bar code tester, oxygen transmission rate tester, vapor transmission rate tester, thermometers, and gas chromatograph.

During on-site audit, found that related operators were aware of the procedures to be undertaken.

Mandatory calibration once per year for main measure meters, with calibration certificates.

Some calibration records from third parties were reviewed and checked.

gas chromatograph, thermometer, pressure tester, thickness gauge, balance, sealing tester ---- calibrated by third-party calibration service on Aug.10, 2023

An internal measure device checking plan was in place.

Scales----standard weights were used to check scales in work conditions.

Ruler---- compare with other rulers, which have been calibrate.

Calibration was conducted according to calibration plan. Calibration was traceable to a recognised national or international standard.

Corrective action and reporting procedures were established and documented in the event of the monitoring and testing procedure identifying any failure of product inspection, testing or measuring equipment.

# 5.6 Product inspection, testing and measuring

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

Procedures such as Process and Product Monitoring and Measurement Control Procedures, Product Analysis and Testing Management Control Procedures and undertaking inspection, as defined to HACCP Plan & Quality Plan were in place.

Quality checks were carried out to demonstrate that the product was within the tolerances. The lab could test appearance, dimension, weight, function and so on.

Analysis critical to safety and legal was tested by local authority and another accredited agent.

- ----Incoming raw resins & film: see 5.8
- ---- Semi-finished products: main items as below:
- 1) at printing----in-line automatic visual system; checking by printing operators: sensory assessment (colour, word, over printing, other), heat resistance ability of ink, ink adhesive ability.
- 2) at laminating & curing----sensory assessment, size (thickness), peer strength, hot sealing strength, solvent.
- 3) at bag making---sensory assessment, size, sealing ability, cooking testing, dropping testing, pressure resistance ability.
- ---- Finished products----sensory assessment, dimension, function performance, solvent residues, pressure resistance, dropping test.

During on-site audit, some records were sampled for below products:

- ----product name: Moon Cheese WCBP bag A03225
- ----batch number: 2023-06-27

The testing plan for half-finished products and finished products was respected.

During on-site audit, some testing reports from third party labs were reviewed, such as:

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Composite bag ----testing report Qingwei2023-08-0338 on Sep.7, 2023----based on GB 4806.7 & (EU) No. 10/2011 & (EU) No. 2020/1245.

Main in-line testing equipment:

1. Automatic printing information checking system.

Standard samples with defined quality defects will be used to verify the system in work conditions.

2. Automatic quality defects (such as black dirt) inspection system: by doctor machine.

Standard samples with defined quality defects will be used to verify the system in work conditions.

# 5.7 Control of non-conforming product

A non-conforming product control procedure CWL-QP-PK-09 is defined and implemented.

The procedure was well understood by related controllers based on questionnaires during the audit. Special container in special area for non-conforming products were provided and stored separately.

- For incoming raw materials, non-conforming products will be identified, marked and disposed by incoming quality controllers.
- For semi-finished product, production operator will isolate and label non-conforming product, and on-site QC will assess and dispose them.
- For finished products, quality controllers will isolate, mark and dispose non-conforming products. No Batch failure.

No rework.

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, color, strength, and leakage. The potential trends were reviewed in monthly management meeting and corrective action will be followed in next circle.

Non-compliance records and corrective actions were reviewed in Aug and Oct of 2023. Such as 2023-10-16 bag broken.

2023-08-15 bag folds.

2023-05-02 bad printing

# 5.8 Incoming goods

Purchase control procedure was established to control incoming goods match purchase or product specifications. Purchase orders were sent to suppliers to define the material types, quantity, specifications etc.

A raw material control procedure was in place. Incoming materials were attached with delivery note and COA. Inspection activity was done every delivery (condition, cleaning, and pattern of loading).

FIFO was observed with shelf life.

Raw material acceptance standards were in place. For incoming materials, main testing/inspection items as below:

PE resin---- Sensory assessment and COA checking.

Plastic films----sensory assessment, size, functional parameters, COA checking.

Ink/glue---label checking and package checking.

During on-site audit, some records in May - Sep of 2023 were sampled and reviewed, such as:

PE film 890X65----incoming date Jun.8, 2023

PET film 895X12----incoming date May.15,2023

APET white 885X80----incoming date Jul.16,2023

The third-party test reports of incoming goods were reviewed. Such as:

VMPET film, BB/T0030 + GB4806.7, Qingwei2023-04-0674, 2023-05-09

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BOPET film, GB/T16958, TQT00-2456-2022, 2022-12-12

AL foil, GB4806.9, TSNEC2301754802, 2023-07-06

PE film, FDA 21 CFR 175.1520, CANEC2306995101, 2023-05-19

Adhesive, 1907/2006 REACH regulation, SHAHL22005184902, 2023-01-04.

The compliance for raw materials PE film, PET film, and glue were reviewed.

The received materials were verified by authorized person such as incoming QC prior receiving.

Raw materials, AL foil and plastic films, were stored in incoming materials warehouse, and used by FIFO rule based on related label information.

# 5.9 Storage of all materials and intermediate and finished products

The storage and delivery control procedure was established. Storage management procedure was defined how to manage all materials and products to minimise the risk of contamination or malicious intervention, including requirements of finished product packing, segregation of products, storage off the floor and away from walls, specific handling or stacking etc.

Receipt document, stock cards, order sheet were facilitated for correction of stock rotation.

Storage area for raw materials and finished products were maintained in good condition. Plastic pallet was checked before use. No external storage of finished product.

During on-site audit, found that all materials were separately stored and clearly identified.

Finished or intermediate product storage meet customer requirements. The stock rotation is based on FIFO rule.

Plastic pallet was used for storage or dispatch of intermediate or finished products, which were checked before use.

Raw materials, intermediate procures and finished products were separately stored and clearly identified. Chemicals are stored in separated warehouse and handled in such a way that minimized the risk of product safety, quality and legality.

Materials intended for recycling were segregated and labelled.

No hazardous chemicals were found stored at warehouse.

Recycled material protected.

No off-site storage used.

# 5.10 Dispatch and transport

A document transportation control procedure is in place.

During the audit, the loading area was clean, and the condition was followed the transportation requirements.

The warehouse keepers will inspect the container before loading. The inspection items: cleanness, pest activity, dilapidation etc. The container is not used until inspection results is OK.

Plastic pallets and wooden pallets were checked before use. The wooden pallets were sound, dry, clean, free from damage and contamination, and didn't come into direct contact with finished products or raw materials.

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.

Finished product was in normal temperature and load with containers and sealed vehicles. Its transportation was outsourced by 3rd party transport company. The contract was in place. The requirements of transportation and vehicle drivers were defined. The third-party transport personnel weren't permitted to enter storage or production areas.

Vehicle inspection records on 2023-10-16, 2023-07-30, 2023-07-17, 2023-06-02 were reviewed.

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During the audit, the loading area was clean, and the condition was followed the transportation requirements. Cleaning check records were available.

Non-applicable clauses

5.3.5 N/A as no composite printing.

# 6. Personnel

6.1 Training and competence: raw materials handling, preparation, processing, packing and storage areas

H. R control procedure CWL-QP-PK-04 is in place for employee training and employees' performance monitoring.

The training program and plan was established, implemented, and maintained for all staff which carries out activities critical to product safety, quality and legality.

For contractors or other visitors to production areas or warehouses, an internal person will accompany them to train and direct them to respect hygiene or other rules.

The training plan was updated yearly basing on the results of operators' performance assessment and training needed from each department.

The training plan was in HACCP, GMP, security controls, BRCGS packaging standard, test, calibration, work instructions, product defence and other necessary items. The trainer, trainee, content, training date with duration were defined in the plan.

The site has defined and documented how new or changed procedures, working methods and practices related to product safety or quality are communicated to relevant personnel.

Training methods include meeting room courses and on-site performance training. Training results were assessed based on paper examinations, questionnaires, and on-site performance assessment. Key operators about product safety and quality can't engage in production if training assessment not passed. Examples for training records:

- 1. BRCGS package standard ---- Jun.18,2023
- 2. HACCP plan for HACCP team members on Jun.16, 2023
- 3. Process controls & food safety ----for workshop employees on Sep.21,2023
- 4. Pest controls & food safety defence ---- for operators on Jun.15,2023
- 5. personal hygiene policies---for all employees on Jun.18,2023
- 6. Quality---for QC on Apr.29,2023

Training records were available. Training records contained trainer, trainee, content, training date with duration.

HR reviewed training plans and training records to ensure training controls were effective.

# 6.2 Personal hygiene: raw materials handling, preparation, processing, packing and storage areas

Documented personal hygiene control procedure is developed and implemented. The company regulations did not allow wearing any jewellery to preparation, production and storage area. Fingernails was asked to kept short and clean. False fingernails, nail varnish/polish or nail art was not permitted. No drinking, eating, smoking and no perfume in production area and storage area.

Personal items and belongings, including personal mobile phones were not permitted to take into production areas.

It was adopted for all staff, contractors and visitors. Personnel hygiene inspection was done once per day and a whole GMP inspection was done once per month.

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Hand washing procedure was in place. The company provided hand washing method and frequency such as after going to toilet, before entering into processing area and during working. Controllers have been appointed to monitor the effectiveness of hygiene procedures periodically.

Drink water was permitted in a designated area.

Control the use and storage of personal medicines was described in personnel hygiene. Medicines were stored in personal belongings cabinet out of the workshop.

Blue plasters were used to cover cuts and grazes on exposed skin. When used, plasters will be checked and registered before and after use to avoid product contamination.

During on-site audit, found that the rule was respected.

#### 6.3 Staff facilities

There were enough staff facilities such as changing room, toilet, and hand washing station and lockers. Good designed and operated for staff facilities. No potential contamination risk was observed during onsite assessment.

Changing facilities for staff and visitors were sited at the entrance of production area. Changing room locates at entrances before entering production areas. Employees must change personal things inside changing room and wear protective clothing.

Sufficient storage facilities for personal items were provided for all staff. The provision of stored outdoor shoes, clothing and other personal items were stored separately from work wear. Personal items are stored in small closet in changing- room.

No eating, drinking and smoking in locker, changing rooms, production and store areas.

Suitable and sufficient hand-washing facilities were provided at the entrance of workshop to enable cleaning of hands before commencing work, after breaks, and as necessary during work.

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

- Hand-free taps in the hand washing stations
- Running water
- unscented liquid soap
- 75% alcohol
- -- dryers
- Hand washing policy is defined and posted.

During on-site audit, found that hand-washing stations were in good conditions.

Man and woman toilets are adequately segregated from production areas and storage areas, and do not open directly into storage, with hand-washing facilities.

Facilities for visitors and contractors were compliance with the hygiene pllicy.

Catering facilities are in a special isolated area, segregated from production and storage areas.

Drink was permitted in a designated area out of the workshop.

Smoking was allowed only at living area or designated area.

The used cigarette butts, beverage bottles and cookie bags were found in the garbage bin at the hand-washing disinfection area in workshop.

A minor CAR was raised.

### 6.4 Medical screening

The medical screening procedure is in place for all employees or visitors who will work in or visiting areas where product safety could be compromised. Report channel was defined and implemented. Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the employees were aware of the symptoms of infection, disease or condition which would prevent a person working. The site had a procedure for the notification by personnel, including temporary

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personnel, of any relevant infections, diseases or conditions with which they may have been in contact or be suffering from.

Based on risk, internal medical screening for staff were conducted. The workers should provide health certificates.

New staff was required to provide health certificate before beginning work. Old staff would be conducted with medical screening once a year. Four operators' health certificates were reviewed. Valid health certificates were in place.

For visitors or contractors, a health questionnaire will be done to conform that they are not suffering from any symptoms which may put product safety at risk before allowed into production or storage areas. Onsite, auditor was required to fill in a health questionnaire when into the production site.

6.4.3 N/A as all operators in production areas may produce plastic products which will contact food directly.

The auditor wasn't required to fill in a health questionnaire. A minor CAR was raised.

# 6.5 Protective clothing

Clothing control procedure was in place. Company provided protective clothing. Staff must wear protective clothing before entering production areas, also for visitors and contractors. The wearing process of protective clothing was in place.

Protective clothing must be changed in changing room before to toilet and away from production area.

Protective clothing: hats, working clothing, mask, hairnets and working shoes. Each employee has at least 3 protective work uniforms.

The management of protective clothing was defined and applied by the risk analysis. The clothing provides adequate coverage and has no external pockets on the upper body garments or sewn-on buttons. Home laundry was used. A work instruction was in place to direct employees clean protective clothing correctly. Protective clothing was cleaned by themselves. And internal controllers were appointed to check the conditions of protective clothing daily.

Clean and dirty clothing were segregated and controlled to prevent cross-contamination. A waste bin was used to collect disposable protective clothing.

During on-site audit, found that protective clothing was in clean conditions.

# 6.5.6 N/A. No gloves were used.

clauses	<ul><li>6.4.3 as all operators in production areas may produce plastic products which will contact food directly.</li><li>6.5.6 No gloves were used.</li></ul>
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#### Requirements for traded products

7.1 Approval and performance monitoring of manufacturers/packers of traded packaging products

Not applicable

7.2 Specifications

Not applicable

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7.3	Product inspection and laboratory testing	
Not applicable		
7.4	Product legality	
Not applicable		
7.5	Traceability	
Not applicable		
Non-applicable clauses		Not applicable

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