Audit Report
Global Standard Packaging Materials Issue 6: August 2019

Audit summary			
Company name	Qingdao funuoda Packing Co., Ltd.	BRCGS site code	4998792
Site name	Qingdao funuoda Packing Co., Ltd.		

Audit scope	
Scope of audit	Gravure printing, lamination of films (BOPA, PE, PET,VMPET, CPP, BOPP and Aluminium Foil), cutting and bag making of bags for food use
Exclusions from scope	None
Justification for exclusion	No

Additional 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	Choose an item

Number of non-conformities		
	Major against SOI of Fundamental	0
	Critical	0
	Major	1
	Minor	6

Company details			
Address	800 meters north of zaohu community neighborhood committee, Chengyang street, Chengyang District, Qingdao City, Shandong Province 266109		
Country	P.R. China	Telephone	+8653283531398
Commercial representative Name	Mr. Degang Hu	Email	qdfunuoda@163.com
Technical representative Name	Mr. Degang Hu	Email	qdfunuoda@163.com

Company profile					
Plant size (square metres)	<10K sq.m	No. of employees	1-50	No. HARA Plans	1-3
Subcontracted activities	No				
Outsourced processes	No				
Other certificates held	No				
Regions exported to	Europe Choose a region Choose a region Choose a region Choose a region				
Major changes or auditor observations since last BRCGS audit	This is initial BRCGS audit				
Company description	Qingdao Funoda Packaging Co., Ltd.is located at 800 meters north of zaohu community neighborhood committee, Chengyang street, Chengyang District, Qingdao City Shandong Province. The total area of the factory is 5000 square meters & construction area is around 8500 square meters free from contamination. Main products manufactured are printing of BOPA, PET, BOPP, laminating of PE, PET, BOPA, BOPP, VMPET, aluminium foil, cutting then bagging for food The Key customers are focusing on internal market and foreign market. The factory has a business license valid to forever, was granted by local competent authority. 1 HACCP were established for the product scope, at present 42 workers were working in the packaging for food use. The equipment used in the factory is listed as following: Computerized rotogravure printing press, Plastic bag testing machine, High speed dry laminating machine. Testing devices covers: intelligent electronic tensile machine, puncture device.				

Product and process characteristics	
Manufacturing Categories	05 - Flexible plastics 07 - Print processes Category Category Category Category
Products in production at the time of the audit	PET and PE bag

Audit duration details			
Finish date	2020-09-20		
Re-audit due date	2021-09-19	Previous audit date	Select a date
On-site duration	12 hours	Duration of production facility inspection	6 hours
Reasons for deviation from typical or expected audit duration	Product directly contact food and hygiene-sensitive products, so no deviation, and audit duration per to 5000 s.q.m facilities, 42 employees and 1 HARA plans		
Next audit type selected	Announced		

Audit duration per day			
Audit days	Date	Audit start time	Audit finish time
1 (start date)	2020-09-19	09:00	17:30
2(end date)	2020-09-20	08:00	12:00

Auditor information		
Auditor number	Auditor Name	Role
176545	Ruth GUO	Lead Auditor

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.8) Name / Job Title	Opening meeting	Site inspection	Procedure review	Closing meeting
Mr. Yin Px GM/Plant Manager	X			X
Mr. Hu DG/ Production Director	X	X	X	X
Mrs. Liu Xn/ Warehouse Director	X	X	X	X
Mrs.Cui JP/ QA Engineer	X	X	X	X
Mrs. Yang L/ Purchasing Director	X	X	X	X

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced

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	Corrective action taken	Proposed preventive action plan	Root Cause Analysis	Date reviewed	Reviewed by
1	4.9.2.3	One snap-off blade knives was found in workshop	Remove the snap-off blade knives from workshop and used other knives.	Training the related staff for clause 4.9.2.3.	The related staff work careless and didn't remove the snap-off blade knives in time.	2020-10-11	Ruth GUO

Minor							
No.	Clause	Details of non-conformity	Corrective action taken	Proposed preventive action plan	Root Cause Analysis	Date reviewed	Reviewed by
1	3.11.1	The printing record was checked on site, and only recorded the red colour ink batch and quantities.	Recorded the correctly and all data in printing record.	Training the related staff for clause 3.11.1.	The related staff work careless.	2020-10-11	Ruth GUO
2	4.2.5	One lamp without cover was found over the materials in bag making workshop.	Replaced the lamp without cover with LED Lamp.	Training the related staff for clause 4.2.5.	The related staff work careless	2020-10-11	Ruth GUO
3	4.6.3	One broken wooden plate was found in workshop	Replaced the broken wooden plate with well condition plastic plate.	Training the related staff for clause 4.6.3.	The related staff work careless.	2020-10-11	Ruth GUO
4	5.5.1	The thermometer in the curing room has been calibrated internally, but the evidence of calibration of the standard thermometer for internal calibration was not provided.	Calibrated the standard thermometer in time	Training the related staff for clause 5.5.1.	The related staff work careless and didn't calibrate the standard thermometer	2020-10-11	Ruth GUO
5	5.9.2	One rolls of semi-finished product without identified was found in workshop	Identified the rolls of semi-finished product in time.	Training the related staff for clause 5.9.2..	The related staff work careless.	2020-10-11	Ruth GUO

6	6.5.4	The visitor's protective clothing has external pockets on the upper body garments and buttons	Removed the external pockets and buttons from protective clothing	Training the related staff for clause 6.5.4.	The related 6: work careless.	2020-10-11	Ruth GUO

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

Continual improvement control procedure was documented and implemented. And its GM demonstrated they were fully committed to the implementation of the requirements of the Global Standard for Food Safety including provision of adequate resources, effective communication, systems of review and actions taken to effect continual improvement, and opportunities for improvement was identified, implemented and fully documented.
The safety and quality policy is defined in manual signed by GM on 2020-06-10, safety and quality policy statement is clear defined covering legality and product safety requirements. The policy is communicated to all levels of staff by management team.
The policy was stated as the following:

- Based on food safety, protection of environment, to obey legislation and requirement of customer, to make customer satisfaction, prefect quality and continuously improve.

Summary of targets sets such as:

- Delivery on time≥90%, increasing by 1% per year;
- Contract performance rate ≥98%;
- Customer satisfaction level ≥ 90%, increasing by 1% per year;
- Finished product qualification ratio: 100 %;

The targets are disassembled to each department with detailed objectives of each department, each department will review and communicate the detailed objective of own department once every month, and then in quarterly meeting managers of each departments reviews the summary target to see if it is archived. The KPI is communicated through meeting, e-mail, training course and board displayed in site entrance and workshop.
Last reviewed and reported on 2020-08-31. And the targets were achieved.
GM has committed to provide human resource and financial resource to support BRCGS standard and maintained product safety and quality management system.
Channels of meeting, e-mail and board notice are implemented according to organization structure chart following employee- shift chief- manager-(HACCP team leader)-GM.
Communication channel system includes customer, CIQ and internet.
Example for:

Legislation	Article
EU 10/2011	plastic
2011/65/EU	RoHS
EC 2023/2006	GMP
FDA 21 CFR 177.1520	plastic
GB4806.6	PE/PA

Finished product third party test report:

May.20, 2020, BOPA/LDPE laminated bag, cover heavy metal, solvent residue, toluene diamine, results met QB/T1871, testing by Qingdao product quality supervision and testing research institute, No. 202015001158. CNAS L1184.

	Dec.31, 2019, PET/AL/PE laminated bag, cover heavy metal, solvent residue, toluene diamine, results met GB9683, testing by Qingdao product quality supervision and testing research institute, No. QTC-915004891. CNAS L1184. Mar.27, 2020, BOPP/LDPE laminated bag, cover heavy metal, solvent residue, toluene diamine, results met GB9683, testing by Qingdao product quality supervision and testing research institute, No. 202015000614. CNAS L1184. The most senior production/operations managers on site was GM, QA Manager and Production Supervisor available during opening and closing meeting and available for management interview after the opening meeting. This was the initial audit.
1.2	Management review
	The management review procedure FND/CX-2020-20 was documented and implemented. The frequency of the management review was planned once per year. Latest annual management review conducted on 2020-09-10. The management review is hosted by the following key departments: GM, QA, Production, Sale and other departments. Summary of input: customer complaints, result of monitoring main processed, suppliers' performance, emergency and withdrawal, objective and policy reviewed, communications, the performance of product safety management, internal audit result, 2nd party audit and 3rd party audit, any change in the management system. Output includes any action needed to improve the system. Summary of output: the management review result 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 and resource requirements. Objective was also reviewed in meeting. Total 1 decisions were raised and corrective action plans were established for review. The action and responsible of each output had been defined, and planned to be completed. Monthly meeting about management is also 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 action.
1.3	Organisational structure, responsibilities and management authority
	Quality manual organisational chart and responsibilities were defined, including those with an impact on product safety, legality and quality. Clear organization structure was established covering all business processes. Designated manager is YPX and deputy is HDG The organisation chart was reviewed on 2020-06-10. Responsibilities were documented in job description of each position. Documented arrangement in place to cover for the absence of key staff: 2020-07-20 Work instructions are available, communicated and in place for staff that responsible for every key activity related to product safety, legality and quality. Communication channel includes GM→ management representative (Team leader) → department → operator and versa. No non-compliance is found in this section during the audit.

Non-applicable clauses	1.1.7 This was the initial audit. 1.1.9 This was the initial audit. 1.1.10 This was the initial audit.

2.	Hazard and risk management
2.1	Hazard and risk management team
	HARA plans were established and maintained based on the codex Alimentarius HACCP principles. HACCP plans for its products, FND/HACCP-2020, version A/0 was valid on 2020-06-10. HARA plans approved by general manager Mr. Yin PX The multi-disciplinary team comprises members including：Quality department, production department, maintenance, sales department, purchasing department, checkers and operators. Mr Yin (GM) was appointed to HARA team leader. He had more 20 years experiences in plastic products plant and better understanding of HACCP principles and their application. He had received HACCP and BRCGS PM V6.0 internal auditor training course in company. The HARA team members have received HACCP principle training. Such as Mr. Hu Dg and Mrs. Cui Jp had received HACCP and BRCGS PM V6.0 internal auditor training course on 2020-06-15 and 2020-03-15.
2.2	Hazard analysis and risk assessment
	The product scopes are clearly identified in HACCP Plan. Product scope was plastic laminated bag for food and pet feed use. The potential hazards for all steps are identified and conducted hazard analysis and control measure are established, monitored, verified and recorded. Documented PRP was in place, including layout, maintenance of equipment and facilities, purchasing, allergen, cleaning, pest control, personnel hygiene, training and others. Training and meeting reviewed for HA. Consideration such as:

Legislation	Article
EU 10/2011	plastic
2011/65/EU	RoHS
EC 2023/2006	GMP
FDA 21 CFR 177.1520	plastic
GB9691&GB16331&GB 4806.7	PE/PA

A full description of the product developed includes:
Raw materials and package materials characters were in place.
Final product descriptions were adequate:

Product	plastic bag for food
Composition	Plastic and films
Raw materials	BOPA, PET, VMPET, PE and AL film, ink oil and adhesive
Properties	60 degree 2hour ≤30, 65% ethyl alcohol 20 degree 2 hours ≤30; K4MnO4 consume 60 degree 2hours ≤10, heavy metal Pb ≤1.
Intended use	Packaging for food or pet feed etc.
Shelf life	12 months
Storage condition	ambient temperature

Packing and print	Gravure printing. The inner packaging-plastic bag, outer packaging-carton.

Main processing flow diagram is as following:
Materials Receiving--- receipt and approval of artwork and specification-preparation—printing --laminating--curing-bag making--packing-storing and dispatching.
Flow diagram was confirmed by FST on 2020-06-10.
Flow diagrams in certified scope were verified during on site audit and compliance with written flow diagram was observed.
The hazard analysis is considered chemical, physical, biological, malicious intervention, raw material fraud, foreseeable misuse by the consumer, unintended migration of substances from the packaging material into food or other hygiene-sensitive products, potential problems arising from the use of recycled materials, defects critical to consumer safety and hazards that may have an impact on the functional integrity and performance of the final product in use.

Potential hazards are evaluated with likelihood of low to high (5 level) and severity of low to high (4 level) then risk grade of low to high is gained through risk matrix, risk grade is defined as low and high after risk assessment, then assessments are conducted based on the following selection and categorization.
After hazard analysis, CCP (HACCP plan) and OPRP then planned.
CCP

CCP number	Process
1	curing

CQP

CQP number	Process
1	Printing
2	laminating
3	Bag making

The CLs of CCP:

CCP number	Process	CL
1	curing	Temperature as SOP, such as 40-60℃, time 24-72h

All critical limits are based on subjective data. HACCP validation records are retained on file. CL based on China and FDA regulation or best practice.
The monitoring system is established for CCPs and monitored by trained staff.
The CCP monitoring as below:

CCP number	Process	Monitoring
1	curing	Each batch

The CQP monitoring as below:

CQP number	Process	Monitoring
1	Printing	Pressing and tension
2	laminating	Adhesive quantity and tension
3	Bag making	Sealing temperature

The correction and corrective action taken are clearly identified in CCP monitoring table both of process and product handling to before the CCP deviation will be met to specification.
The corrective action is as followings:

CCP number	Process	Corrective action
1	curing	Adjust temperate and segregate non-conformity product, rework or scrap

CQP number	Process	Corrective action
1	Printing	Adjust equipment non-conformity product scrap
2	laminating	Adjust adhesive quantity and equipment non-conformity product scrap
3	Bag making	Adjust temperate non-conformity product scrap

The documentations and records related with product quality and safety are kept in suitable condition.
Documents and records reviewed found that there was no deviation for the CCP. The monitoring records of CCPs were available for review. E.g. 2020-08-26 and 2020-07-10.
Procedures of validation and verification to confirm that the HACCP system working effectively is in place. Last validation for its products was carried out on 2020-08-15. Reports were maintained.
The HACCP records were maintained at least 3 years.
The company operates a formal sign off process for all new products and significant changes and new equipment which includes sign off by the HACCP Team leader to confirm the impact of any changes have been assessed.
The company should be reviewed its HACCP system and prerequisite programmes yearly. Last HACCP and PRPs reviewed on 2020-08-15.

Non-applicable clauses	None

3.	Product safety and quality management
3.1	Product safety and quality management system
	Product safety and quality management system is edited by quality management team/HACCP team, then it was assessed through documented manual and procedure to each department, it was revised by quality manager and then assessed in management meeting, at the end GM approved it. The manual is managed and controlled by quality manager/HACCP team leader. The copies of product safety and quality manual are distributed to each department. Key staff could access the up-to-date version of the quality manual. Working methods and practices are documented within product safety and quality manual. The manual is comprehensive and covered all BRCGS PM Standard requirements. The system is reviewed at planning intervals with at least once every 3 years. No non-compliance is found in this section during the audit.
3.2	Document control
	Working methods and practices are documented within product safety and quality control system. The manual is comprehensive and covers all BRCGS PM Standard requirements. Document control procedure FND/CX-2020-25 was developed. Documents are approved by authorized person. All documents including e-copy which concerned all systems are properly approved by authorized person. Electronic document and record form were stored with password-protected, and only authorized person could access, amend and delete. Electronic document and record form were backed up in storage device in place and with password-protected The controlled document list is established and indicates the latest version number. The document replacing system is implemented. No non-compliance is found in this section during the audit.
3.3	Record keeping
	Record control procedure FND/CX-2020-26 was established and implemented. Legible records are observed from the reviewing of existing maintained records. Signatures, straight line crossing wrong words, good justification recorded are observed from the reviewing of existing maintained records. Records will be kept for long time (over 3 years) according to each kind product. No non-compliance is found in this section during the audit.
3.4	Specifications
	Specification: - Incoming materials, semi-finished product and finished products. Specification list for specifications established. Specification covers packaging material, raw material and finished product that adequate and accurate requirement as standard such as migration limit, heavy metal and other performances. Raw and finished product specifications are agreed with relevant party through document contract. Manufacturing plan is established and implemented according to prescriptive specifications.

	Declarations of compliance are reviewed onsite such as recommend letter from supplier and to customer that complied with GB. The declaration of compliance contains 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. Company also qualified each material to the third party to confirm to its conformity. Trade mark will be reviewed with agreement signature by Sales and Customer. Specification is reviewed at start up, changed and once every 3 years. Last reviewed on 2020-05-16.
3.5	Internal audits
	Internal audit control procedure FND/CX-2020-17 was established and implemented. The company had established an internal audit plan once per year. The audit standard is included HACCP and BRCGS standard. The audit frequency is based on the risks associated with the activity and previous audit performance. The last internal audit for BRCGS was carried out on 2020-09-05, audit scope was all BRCGS causes and departments. And internal audit results were maintained on files. The internal auditors included: Mr Hu (Leader), auditor: Mr Yin Px, Mr Cand Mr LTJ who were competent (BRCGS training (2020-05-16~2020-05-19), plastic package experiences), and they were all independent from the audited department. Internal audit records included attendance record of open/close meeting, non-conformities record, summary report, corrective action report and internal audit checklist were in place. 1 minor CARs was raised in the internal audit. Audit findings were confirmed with the auditee, and the corrective actions and timescales were also confirmed. Details of non-conformities of Internal CAR have been followed up corrective action and within specific timeframe. Example for CAR:

CAR no.	Non-conformity	CA time
001	Found external pockets on the upper body garments	2020-09-07

	The corrective actions were taken and all were verified by internal auditor. Internal audit report was filled with evidences of conformity together with non-conformity to cover requirement of BRCGS PM. The frequency of GMP inspection is once per day in open product areas. The frequency of GMP inspection is once per week in plant yard and storage areas, the check records were kept on files. E.g. 2020-07-18 and 2020-08-08. The responsibility of checking is defined clearly, e.g. production, warehouse, office and HACCP team.
3.6	Corrective and preventive action
	Corrective and preventive actions procedure FND/CX-2020-18 is established and implemented. QA department is responsible for this issue. Records reviewed found that the company took corrective actions in a timely manner for non-conformities and consider the analysis (root cause) of non-conformities for trends, a non-conformity places the safety, legality or quality of a product at risk.

3.7	Supplier approval and performance monitoring

Purchase control procedure FND/CX-2020-24 was defined.
All suppliers of products and services have to be approved at first and then entered onto the system before they can be used.
Assessment is based on hygiene and quality risk to the product with suppliers categorised in risk levels L to H. Grade L supplier is subject to in house check before approval and M/H need to be evaluated yearly. Supplier also has been reviewed the performance within a special “trial” of three previous batches.
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.
Assessment was based on the hygiene and quality risk to the product and legal requirement on 2020-06-10.
The approved suppliers including raw material supplier, packing material supplier shall be assessed at least annually.

The detailed exception was defined in procedure, no exception happened till now.
Approved suppliers were registered in approved supplier list. 2020-05-15

Example for supplier:

Material	Supplier	Evaluation date on report	Evaluation result
BOPA	Cangzhou Donghong Packing materials Co., Ltd.	Annual performance 2020-06-01	Qualified
PET	Yingkou Kanghui Petroleum and Chemical Corporation	Annual performance 2020-06-01	Qualified
AL	Kunshan Aluminium Foil industrial Co., Ltd.	Annual performance 2020-06-01	Qualified
PE	YANTAI Meifeng Plastic products Co., Ltd.	Annual performance 2020-08-01	Qualified
Ink oil	Jiangmen dongyang Ink Co., Ltd.	Annual performance 2020-08-31	Qualified
adhesive	Hebei Huateng industry Company	Annual performance 2020-06-01	Qualified

	The raw materials third party test report: Raw material BOPA, testing report No.: A2200043973101001C, done on 2020-03-27, results met Client requirements, CTI (CNAS L5541). PL0500060-2020, results met GB4806.7, done on 2020-01-16, testing by national supervision and inspection center for packaging product quality Jinan CNAS L1177 PET testing report No.: W2020085310311095, done on 2020-08-18, result was compliance with GB4806.7, test by Dalian product quality inspect ant testing institute (CNAS L0010). AL testing report No.: SHAEC2001098306, done on 2020-02-21, result was compliance with RoHS 2011/65/EU-EU 2015/863 and 94/62/EC-11, test by SGS shanghai. Ink oil testing report No.:CANEC2005275919, done on 2020-04-22, result was compliance with RoHS 2011/65/EU-EU 2015/863 and client, test by SGS Guangzhou(CNAS L0167). Adhesive testing report No.: TSNEC2000233502, done on 2020-03-11, result was compliance with RoHS 2011/65/EU-RoHS 2017/2012 and client requirement, test by SGS –Tianjin (CNAS and CMA Certificated).
3.8	Product authenticity, claims and chain of custody
	The site established the procedure of product authenticity. A documented vulnerability assessment was carried out on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution. And this was taken into account: historical evidence of substitution or adulteration, economic factors which may make adulteration or substitution more attractive, ease of access to raw materials through the supply chain, sophistication of routine testing to identify adulterants and nature of the raw material. Last vulnerability assessment was carried out on 2020-06-01. They will keep updated with developing and emerging threats on materials by supplier survey, industry feedback and new information.
3.9	Management of subcontracted activities and outsourced processes
	No subcontracted activities and outsourced processes.
3.10	Management of suppliers of services
	A service supplier approval control procedure FND/CX-2020-24 was in place. The service servicers and qualified certificates were collected and evaluated its performance annual and risk assessment was done on 2020-03-10. This included: waste service, transportation service and lab service. Evaluation records were kept. The related contracts were kept on files. For example: Logistic contractor: Qingdao Zhexing logistic Co., Ltd. Supplier questionnaire on 2020-06-01. Contract valid to 2020-12-31.

3.11	Traceability

Control procedure FND/CX-2020-02 of traceability has been established and implemented.
The company ensured the traceability of all materials used for its products. The code date principle of finished product and incoming materials was in place.
Traceability system demonstrated enough ability onsite.
ID card and label stick well onsite. Obvious identification on packaging with detailed batch number to identify each batch product.
Mock traceability 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, raw material to products:

Traceability time	**2020-07-31**
Description	PET12/PE58 280*210 Food bag, Order No. 201009711LGWWU
Raw materials batch	Raw materials PET12 batch No. KH20200604, receiving date: 2020-06-05
Raw quantity	18000 M
Packing/warehousing	2020-06-09
Quantity	77922 PCS
Traceability effectiveness	100%
Duration	Within 3h
Customer defined	OK

Traceability system demonstrated enough ability onsite.
Example for onsite vertical audit sampled product name:. 170*130 NY15/PE80 bags production date 2020-08-15, order no 201017582LGWWU / quantity: 28150 pcs, incoming raw material NY batch No DH20200806, quantity: 25kg. Effective traceability conducted. The duration was within 3 hours (14:00-16:00). Wastage was 3%.

Minor CAR 1 of 6 has been raised during the audit; for details, please refer to "Non-Conformity Summary Sheet" section.

3.12	Complaint handling

Complaint handling control procedure FND/CX-2020-06 is established and implemented.
QA responded for complaint handling.
Actions will be taken for corrective action with records after making analysis of complaint.
The QA department is responsible for the verification work. The verification person is assigned.
Records will be kept.
0 complaints raised in 2020.
They will be verified. Root causes of the problem will be investigated.
Recurrence preventing will be in place and recorded as well. All records will be verified by QA manager.
Customer complaint will be reviewed via trend analysis every year. They will report to management by meeting.
No non-compliance is found in this section during the audit.

3.13	Management of product withdrawals, and incidents and product recalls

	The emergency preparedness and response procedure was established and implemented. defines how to control and manage effectively incidents and potential emergency situations that impact food safety, legality or quality such as: -disruption to normal production processes -disruption to key services such as water, power, transport, staff availability and communications -events such as fire, wind, flood, epidemic disease or natural disaster -malicious contamination or sabotage, -failure of, or attacks against, digital cyber-security. The company carried out mock drill on 2020-08-19. The recall and withdrawal procedure FND/CX-2020-32 was in place that contained handing method and responsible person of each stage. Classifications of product recall: Class I Recall: This is an emergency situation involving the removal from marketing and distribution channels those products that, because of a deficiency, pose an immediate or long-term serious threat to health or life. An example of such a plastic bag with metal foreign body. In a Class I Recall, top priority must be given to the complete and immediate removal of the recalled products from all levels in the distribution chain all the way down to the consumer level. Class II Recall: This is a priority situation in which a product deficiency may cause temporary or medically reversible adverse health consequences and where the probability of serious adverse health consequence is remote. An example of such a product is a plastic bag containing heavy metal. In a Class II Recall, products must be removed from all levels in the distribution chain. Class III Recall: This is a routine situation in which adverse health consequences of a product deficiency are highly improbable or non-existent. Products are recalled because of adulteration or misbranding not involving a health hazard. Examples of Class III Recalls are situations involving improperly labelled products or products with filth contamination. In a Class III Recall, products must be removed from the wholesale levels of the distribution chain. The list of key contacts, e.g. suppliers, customers, certification body is in place. Key contact list of supplier and customer was kept on file, each supplier and customer has at least 2 contact persons and 2 telephone and e-mail. Communication plan was defined in the procedure. Procedure defines to inform the certification body within 3 days if actual product recall happened, but no recalls had as yet been till now. Mock recall test is conducted at least once a year and test from supplier/raw materials to finished products / customer and vice versa. The current mock test was conducted based on following path: Example for the latest mock test: - Dated on 2020-07-26; - Description: PET/PE280*210, order No. 201020691LGWWU; - Reason: Deviation of printing position. - Finished product quantity: 78000 pcs; - Packing/warehouse: 2020-07-22; - 100% recovery; - Time limited and within 3 hours. - Customer and supplier also defined 100%. No non-compliance is found in this section during the audit.
Non-applicable clauses	3.9 No subcontracted activities and outsourced processes 3.11.5 No rework or any reworking operation and no outsourced or subcontracted activities

4.	Site Standards
4.1	External standards
	The company was built in 2015. The boundary of factory was clearly defined. The overall condition of the facility was maintained in normal condition. The site was located beside package plant and road around the plant. No local activities that would risk product contamination. The building of the factory is in normal repair and maintained with investments regularly planned. The building fabric was maintained to minimise potential for pest entry, ingress of water and other contaminants. External pipework and other access points for the product and raw materials were appropriately sealed and secured. The external areas were maintained in normal order. Grassed or planted areas surrounding buildings were regularly tended and good maintained. External traffic routes under site control were made of asphalt or cement and kept in normal condition and could avoid contamination of the product. The natural external drainage is adequate, no need additional drainage installed. Drains had covered with metal net to prevent entry of pests. Some raw materials were stored in the plant yard, and used plastic film to protect.
4.2	Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas
	Suitable for the type of production. The building of facility for the product was normal maintained. The fabrication of the site, buildings and facilities were suitable for its products process. The building fabric is maintained to minimise 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. Drainage system was in place. Walls were constructed of concrete and steel plate. Ceiling was made of concrete. They were cleaned in normal condition. Appropriately designed and maintained in work condition to prevent contamination. The door and window of fabric were in normal conditions, drainage was equipped with available screen to prevent pest ingress. Floors are constructed of concrete and or coated with paint, generally normal repair. The windows were in the closed manner during audit on site. Glass windows were shielded to prevent breakage, also checked regularly. Sufficient lighting was observed during assessment in all working environment. Bulbs and strip lights, including those on electric fly-killer devices were adequately protected. Air-conditioners and fans were used in processing area, they were maintained. **Minor CAR 2 of 6 has been raised during the audit; for details, please refer to "Non-Conformity Summary Sheet" section.**
4.3	Utilities
	The factory product was plastic products for food and hygiene-sensitive product use No water contact product directly. Municipal water is source of water used in factory for plant cleaning.

	High compressing air without lubricant is filtered with filtration net and Oil/water filtration. High pressure air is used for blowing and cleaning.
4.4	Site security and product defence
	Plant security procedure FND/CX-2020-03 was established and implemented. Procedure defined how to control security of storage and workshop and transportation. -Entrance of factory: security person is prepared; -Office: security person is prepared; -Workshop and storage: special management operator was prepared at entrance to ensure control of these sensitive areas. The unauthorised person can't enter production and storage areas; -Outer visitors and contractors must be accompanied with related responsibility staff; -Computer: password set; -Lab: no need entering for unauthorised person; -Transportation: before loading container to be checked; Effective measures are taken such sealing, locking and escorting. CCTV was installed to monitor the factory with locations and monitored. The latest review record of 2020-06-15 was available. The employee security training was conducted on 2020-08-08.
4.5	Layout, product flow and segregation
	The company was established in 2015 and renovate in 2020, located at Chengyang street, Chengyang District, Qingdao City, Shandong Province, P. R. China. The plant size was 5500 square meters, 42 employees and 1 shifts production. Main products plastic products and processes including materials receiving, gravure printing, lamination, cutting, bag making, packaging, warehouse and dispatch. Canteen located in factory but segregated from production and storage area. There is effective segregation in place to minimise the risk of product contamination and it is identified as low risk, the plan of the site which designates areas where product is at different levels of risk from contamination is defined in PRP. -Incoming material preparing workshop- high risk area; -Processing workshop – high risk area; -Warehouse- basic risk area; All areas are effective segregated well. Working space and storage is sufficient to enable operations to be carried out properly under safe hygienic conditions.
4.6	Equipment
	Equipment have been specified before purchase, and tested and commissioned prior to use. Equipment is positioned well to facilitate cleaning and service. Evidence is available for the equipment in direct contact with product. Most of its equipment and tools were stainless. The main equipment include 2 laminating machine, 1 printing machine and 7 bag making machine. Processing machines ware located in the segregated room and maintained under routine maintenance systems. **Minor CAR 3 of 6 has been raised during the audit; for details, please refer to "Non-Conformity Summary Sheet" section.**

4.7	Maintenance
	Maintenance procedure had been established to ensure the safety and legality of products were not jeopardised. It includes preventative plan which established once a year to cover all equipment and emergency maintenance including daily activities. 2 in-house engineer report to engineering responsibility person who operates computerised maintenance plan. No major breakdowns in last 12 months. 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 maintenance 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. Documented hygiene inspection on start-up completed by QC employees, production can be carried out after start-up check is performed and approved by QC. No food grade lubricant oil was used. Example for maintenance and repair record: -2020-06-20: KGF-1050 SLF1300A laminating machine M/Cs; -2020-06-12: printing machine M/Cs; -2020-07-12: 4# bag making machine M/Cs;
4.8	Housekeeping and cleaning
	Housekeeping and hygiene systems defined cleaning objects, cleaning methods, frequency, used chemicals, operator and safety requirement. 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 onsite operation training. Site operation training result was evaluated by shift chief / QC. The cleaning frequency was shift after finishing work. The cleaning items were defined and implemented including tools, equipment, surface of the contact product, environment. Verification of the cleaning and disinfection by visually check is demonstrated: daily cleaning visually check by QC. Sampled cleaning record: 2020-07 and 2020-08. Cleaning area shall monitoring TPC quarterly. The environmental monitoring programme was in place, and QA is responsible for environmental monitoring, such as testing the TPC for workshop quarterly. Sample record 2020-08. The trend analysis was performed after inspection. But no any non-conformity found till now. Cleaning chemical including soft soap 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 onsite auditing.
4.9	Product contamination control
4.9.1	Glass, brittle plastics, ceramics and similar materials control
	Sharp, glass and brittle material control procedure FND/CX-2020-08 was established. The procedures for handling glass, brittle or hard plastic, ceramic or other materials include the requirement to inspect regularly. 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.

	Checking frequency based on risk assessment is at least once every week now. Example for checking record of 2020-07 and 2020-08. Documented procedures are in place detailing the actions to be taken in case of breakage of glass are in place. The measures include the following: identifying the scope of goods to be isolated; Authorized personnel clearing the production area and releasing the production line for the continued production. Interviewed staff, they showed competency of handling process. Handling records were kept on files.
4.9.2	Sharps and metal control
	Sharp, glass and brittle material control procedure FND/CX-2020-09 was in place. There was no any staple used in workshop and storage area defined in its sharp control procedure. 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 was documented policy for the control of the use of sharp metal in place including no snap-off knife in the workshop. Knives / sharp objects such as scissors and equipment knives were used in workshop to open packaging of materials. They were registered and checked before start-up and at the edge of stopping, product would be segregated and evaluated once breakage happened. But till now not any breakage happened. Check records were kept on files such as: 2020-07 and 2020-08. **Major CAR 1 of 1 has been raised during the audit; for details, please refer to "Non-Conformity Summary Sheet" section.**
4.9.3	Chemical and biological control
	Documented chemical control procedure FND/CX-2020-21 was in place. The approved chemical list and relative MSDS are in place, for example, MSDS and testing report of washing chemical, alcohol, silicone oil and lubricant was reviewed. COA from supplier was in place. Cleaning chemicals stored in a locked room, restricted access. Risk and risk analysis for microbiological hazard is conducted in its risk management and risk analysis sheet. It was used to identify biological risk (salmonella and mould) and allergen and control these risks. Such as raw material reception step can control biological risk based on risk analysis.
4.10	Waste and waste disposal
	Waste disposal was managed by waste contractor, for example waste package materials-Qingdao Guoyue Environment Co., Ltd. contract valid to 2021-12-12; Disposal was well managed. External waste collection container is cleaned in time. External waste is stored in sealed container. Collection containers are available with label and cover. Plant clean external waste collection containers regularly. Unsafe products or substandard trademarked materials were handled should be destroyed by own staffs at first with control record and then confirm with contractor.
4.11	Pest management

	The company was responsible for minimising the risk of pest infestation on the site. The pest control procedure FND/CX-2020-15 was established and implemented. The pest control work was conducted by company self, for the regular inspection (once per day and weekly by company self), and treatment of the site to deter and eradicate infestation. The pest control facilities include flying killers, mouse baffles, glue boards and traps. Fly killers, mouse baffles, glue boards and traps were used for in house treating; Mouse baits were used in external environment. No pesticide used in the company. Pest control was implemented covering all potential areas. Lighting lumps are changed every year or when needed. Check records of pest control were in place, e.g. 2020-06-30 and 2020-07-30. The in-depth, documented pest control survey was undertaken yearly by trained internal trained PCO and external expert. For layout of workshops, pest control devices, equipment, activity of pests and others. The result of survey was as input of next pest control plan. The last survey was conducted on 2020-08-31. Results of pest control inspections were assessed and analysed for trends. Frequency quarterly. Records were in place. Employees had been trained on 2020-07-10 to understand the signs of pest activity and were aware of the need to report any evidence of pest activity to their supervisor.
Non-applicable clauses	4.2.6 No elevated walkways; 4.4.3 No external storage tanks, silos and intake pipes with an external opening

5.	Product and process control
5.1	Product development
	Documented products development procedure was established and has transferred from the site. Product formulation was established. The manufacturing processes have been trialled and product extensively tested to ensure compliance with agreed customer specifications. All new products and changes to product formulation, packaging or methods of processing are formally approved by the risk management team members and it is checked. The critical-use parameters are identified and defined such as artwork, size, colour, thickness etc. all data defined to conduct test in sampling plan. The company did not use recycled materials in its products. The safety and legal issue were confirmed by clients. In the system, the R&D is responsible for informing the recipe/process defined in the trials to the clients via the sales/ customer service staffs. The trail samples were kept in place. Customer related procedure documents have been established in place to ensure that the customer's specification requirements are transmitted to the site system. The document include how to validate the accuracy of data transmission, communicate and update the changes of customer specifications, meet the agreed requirements of customer test methods. And evaluate the impact of customer specification changes on technical specification changes. Settings derived from successfully conducted production trials or equipment installations were transferred accurately to process control documentation.
5.2	Graphic design and artwork control

	Graphic design and artwork control procedure is established. Graphic design is provided by customer, supplier design and produce printed roller with roller no. Factory will check the roller during receiving and confirm artwork at start up. The formal acceptance and approval of final product concepts and artworks by the specifier are in place, it is validated that the agreed product quality and print standards at receiving and confirmed with customer.
5.3	Packaging print control
	Printing methods: gravure printing. Printing control procedure is established. Customer's requirement and specification is provided before printing, confirmation is performed with record and samples. Staff's eyesight is checked serving printing. Printing quality is confirmed at the starting and verified by onsite QC with standard printing source table.
5.4	Process control
	SOP operating procedure has established. The following critical manufacturing process control points are defined after review:

Critical manufacturing process point	Operation Guidance	Limit
printing	ZS/ZY12	• Operation as SOP/ingredient and speed
laminating	ZS/ZY13	• Operation as SOP/temperature
Bag making	ZS/ZY15	• Operation as SOP/Size

Checks are performed at start up, following adjustments and others required in process check schedule.
Operating procedure is implemented.
Quality check is performed as the requirement of designed plan, quality performance and SOP of each process control point with sampling plan according to GB2828.
On site sample: PE and PET bag, the process was under in control.
No any changes happened till now. Company will re-establish process characteristics and validate product data with special report once changes happened.

5.5	Calibration and control of measuring and monitoring devices
	Calibration for the testing and measuring device control procedure FND/CX-2020-29 is developed and covering following: -checking frequency -checking methods -trained staff to carry out the checks when the device shall be internal calibrated.

	Operators are aware of the procedures to be undertaken. Measuring and monitoring devices has been calibrated by government department according to national standard and calibration certificates have been maintained in time in plant. Mandatory calibration once per year: calliper, ruler and weights. For example: -GC certificate no 20YA001070004, type GC-7980, Issued on 2020-08-07, valid to 2021-08-06; -Steel ruler: certificate no 20YA001070006, type1000mm, Issued on 2020-08-07, valid to 2021-08-06; - Tension tester: certificate no: 20YA00107001, type YG024J, Issued on 2020-08-07, valid to 2021-08-06; The external calibration result of reference equipment can traceable to a recognised national and international standard by Shenzhen Huake Metrology & test technology Co., Ltd. Self-calibration records were in place for lab monitoring device. **Minor CAR 4 of 6 has been raised during the audit; for details, please refer to "Non-Conformity Summary Sheet" section.**
5.6	Product inspection, testing and measuring
	Sampling plan was established, product inspection procedure was established and implemented. The plan defined in internal laboratory test and outer contractor test. Internal laboratory test: -Incoming material: appearance, label, colour, size, foreign bodies and COA: once/ batch; -Semi-finished product: appearance, colour, size, weight, printing quality, COF: once/ batch; -Finished product: heat seal, colour, size, weight, appearance, leakage, COF: once/batch. Sample COC: Qingdao product quality supervision and testing research institute and SGS, CNAS and CMA certified. Outer testing report refer to clause 1.1. All results were compliance. (GB standard). The internal laboratory is not accredited, but some methods were taken: Sample record: PET/AL/PE460*310*104 bags, Inspection date: 2020-08-24. PET/PE 280*210*70 food bags, inspection date: 2020-06-09. -comparison testing in internal lab: levels include size, colour, appearance for all lab testing operators; -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; -tester received training course; -Comparison test in internal lab, at least once a year. Last done on 2020-05-20.
5.7	Control of non-conforming product
	Non-conforming product control procedure FND/CX-2020-30 was defined and implemented. Clear process well understood by staffs that are interviewed during the audit. Special container in special area for non-conforming products are provided and stored separately. -For incoming material: rejection in time, responsibility is QA receiver; -For semi-finished product: production operator must isolate and label non-conforming product, QA responsible for assessment and evaluation; -For finished product: test finished products and isolate/evaluate the non-conformity, QA 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 is conducted by QA operator, any potential trend is performed in corrective action report based on each quality levels such as size, appearance, colour etc. The potential trends are reviewed in management meeting and corrective action will be followed in next circle. No non-compliance is found in this section during the audit.
5.8	Incoming goods
	Materials receiving standards were established. Purchase order/ deliver sheet, COA, label and packing condition is checked at first according to receiving standard, then material sampling to check appearance, size and testing in lab based on receiving standard, material will be rejected if non-conformity happened. Raw material and packaging material inspection and test procedure is established and implemented. The received materials were verified by authorized person such as QA prior receiving. Sampled: Raw material BOPA resin 2020-07-08; PE film 2020-07-11, Ink oil, 2020-06-05. IQC record and supplier COA was available. Materials then are stored in incoming materials warehouse and labelled and mostly used by FIFO rule. No non-compliance is found in this section during the audit.
5.9	Storage of all materials and intermediate and finished products
	All materials are separately stored in the storage and clearly identified. All the materials are stored on the pallets and away from floor and are labelled properly. The stock rotation is based on FIFO system. Chemicals are handled in such a way that risk to product safety, quality and legality is minimized. Material intended for recycling is segregated and labelled. No non-compliance is found in this section during the audit. **Minor CAR 5 of 6 has been raised during the audit; for details, please refer to "Non-Conformity Summary Sheet" section.**
5.10	Dispatch and transport
	Document transportation control procedure GMP is in place and during the audit, the loading area is clean and the condition was followed the transportation requirements. The warehouse employee will inspect the container before loading. The inspection item: cleanness, pest activity and dilapidation. The container is not passed until inspection results is OK. Container inspection record: 2020-06-25 and 2020-07-15. Raw material and packaging transport arranged by suppliers. Finished products are shipped in dry container by the third-party company. Example for 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	5.6.6 No in line testing equipment 5.6.9 No automatic detection equipment

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

Training records for all personnel, including temporary personnel and contractors are in place.
Training plan of 2020 year was in place, the training items are detailed including chemical control, safety control, CCP/HACCP, IGMP and BRCGS PM.
Training methods include meeting room course and onsite training.
For CCP training, CCP point was trained at first in meeting course with questionnaire and then onsite operation training. The training result is evaluated by trainer based on meeting room course and onsite training.
Evaluation for staff is conducted through site operation, antitheses, examination or discussion.
Employee can't conduct work if training not passed.
Example for training record:

Course	Location	Date	Trainer	Trainee
CCP monitoring	Meeting room	2020-06-15	LFs	CCP operator
Policy, objectives and procedure	Meeting room	2020-05-15	LFs	All operators
Product inspection, testing and measuring	Meeting room	2020-08-10	LTj	All QCs
WI, SOP and process requirement	Meeting room	2020-08-10	Ltj	All operators
Pest control	Meeting room	2020-07-10	LFs	PCO and operators
Equipment cleaning	Meeting room	2020-06-15	LFs	Operators

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

Documented personal hygiene control procedure s developed and implemented.
Hand cleaning is performed at a reasonable frequency and the effectiveness of hygiene procedure is checked periodically.
Fingernails must be kept short and unvarnished. Jewellery, watches, ring, perfume were not allowed to use in production area. This company regulation was informed to visitor and contractor before entering to production area which checked by production team leader prior to enter.
Smoking, eating, and drinking were allowed in designated areas only.
Hand washing facilities including liquid soap, hand drier, alcohol disinfection and washing instruction with appropriate language was sufficiency provided at every access point.
Staff who had cuts which affect to product safety was removed from processing area to perform others task. Blue plaster and glove were used and monitored onsite.
No watch, jewellery, rings were worn by the employees and managements. And it was checked and monitored by the appointed employee before into the workshop.

6.3	Staff facilities

Sufficient hand-washing facilities were provided at the entrance of workshop:

	Taps are hand-free in the hand washing station; Running water; Liquid soap; Hand washing policy was defined and posted. Man and woman toilets are adequately segregated and do not open directly into storage and provided with hand washing facilities. Catering facilities is a special isolated area segregated from workshop and storage area. Personal items are stored in small closet in changing- room, no food is permitted in production and store area. Food is provided in mess outside production area and storage area. Changing room locates at entrance before entering workshop. Employees must change personal things inside changing room and wear protective clothing. No eating, drinking and smoking allowed in locker and changing rooms. Drinking of water from purpose-made dispensers and special drinking cups were allowed and provided, they were confined to a designated area away from equipment.
6.4	Medical screening
	The medical screening procedure is in place for all employees or visit who will work in or visiting area where product safety could be compromised. The health check for relative employee is carried out by local hospital at least once per year and the licenses are retained on file, for example: -Mr. Ljp, valid until 2021-09-13; -Mr. Jmx, valid until 2021-09-13; -Mr. Lbh valid until 2021-09-13; Health questionnaire will be required to fill by outer contractor, visitor and service person before entering workshop and storage area that defined in its procedure.
6.5	Protective clothing
	Each employee has at least 2 work uniforms including disposable hairnets, coats and work shoes according to different risk grade. Hands washed and sanitised before entering production area. Completed protective clothing should be put on before entering workshop, also for visitors and contractors. Protective clothing must be changed in changing room before to toilet and use of canteen and smoking areas outside workshop. No snoods are worn because very short beards and moustaches only permitted to workshop area. Protective clothing cleaning and disinfection procedure was established. Protective clothing is cleaned by employee. Laundry standard and operation instruction with training course was provided for its staffs. The special hygiene operator must check cleanliness of all protective clothing at entrance. Glove was used in the factory and changed weekly or needed. Check records were in place. Disposable hair cover is worn by employees at workshop and shall be changed every time out/in workshop. **Minor CAR 6 of 6 has been raised during the audit; for details, please refer to "Non-Conformity Summary Sheet" section.**

Non-applicable clauses	6.4.3 Product was direct contact with food or other hygiene-sensitive products