Audit Report

1.Audit Summary			
Company name	FUJIAN UNILAND FOODS CO., LTD	Site Code	5355155
Site name	FUJIAN UNILAND FOODS CO., LTD		
Scope of audit	Sorting, cutting, washing, blanching & IQF of frozen fruits and vegetables included banana, lychee, mango, onions, bamboo shoot, soy beans, soy bean kernel, sugar snap, pea pods, green bean, black fungus, baby corn, cauliflower, broccoli, water chestnut, taro, carrot, corn, okra, sweet pepper, green pea , chestnuts, potato and sweet potato; packed in the plastic bag.		
Exclusions from scope	None		
Justification for exclusion	Not applicable		
Audit Start Date	2021-01-10	Audit Finish Date	2021-01-12
Re-audit due date	2022-01-28	Head Office	No

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

2. Audit Results					
Audit result	Certificated	Audit grade	B	Audit type	Announced
Previous audit grade	B	Previous audit date	2020-01-20		
Certificate issue date	2021-03-02	Certificate expiry date	2022-03-11		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	1
	Minor	9

3.Company Details

Address	Lumei Village, Changqiao Town, Zhangpu County, Zhangzhou, Fujian Province, 363200,		
Country	P. R. China	Site Telephone Number	865963850888
Commercial representative Name	Mrs. He Shunzhou	Email	378898708@qq.com
Technical representative Name	Mr. Cao Yiwei	Email	2084148483@qq.com

4.Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Shift Pattern	8 hours per shift, 1 shift per day, 5~6 days per week
Subcontracted processes	No
Other certificates held	ISO22000, Kosher, Halal
Regions exported to	Asia North America Europe South America Oceania Choose a region
Company registration number	FDA12966060170
Major changes since last BRCGS audit	One old workshop was finished construction, one new cutting machine was purchased.

Fujian Uniland Foods Co., Ltd. The company occupies more than 30,000 square meters of land which is built in 1994. It has built up low temperature and preservation warehouse with a capacity of 6,600 and 500 tons respectively. Total manufacturing size is about 9,980 square meters. There are 2 workshop building, 1 dining room and 1 staff restroom in site. Total staff is about 100 staff, 1 shift per day and 6 days per week. Working time is 0800~1800.
The new workshop was built in May 2012 according to Chinese Sanitation registration regulation, American FDA regulations and related instructions of EU. The old workshop in the facility was not used. Factory has been certified BRCGS since 2007 and The BRCGS audit in 2012 was cancel due to business reason, now new factory began production since 2018, so factory re-applied BRCGS.
All products were selling oversea. Main products of company are: soy beans, soy bean kernel, sugar snap, pea pods, green bean and so on. They sell in Japan, Taiwan district, Southeast Asia, Europe,

4.Company Profile

Australia, America and other countries.
Factory has export 4000 in 2020 and about 100 tons product are sell in domestic market.
Factory has been award ISO22000, KOSHER and Halal certificate.
Factory was located near road side; the neighbour is local resident and wood product plant.
No product recall and withdraw happen in 2020.

5.Product Characteristics

Product categories	06 - Prepared fruit, vegetables and nuts Category Category Category
Finished product safety rationale	The key processing is blanching and freezing, shelf life is within 24 months, core temperature of the finished frozen vegetable and fruit -18C. Adequate cooking for eating or supplied to other factory for further processing

High care	Yes	High risk	No	Ambient high care	No

Justification for area	Low risk, high care and enclosed area in plant. Raw storehouse and finished product storehouse are enclosed area, blanching area and packing area are high care area, other areas are low risk area.
Allergens handled on site	Soya Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	No
Product recalls in last 12 Months	No
Products in production at the time of the audit	Frozen black fungus slice and packing of green bean

6.Audit Duration Details

On-site duration	22 man hours	Duration of production facility inspection	11 man hours
Reasons for deviation from typical or expected audit duration	Time as per BRCGS audit duration calculator		

6.Audit Duration Details	
Next audit type selected	Announced

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1	2021-01-10	09:00	18:30
2	2021-01-11	08:30	18:00
3	2021-01-12	08:00	14:30

	Auditor number	Name	Role
Auditor Number	20456	Amelink Wang	Lead Auditor
Second Auditor Number	N/A		Please select

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 1.1.11)				
Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Zhong Yuewen / Director of plant	X	X	X	X
Lan Jiawei / QA manager	X			X
He Chaoming / Purchase	X			X
Luo Siqin / Packing chief	X			X
He Shengqing / Plant manager	X		X	X
Yue Yanchun / Production chief	X			X
Huang Yaozhi / Vice plant chief	X			X
Chen Minglong / QA	X	X	X	X

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No	Clause	Detail	Critical or Major	Ant. re-audit date

Critical			
No.	Clause	Detail	Ant. Re-audit date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	4.14.10	Pest management survey was conducted annually by external pest company, but factory did not provide this report in time.	We had convened Asked Pest management survey from external pest company. Conducted training to document controller about the BRCGS Food 8 and “Documents and Data Control Procedures” XP-QP-01-2019	To ask the Pest management survey from external pest company. In addition, the external pest company promise will provide annual pest management survey on December 20 each year, our document controller will responsible for collection and Archive it. XR-QP-01-2019.	Due to change a new pest company on July 1st, 2020, we forgot to ask for the pest management survey in a timely manner.	2021-02-02	Amelink Wang

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	2.5.1	HACCP flow chart is not included sieve stage.	We had convened update HACCP Flow chart, add sieve stage in it. Conducted BRCGS food training to the food safety team	To validate the sieve process and add it into HACCP flow chart. To provide BRCGS food training for our food safety team	Our food safety team didn’t describe clearly in the HACCP flow	2021-02-02	Amelink Wang

Minor							
					chart, actually the drain process is exactly mean the sieve and drain stage.		
2	2.10.2	CCP1 record of green pea on 2020-07-11 was unfinished, it was with key-in mistakes.	We had convened XR-QP-02-2019, complete CCP1 record, identify the traceability number and processing method and date Conducted the “Management Record Control Procedure" XR-QP-02-2019 Training to our quality engineer Mingrongchen.	To finish the CCP1 record, it already approved by our plant director. To conduct the BRCGS and the “Management Record Control Procedure" XR-QP-02-2019 Training to our quality engineer Mingrongchen.	Quality engineer Mingrong Chen didn’t understand the “Management Record Control Procedure" well.	2021-02-02	Amelink Wang
3	3.4.4	The monthly hygiene and GMP checking record on 2020-12-24 was unfinished. It was not included year 2020.	We had convened already, added the year 2020 into hygiene and GMP checking record. Conducted the BRCGS food V8 training and “Management Record Control Procedure" XR-QP-02-2019 to Sanitation manager.	To add the year 2020 into hygiene and GMP checking record. And will indicate the specific date, month and year in all documents To conduct the BRCGS food V8 and “Management Record Control Procedure" XR-QP-02-2019	The Sanitation manager forgot to write the year in the record.	2021-02-02	Amelink Wang

Minor							
				training to Sanitation manager.			
4	4.2.3	During auditor visit factory, the security of gate did not check background information of auditor.	We had conducted training BRCGS food 8 about security responsibilities to Factory security guard, then required auditor signed	To understanding of the standard of BRCGS food 8, and do not know that the auditor also needs to sign a security check record. To train on BRCGS food 8 of security guards and related standards.	Factory guards did not fully implement factory security procedure and did not required auditor sign in while auditor enter factory.	2021-02-02	Amelink Wang
5	4.4.1	The wall of package stage of number 1 workshop is with some rust.	We had convened according to BRCGS food 8 about plant facilities requirement, repaired the rusty wall and replace the stainless-steel plate. Conducted BRCGS training to Plant director and Sanitation manager.	To repair the rusty wall and replace the stainless-steel plate throughout the factory. The Sanitation manager will be required to regularly check the maintenance of the workshop environment, and conduct BRCGS training to plant director and Sanitation manager.	The number 1 workshop has been suspended for 3 months, it is long neglected and in disrepair. Didn't understand well about the BRCGS Food 8.	2021-02-02	Amelink Wang

Minor							
6	4.4.3	The water drainage of raw pre-process workshop was broken.	Convened according to BRCGS food 8, repaired the water drainage of raw pre-process.	The sanitation manager will be required to regularly check the maintenance of the workshop environment. To conduct BRCGS training to plant director and Sanitation manager.	The number 1 workshop has been suspended for 3 months, it is long neglected and in disrepair. Didn't understand well about the BRCGS Food 8.	2021-02-02	Amelink Wang
7	4.8.6	One cigar end was found on ground corner of pre-process workshop of number 1 workshop that near raw receiving yard.	Convened Clean up cigar end. Conducted the BRCGS food 8 and "Hygiene management procedures" training to cleaners.	To clean up the cigar end and check the non-smoking area of the whole plant. To divide smoking and non-smoking areas. To conduct the BRCGS food 8 and OPRP/PRP training to cleaners, the sanitation manager will require to check the sanitation status of the factory every day and make records.	The Number 1 workshop has been suspended for 3 months, we have to ask external installer to rectify the equipment. We didn't emphasis that this place is not allow to smoking.	2021-02-02	Amelink Wang

Minor							
8	4.9.1.1	One empty plastic bottle with cleaning chemical was found on corner of number 2 workshop near raw receiving yard, it was not stored in secured place.	We had convened clear up the empty plastic bottle. And conducted the BRCGS food 8 training to test engineer.	To clear up the empty plastic bottle. To conduct the BRCGS food V8 and "Control Procedures for Toxic and Hazardous Substances" XR-QP-27-2019 training to test engineer.	After preparing NACLO, the test engineer forgets to send the empty bottle to the poisonous room	2021-02-02	Amelink Wang
9	4.10.2.2	Sieve checking record reference number is XR-SSOP003 on December 2020 was provided for check, it was not with year information.	We had convened already add the year 2020 into sieve checking record. Conducted the BRCGS food V8 training and “Management Record Control Procedure" XR-QP-02-2019 training to Sanitation manager.	To add the year 2020 into sieve checking record. And will indicate the specific date, month and year in all documents. To conduct the BRCGS food V8 training and “Management Record Control Procedure" XR-QP-02-2019 to Sanitation manager.	The hygiene administrator wrote records, cut corners and omitted the year	2021-02-02	Amelink Wang

Comments on non-conformities
None

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit due date

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

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

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Food Safety and Quality Management System has been established and implemented; it was developed which base on GB14881, ISO9001, ISO22000 and BRCGS food issue 8, refers to XR-FSMS-2019.

Documented quality and food safety policy was clearly stated and signed by the GM.

- Continue meet customer request, make sure product safety.

Documented food safety culture strategic plan was established, it was communicated with management and relevant manager had an awareness of food safety culture, refers to XR-SP001. It was reviewed in management review. Review record on 2020-12-19 was provided. It will be reviewed in management review. A wide range of activities are incorporated into food safety culture development plan, some of which the company may already be conducting. For example:

• feedback mechanisms (e.g. staff concerns)

• training review and staff development

• teamwork (e.g. staff involvement in setting product safety objectives)

• activities to demonstrably maintain product safety standards, for example: cooperated with consultant company.

Food safety and quality objectives were in place and have been communicate to staff.

The general food safety and quality objectives were set by GM as following:

- Food quality and safety complaint ratio is less than 2%.
- Customer satisfied ratio is more than 85%.
- Product testing qualification rate by CIQ is more than 95%.

Progress against targets were reviewed and reported to senior management quarterly, all the targets were achieved from January to December 2020. Record with date on 2020-12-25 was provided.

Senior management review meeting was conducted annually, (last 2020-12-25), attended by GM and other relevant department manager, the agenda item and sufficient information has been provided, the meeting was demonstrated through a review of the inputs, minutes of the discussion of the items and agreed action plan, the action were followed up and completed within the set timescale.

Confidential reporting system was established and refer to XR-QP-58-2019, whistleblowing policy stated that concerns can be reported using email or telephone number, the content of which was collated and submitted to relevant manager.

Resources of financial and human to maintain the food safety system and produce safe food were sufficient.

Technical knowledge and information for food safety issues and legislative requirement were kept. These included products standard, Chinese legislative requirement, Non-CN (such as pesticide MRLs, EU No 1169/2011, directive 2000/13/EC and so on.

The site has availability of a copy of the BRCGS Food Safety Standard version 8, also it was aware of any changes to the Standard or protocol that were published on the BRCGS Global Standards website.

This audit was conducted in the audit due date.

The assistant of GM, most senior production and operations manager were attended the opening and closing meetings of the audits. Relevant department managers were available during the audit.

Non-conformities identified in previous BRCGS audits have been fully and effectively rectified and these were checked during the current audit.

BRCGS global standard logo was not misuse.

For Covid 19, the company established related control measures, such as check all personnel's temperature and the healthy code before entering factory, all staff and visitor must wear mask in any time, keep space when in canteen, washing hands and disinfecting in time.

1.2 Organisational structure, responsibilities and management authority

The organization chart was described in quality manual. The following departments were included: Admin, QA, Stock, Purchase and Production.
The QA Manager Mr. Lan JW had food production experience over 5 years.
The job responsibilities were established and included in food safety and quality manual.
The back up document for key position related with food safety was developed and updated, procedure XR-QP-43-2019.
Samples were taken for interview some staffs for their role or responsibility. E.g. for QA manager and Admin. manager.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
N/A	

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2 The Food Safety Plan – HACCP

HACCP Team leader was Management Representative-Mr. He CM, who was trained with HACCP principle (CQC) and experienced with HACCP and over 15 years' experience of frozen food. 10 members comprise the team belonging to different functions such as general manager, sale manager, office, production, maintenance, purchase and laboratory.

Internal auditor certificate was showed to auditor. For example: HACCP team member, Mrs. Xu ZZ attend ISO9001 and ISO22000 training course from CQM on June 12~16, 2017, certificate number is CQMFAC-2017-QF-41-36; Mr. Lan JW attend BRCGS training course from SGS on March 18~19, 2019, certificate number is SGS/CN/XMN-PT19011/016; Mrs. He SZ attend BRCGS training course from SGS on March 18~19, 2019, certificate number is SGS/CN/XMN-PT19011/015. HACCP internal auditor training of HACCP team member are retained.

Detail HACCP plans for different products: Frozen soya bean, frozen lychee: frozen bamboo shoot. XR-HACCP-2020-01~04, HACCP plan are set for non-allergen vegetable with blanching step; fruit without blanching step; allergen vegetable with blanching step; water chestnut.

HACCP plans were established and maintained based on the codex Alimentarius HACCP principles. PRP was established, procedure like pest control, cleaning procedure, staff training is showed to auditor.

- HACCP team maintains a reference library such as Codex, GB 14881, GB 27341, ISO22000, BRCGS, which is used as an information source. Adequate information appears to be available.

Frozen vegetable product descriptions were adequate, raw materials and package materials characters are also considered.

1. The composition is vegetable

2. Storage temp. -18C.

3. Complex plastic film, BOPP/LDPE,

4. Shelf life is within 24 months,

5. The key processing is blanching and freezing.

For each kind of frozen vegetables and fruit are suitable for general public, cooked for eating or supplied to other factory for further processing.

The following flow diagrams are in place, for non-allergen vegetable with blanching step, frozen green bean:

Raw material inspection (CCP1), dip by water, cutting, cleaning, blanching (CCP2), cleaning, dip water, frozen, semi-product packing, incoming storehouse, out storehouse, selection, weighing & filling & carton, metal detector (CCP3), incoming storehouse, dispatch.

For fruit without blanching step, frozen lychee:

Raw material inspection (CCP1), selection, cutting, cleaning, disinfection (CCP2), cleaning by clear water, dip water, frozen, semi-product packing, incoming storehouse, out storehouse, selection, weighing & filling & carton, metal detector (CCP3), incoming storehouse, dispatch,

The HACCP team had verified the accuracy of the flow diagrams by on-site audit in 2020 and records were maintained, for example, frozen non-allergen vegetable with blanching step record of 2020-06-01

A hazard matrix has been used to assess the hazard controls at each process step and the results were documented. Likely and severity are considering.

For example: Frozen soya bean

CCP1 raw material inspection is considered pesticide residue;

CCP2 blanching is concerned about micro growth and survives; temperature is 96~100 C, Time is 90~120 seconds.

CCP3 Metal detection is concerned about the foreign metal material, Fe 2.0mm, Non Fe: 2.0mm and SUS 3.0mm for small packing, Fe 2.5mm, Non Fe: 2.5mm and SUS 3.5mm for big packing. Metal Detectors checked hourly.

For example: Frozen lychees

CCP1 raw material inspection is considered pesticide residue;

CCP2 disinfection is concerned about micro growth and survives; chlorine is 20~50PPM, Time is more than 30~60 seconds.

CCP3 Metal detection is concerned about the foreign metal material, Fe 2.0mm, Non Fe: 2.0mm and SUS 3.0mm for small packing, Fe 2.5mm, Non Fe: 2.5mm and SUS 3.5mm for small packing. Metal Detectors checked hourly.

The HACCP food safety team validates each CCP yearly; CCP validated would be considered published date, expert advice, experimental date, regulatory guidelines, regulatory guidelines, mathematical modelling, or best practice.

HACCP validation was done on 2020-11-08 and HACCP verification was done on 2020-11-09. Related reports were provided to review.

PRP, HACCP system was verified annually and the CCPs were also been review annually.

Test report of raw fungus that test by laboratory comprehensive technology service center, Zhangzhou Customs house. Date on 2020-12-12, certificate of analysis number: 21202009027.

Test report of raw bamboo that test by laboratory comprehensive technology service center, Zhangzhou Customs house. Date on 2020-07-07, certificate of analysis number: 21202005623.

Test report of IQF black fungus that test by laboratory comprehensive technology service centre, Zhangzhou Customs house. Date on 2020-12-02, certificate of analysis number: 21202000651.

Test report of IQF lychee that test by laboratory comprehensive technology service centre, Zhangzhou Customs house. Date on 2020-12-21, certificate of analysis number: 21202016632.

Test report of IQF bamboo shoot that test by laboratory comprehensive technology service centre, Zhangzhou Customs house. Date on 2020-12-02, certificate of analysis number: 21202002251.

Last HACCP internal review was conducted on 2020-10-09, it is part of ISO22000 internal audit.

HACCP flow chart is not included sieve stage.

Minor CAR 1 on 2.5.1 was raised.

CCP1 record of green pea on 2020-07-11 was unfinished, it was with key-in mistakes.

Minor CAR 2 on 2.10.2 was raised.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
N/A	

3. Food safety and quality management system

3.1 Food safety and quality manual

The food safety and quality manual were established, refers to XR-FSMS-2019.

Policies, procedures and work instructions were in place. The manual included an overview of how the company's policies and procedures are organised. Availability of the food safety and quality manual to staff. Relevant members via internet link, hard copy obtained the manual. Clear procedures and work instructions for staff in Chinese languages.

3.2 Document Control

The company had in place a documentation control procedure XR-QP-2019-01 and records control procedure XR-QP-2019-01 Records regarding product requirements (24 months) are maintained for 3 years.

Documents control procedure has been established for document creation, revision, update, distribution and deletion. Document changes have to be coursed through a Document

The necessary procedures, WI and practices were collated in electronic quality manual.
Electronic documents are kept by each department.

3.3 Record completion and maintenance

The company had in place a documentation control procedure XR-QP-2018-01 and records control procedure XR-QP-2019-02 Records regarding product requirements (24 months) are maintained for 3 years.

Factory has provided record of January 2018 for review.
During audit, records observed were legible, unambiguous, and clearly detailed. Reason for changes was recorded in document action request.

3.4 Internal audits

Internal audit procedure is established and implemented, refers to XR-QP-04-2019

Internal audit was conducted according to the agreed plan. Scope and frequency is scheduled programme of internal audits throughout the year with a scope which covers the implementation of the HACCP programme, prerequisite programmes and procedures implemented to achieve this Standard. Total 12 audits are set for 2020. Factory also provided record of ISO22000 internal audit on 2020-10-09, BRCGS internal audit 2020-04-18, 2020-12-09 are sampled for check.

The audit standard is included company procedure, ISO22000 and BRCGS standard. All internal auditors are competent, internal auditor training records are retained on file. BRCGS training certificate of internal auditor was reviewed for Mr. Lan JW attend BRCGS training course from SGS on March 18~19, 2019, certificate number is SGS/CN/XMN-PT19011/016; Other internal audit team member also attended related training.

The internal audit records as following:

1). Internal audit plan.

2). Attendee signature record.

3). Internal audit check list.

4). Corrective action record.

5). Internal audit report.

The raised CARs were corrected and followed, and the records were retained. And the raised CAR was verified and closed by auditor within defined timescale. For Internal audit reports were identified conformity as well as non-conformity.

Monthly hygiene and GMP checking carried out and the records were kept on file. Last checking was conducted on 2020-12-24 of the fabric, hygiene and equipment's were checked and inspected, and inspectors were come from QA, Stock and Production.

The monthly hygiene and GMP checking record on 2020-12-24 was unfinished. It was not included year 2020.

Minor CAR 3 on 3.4.4 was raised.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Documented supplier approval procedure XR-QP-25-2019 based on risk assessment was in place, and the supplier review was carried out by production department, purchase department and QA department effectively. Three grades suppliers were defined according to the risk of affecting products and onsite audit or questionnaire investigation methods were defined.

The documented risk assessment of each raw materials including allergen contamination, foreign body risks, microbiological and chemical contamination and substitution were in place in the facility and it was updated and reviewed annually. The last assessment was conducted it was done on 2020-02-23 and the records were maintained.

All suppliers of the materials (raw fresh vegetable), ingredient (such as salt), packing products and the services must be approved at the first and then enter the system before they can be used. There was a qualified supplier list CR-03.

The up-to-date list of approved suppliers was in place, supplier audit was assessed for middle risk supplier and supplier questionnaires was assessed for low risk only.

Approved supplier policy is defined in documented Purchasing Control Procedure.

Fruit and vegetable supplier:

Water chestnut, Guangxi Jiabao Food Group Co., Ltd, CIQ register number: 450000SC00063.

Tara, Huaan County Gaochexiang Jitoucun Tara base, CIQ register number: 350623SC50606.

Soya bean, Pinghe County Xiufeng Vegetable base, CIQ register number: 350623SC50605.

Packing material

PE bag, Longhai Minghua Plastic Co., ltd, business number: 913506817640514227

Carton, Longhai Haoliyou Packing Co., Ltd, business license: 91350681MA346EEB6N.

No use of agents and brokers.

Exception purchase are defined in procedure.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Raw materials (including ingredients and primary packaging) from approved suppliers meet agreed specifications and do not compromise the safety, legality, quality or authenticity of products. Acceptance of raw materials including primary packaging were in place.
Checking the accuracy of the order to ensure that the correct materials, grades and quantities have been delivered, specific checks would be based on the risk assessment and the specification), and included the following: 1). specific raw material testing to ensure conformance with the specification before acceptance or use. 2). temperature checks if necessary. 3). visual inspection included cleanliness and damaged packaging. 4). the accuracy of printed packaging and labels. 5). sampling included the timing, method and responsibility. 6). management of non-conforming product. 7). certificates of analysis and certificates of conformance. 8). all legal requirement.

A list of raw materials (including primary packaging) and the requirements to be met for acceptance were available. Records of the raw material checks for each batch of material were maintained. Randomly checked records of August to November 2020 of rape flowers, cauliflower, broccoli, shiitake mushroom, lotus root, bamboo shoots, salt, oil and maltose. These were satisfaction. Communicating changes to goods receipt was defined. When this occurs, this requirement was designed to ensure that changes are communicated throughout the site so that only the relevant materials would be shipped into the site.
3.5.2.3. Not Applicable, as no live animal use raw materials.

3.5.3 Management of suppliers of services

The service supplier control procedure was established and included in the purchase control procedure. The service suppliers in the site were transportation, waste handling and Lab testing. The licenses and certificates were collected, and the contracts were signed.
E.g. the contract with pest control supplier- Zhangzhou Lijing Biological Technical Co., Ltd was signed on 2020-07-01. It was valid 3 years.
The contract with shipping supplier – Xiamen Kaiyun Logistic Co., Ltd was signed on 2018-05-30. It was valid 3 years.

3.5.4 Management of Out sourced processing

No outsourced processing and packing.

3.6 Specifications

The specification of raw material, ingredient, packing material and finished products were defined, and following specifications where reviewed-they are based on the local mandatory hygiene standards or client specification, detailed as below,

The specification of raw material, ingredient and packing material was defined; review frequency is once per one year. Detailed as below,

Raw vegetable materials including colour, taste, size, pesticide residue, for example, Raw tare specification was defined in HACCP plan.

Ingredient including microbe, packing condition, physical inspection.

Packing material including packing condition, size, chemical residue, microbiological, for example, plastic packing material specification GB 9683.

Finished frozen vegetable including size, colour, taste, microbiological, pesticide residue.

Specification will have been reviewed once per year, latest report on 2020-08-09 was provided.

3.7 Corrective and preventive actions

Documented corrective and preventive actions were established, refers to XR-QP16-2019

Management of corrective actions for handling failures in the food safety and quality system was defined.

All failures or non-conformities generated by the site (for example non-conforming product, internal audits, third-party audits or customer complaints) would be subject to corrective action.

Non-conformities with associated safety, legality or quality risks for investigating the cause of problems and ensuring that an adequate response would be taken.

Action would be undertaken as soon as possible after the detection of the non-conformity.

All corrective actions would be completed in a timely fashion.

When errors occur, such as non-conforming product, product recalls, or non-conformities raised at audits, the site would prevent recurrence of these errors using root cause analysis.

3.8 Control of non-conforming product

Documented control of non-conforming product was established, refers to XR-QP-12-2019

It was handled efficiently with any out-of-specification production that has the potential to affect product safety or quality. Management of non-conforming product was included the following: 1). All staff are aware of the need to report issues that may affect product safety, quality or legality, and to whom. 2). The system for labelling and identification of non-conforming product. 3). Segregation or isolation of non-conforming product. 4). Referral to the brand owner where required. 5). Details of staff responsibilities, including which staff are authorised and responsible for decisions relating to non-conforming products. 6). Records of all products placed on hold. 7). The ‘on hold’ procedure employed while an investigation was completed. 8). The effective safe disposal of product.

Checked the records of 2020, root analysis was analysed and CAs was adopted. QA manager was authorised for decision making of NC materials. Logs of products which were on hold and to undertake periodic physical checks of held stock to ensure that accidental release has not occurred. The summary of products was held, and actions taken were reviewed as part of the management review process.

3.9 Traceability

There was a product identification and traceability control procedure (XR-QP—35-2019). Traceability was mainly based on raw material batch and production batch number. Traceability system operates through paperwork enables trace of raw materials and packaging from supplier through processes to packing and despatch. Traceability test carried out once per year. Rework authorised by senior manager and clearly labelled through process chain.

The latest traceability test was done on 2020-06-20

Time: 09:05~11:00.

Raw batch: water chestnut, K01200108Y.
Raw quantity: 24116 kg
Finished product batch: 2020020
Finished product quantity: 22 tons
The mass balance was acceptable.
The spent time was within 4 hours.
Auditor random sampled product for traceability test.
Date: 2021-01-10
Time: 16:00~16:45.
Raw batch: bamboo shoot, H01190821Y
Raw receiving date: 2020-08-21
Raw quantity: 26611 kgs
Packing material batch: 20200821
Packing material quantity: 2310 pieces
Finished product batch: 2069/2020
Finished product quantity: 23 tons
Product packing date: 2020-10-25
The mass balance was acceptable.
All the relative records were available and acceptable.

3.10 Complaint-handling

Documented complaint-handling was established, refers to XR-QP17-2019.

It was handled effectively, and information used to reduce recurring complaint levels.

All complaints need to be captured to a specified location to ensure they are adequately assessed and investigated, and the results of this investigation recorded.

Investigation would be completed within a defined timeframe and feedback provided to the complainant.

Complaints would be handled by trained staff to ensure that a proactive system identifies the severity, and therefore the significance, of any complaints received. A rapid response and actions would be to the seriousness of the complaint.

Data on customer complaints would be analysed to identify trends. This data would be communicated to relevant staff and may include graphical displays on staff noticeboards or discussion at routine operations meetings. According factory claim, not complaint happen in 2020.

3.11 Management of incidents, product withdrawal and product recall

There was incident management control procedure, refers to XR-QP-22-2019. Power off, water off, infectious disease and other incidents were planned. The key contact list was available, including emergency incident handling team, supplier, customer, emergency services, raw material suppliers and third body certificates. The drill of power off was conducted on 2020-07-01.
The epidemic situation for COVID-19 pandemic management and control procedure was developed and implemented, the entrance guard checked the temperature and the travel map for every personal who will enter the factory.
Crisis plans included the following: 1) disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications, 2) events such as fire, flood or natural disaster, 3) malicious contamination or sabotage, 4) failure of, or attacks against, digital cyber-security.
Documented withdrawal and recall procedure were established. These was included the following: 1) Details of the recall management team members, including their roles, responsibilities and contact details, 2) Guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be

maintained, 3) An up-to-date list of key contacts, 4) A communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner, 5) Details of external agencies providing advice and support as necessary, 6) A plan to handle the logistics of product traceability, recovery or disposal of affected product and stock reconciliation, 7) A log of activities created as the event unfolds and real-time observations, which could, for example, be used in discussions with customers or regulatory authorities, 8) reference to the root cause analysis procedure, so that relevant preventive actions can be introduced.
No actual recall or withdrawal has occurred since previous BRCGS audit.
Tests of the withdrawal and recall procedures was established, XR-QP-33-2019. The withdrawal and recall were tested annually.
1). Last mock recall was conducted 2020-12-02
2). Test time from: 08:10~11:30.
3). Product name: green pea
4). Batch number of the finished product: 2020163
5). Quantity of finished products produced: 23 tons.
6). Production date: 2020-07-11, packing date: 2020-09-02.
7). Shipment date: 2020-09-15.
8). Recovery is 100% within 3.5 hour.
Notification of recalls to the certification body taken within 3 working days was defined.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
N/A	

4. Site standards

4.1 External standards

The building was located in a large wood pallet production area with green fields around the plant. No local activities that would risk product contamination. Factory was built in 2004. One new workshop was built in 2012 and old production workshop was re-constructed July 2020. Now building is in normal repair and normal maintained. Factory usedtwo workshops for production

Site plan was available to indicate neighbouring actives were included derelict buildings, rubbish dumps, wasteland and so on which could harbour pests, adjacent watercourses at risk of flooding, neighbouring companies and the nature of their business.

Maintenance of external areas were regularly maintained. Overgrown area and drainage in external areas were regularly maintained. External floor was suitably surfaced and maintained in general repair to mitigate the risk of contamination of the product.

The outside of buildings was monitored and maintained in a condition such that they do not present a risk of product contamination.

The site has the total area 9980 square meters, included production area 6000 square meters and storage area 3000 square meters. The site audited consists of 5 buildings, one main building which contained office and production workshop and packing material storage house. One building which contained reconstructed production workshop and finished cold storehouse.

There are building with one boiler room and one ammonia room, one sewage treatment pool, one building with a canteen and a dormitory building in site.

Separation of production area and dormitories area were defined.

4.2 Site security and food defence

Documented site security and food defence were established, refers to RX/FDPW-02.

Documented assessment of security and food defence was conducted annually. The threat assessment was considered both external threats and internal threats. Last done 2020-08-25.

The site provided the following countermeasures included electronic access control, fencing, gates, access-controlled automated turnstiles, security controls, closed circuit TV (CCTV), about 100 monitors, adequate external lighting, and alarm system. The system was reviewed annually, last done 2020-08-25.

Only authorised staff would have access to production and storage areas.

Restriction of access to areas where sensitive materials are stored (e.g. Warehouse, laboratories, maintenance areas or document storage areas) also were in place. These areas would be locked when not in use.

A visitor-reporting or monitoring procedure was established. When visitors or contractors come on site they would not be able to enter production areas without first reporting to site representatives, who will make them aware of site rules and issue them with protective clothing.

All staff were trained in the company security procedures and be part of the security arrangements. Last training was done 2020-04-09. Staff were encouraged to make enquiries on or report unknown persons in the facility.

During auditor visit factory, the security of gate did not check background information of auditor.

Minor CAR 4 on 4.2.3 was raised.

4.3 Layout, product flow and segregation

There is effective segregation in place to minimise the risk of product contamination. Working space and storage is sufficient to enable operations to be carried out properly under safe hygienic conditions. The

plan of the site which designates areas where product is at different levels of risk from contamination is defined in prerequisite programmes.
The layout map was defined the access points for personnel, access points for raw materials. Routes of movement for personnel, routes for the removal of waste, and so on.
There is effective segregation in place to minimise the risk of product contamination: raw material dealing workshop, freeze zone, semi-finished product inspection and packing zone, raw material warehouse, semi-finished frozen cold storage, finished product cold storage. Working space and storage is sufficient to enable operations to be carried out properly under safe hygienic conditions. The map of the site which designates areas where product is at different levels of risk from contamination is defined in prerequisite programmes. The map of people, work flow and waste are also provided for check.
The semi-finished product inspection and packing zone are separated and well managed. Product pre-process area are low risk area, cooking and packing area are high care area, only storehouse is considered as enclosed area. No high risk area.
The process flow from intake to dispatch is arranged well to minimise the risk of product contamination.
Physical barriers were in place to minimise the risk of the contamination of raw materials, packaging, finished products and different processes.
Segregation takes into account the flow of product, nature of materials, equipment.

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The design, construction and maintenance of the interior of the facility was supported effective cleaning and protected products from contamination.

The type of walls, floors, drainage, ceilings and overheads, suspended ceilings were suitable for the intended purpose, and regularly maintained, except some minor CARs were raised. Below are detail.

There are two workshop in site, both are repaired by maintenance deparment according business plan.

The floor of all workshop is made of cermet with special oil paint.

The walls in the production workshop are made of marble and stainless-steel plate.

The ceiling of all workshop is made of color steel plates.

4.4.6. Not Applicable, as no elevated walkways.

Use of windows for ventilation were adequately screened to prevent ingress of hazards such as pests or dust.

Both internal and external doors were regularly maintained in general condition.

Suitable and sufficient lighting were provided for correct operation of processes, inspection of product and effective cleaning. The lights are with cover.

Adequate ventilation and extraction were provided in product storage and processing environments to prevent condensation or excessive dust.

The wall of package stage of number 1 workshop are with some rust.

Minor CAR 5 on 4.4.1 was raised.

The water drainage of raw pre-process workshop was broken.

Minor CAR 6 on 4.4.3 was raised.

4.5 Utilities – water, ice, air and other gases

Documented utilities included water and steam were established.
The processing used water used on site is city water. The water was used for cleaning purpose and also used for as one ingredient in processing. It was test once per year by local government like laboratory of comprehensive Technology Service Center, Zhangzhou Customs House.
The latest test complies with China potable water standard GB5749-2006 was conduct on 2020-09-07 by laboratory of comprehensive technology service center, Zhangzhou customs house, total 38 test items covered, physical, radioactive, microbiological and chemical quality), report 21202008819, the water quality test was according to GB 5749. Report number: 21202008671.
The company had established the water self-control rule defined in SSOP and water distribution plan, the sampling points and frequency was be clearly defined in procedure. And the self-test items were chlorine residual and test daily for water and TPC, coliform test weekly for water and bi-weekly. Record (SSOP-001) on July 2020 was provided.
Only potable water was in use in the factory.
No air, gases and steam used directly in contact with or as an ingredient in products.

4.6 Equipment

Equipment's have been specified before purchase, tested and commissioned prior to use.

Equipment is positioned to facilitate cleaning and service. Evidence is available for the equipment in direct contact with food.

Most of its equipment and tools are stainless.

The machines were included two product line are located in the IQF workshop and maintained under routine maintenance systems. The machines were included four product line frying boilers are located in the VF workshop and maintained under routine maintenance systems. 2 IQF production lines, 3 sealing machine and 3 pieces of metal detector are located in the workshop and maintained under routine maintenance systems.

4.7 Maintenance

In-house engineers reported to maintenance supervisor who operated documented maintenance plan. Mr. Xie JL's electric certificate was showed to auditor, certificate number: 0813061032300019.

If temporary repairs were necessary, safety of product would be protected. Tools and parts into workshop were count and collected at beginning and finishing, relevant records were in place. The maintenance workshop was sited away from the workshop and kept in normal condition. Tools for high care are separated for other area.

Lubricant- High Temperature Food Machinery Grease used was food grade and its NSF H1 grade (NSF registered #147898).

No major breakdowns in last 12 months.

Maintenance workshop was a separated room which was far away from the processing area, on site found the maintenance workshop was kept in acceptable condition. Maintenance activity on high care area is follow the serration requirement of this area.

Documented hygiene inspection on start-up completed by production managers.

Maintenance workshops were kept clean and tidy, operated in a controlled manner, and was included in the housekeeping and cleaning procedures. Some maintenance engineer's certificates are provided: Mr. Fang YQ, FJE20151386000.

4.8 Staff facilities

Staff facilities were sufficient to accommodate the required number of personnel and were designed and operated to minimise the risk of product contamination. The facilities were maintained in good and clean condition.

Designated changing facilities were provided for all staff (including visitors and contractors).

The size of the facilities was adequate for the number of staffs working at the factory and at times of peak staff numbers. Changing facilities were located with direct access to the production, packing or storage areas. Storage of personal items to prevent staff from bringing personal items (e.g. keys, mobile phones or coins) into production and storage areas were enough. The facilitate was general practice and cleaning. A locker with a divider to separate work clothing from personal clothing was enough. The clean and dirty of work clothing was separated.

Dedicated hand-washing facilities were provided at entrances to production areas. The hand-washing facilities were equipped with the following: signs to prompt hand-washing, enough quantity of water at a suitable temperature, water taps with hands-free operation, liquid and air driers. Toilets were adequately segregated from production areas and must not open directly into production or packing areas. The hand-washing facilities provided in toilets were adequately. Smoking control policy was established. Smoking area was designated for staff to smoke. The positioned facilities for waste generated by persons smoking was provided. Staff food control policy was established. Storage facilities were provided for food brought on site, and in a hygienic manner. Designated outside area for staff to eat food was provided and control of waste was available. Catering facilities were provided on site, it was separated from workshop area, and no risk of a source of food poisoning or introduction of allergenic material to the production site.

One cigar end was found on ground corner of pre-process workshop of number 1 workshop that near raw receiving yard.

Minor CAR 7 on 4.8.6 was raised.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Documented chemical control was established, refers to SSOP.
Storage and handling of non-food chemicals were controlled.
An approved list of chemicals included cleaning chemicals, printing ink and other chemical which was used in the production environment.
The MSDS and specification of the chemicals were in place, with up-to-date and accurate.
These chemicals were suitable for use in food processing area, without strong-scented.
All chemicals were labelled. Chemical storage was restricted locked by authorised personnel.
Chemicals were used by trained personnel.
Where strongly scented or taint-forming materials have to be used, a risk assessment of the information were completed prior to commencement of the work.
One empty plastic bottle with cleaning chemical was found on corner of number 2 workshop near raw receiving yard, it was not stored in secured place.

Minor CAR 8 on 4.9.1.1 was raised.

4.9.2 Metal control

Documented metal control policy was established.

Sharp metal implements were controlled, this was included knives, cutting blades on equipment, needles and wires. Records of inspection for damage and the investigation of any lost items.

Snap-off blades were not permitted in any area of production or storage.

Staples, paper clips and similar metallic items were not used in open product area.

No staples used for ingredients and packaging materials on site.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Documented glass, brittle plastic, ceramics and similar materials was established, refers to XR-QP-30-2019.

Glass and other brittle materials used in open products were protected using adhesive plastic sheeting for breakage.

Documented handling glass and other brittle materials procedures were in place. There were included list or register of items, detailing their location, number, type and condition, routine inspections to verify the condition of these items, inspection was carried out based on risk assessment, inspection was done even when there is no change in the condition, also replacing bulbs in fly-killing devices.

Breakage procedure was in place, this was included training of staff in correct procedure, quarantining the products and production area, cleaning the site, inspection the site and authorising production to continue, identification of authorised staff to complete the work, recording the breakage incident and safely disposing of contaminate product.

Glass windows were protected using adhesive plastic sheeting for breakage.

The site was assessed where light bulbs and strip lights pose a risk to product, where full protection cannot be achieved, the monitoring procedure was defined.

4.9.4 Products packed into glass or other brittle containers

N/A. No glass jar or other brittle containers used for the packaging of final products.

4.9.5 Wood

Documented wood control was established, refers to XR-QP-33-2019.

The use of wood was not permitted in production areas except where it was a requirement of the process.

On site one wood pallet was observed in open product areas.

Where wood cannot be avoided, the procedure was included the use of wood covered by HACCP risk assessment, identify damaged items, reduce the potential for contamination, by regular checks to ensure it was in good condition and clean.

4.9.6 Other physical contaminants

Documented other physical contaminants was established, refers to SSOP.

Other physical contaminants included raw material packaging and control of pens.

Prior to packaged raw materials being taken into open product or processing areas, the packaging was visually checked for any potential sources of contamination and cleaned if necessary.

Pens used in open product areas were designed without small parts and detectable by foreign-body detection equipment.

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

Documented assessment of foreign-body was established, refers to SSOP.
The HACCP analysis was the starting point for implementing effective foreign-body control program.
Potential hazards and their sources were identified so that control procedures can be put in place to minimise the likelihood of product contamination. Last assessment of foreign-body was conducted on 2020-10-09.
The choice of location for foreign-body detection equipment was vital for its effective use.
System monitoring and corrective action, investigation of rejected material were defined in the procedure.
After risk assessment, the sieve and metal detection were used in frozen products.

4.10.2 Filters and sieves

The sieve are used for foreign material control. The size was documented, and details made easily available to staff using the equipment.

Routine inspection of sieve was monitored to ensure themselves size and grade, and were working effectively.

Documented procedure was included frequency of checks, responsibilities, and action to be taken when issues are identified.

Sieves were 1.0 X1.0 mm sieve, inspection records were in place.

Sieve checking record reference number is XR-SSOP003 on December 2020 was provided for check, it was not with year information.

Minor CAR 9 on 4.10.2.2 was raised.

4.10.3 Metal detectors and X-ray equipment

Metal detection equipment was installed in final product and it was identified as CCP, relevant information refers to Chapter II.

The metal detector was incorporated belt-stop-style metal detector rejection systems, and this will typically include the use of a container into which rejected product is placed, which is secured so that only authorised staff can remove the product.

Documented metal detector procedure for the operation (including effectiveness and sensitivity) and routine monitoring was defined. The frequency of testing was considered: start-up and finish of shifts, product changeovers, change in machine settings following downtime for repairs and regular checks throughout production.

Metal detector testing procedures were established. Fe 2.0mm, Non Fe: 2.0mm and SUS 3.0mm for small packing, Fe 2.5mm, Non Fe: 2.5mm and SUS 3.5mm for big packing. Metal Detectors checked hourly. Metal Detector is tested at begin, final and per hour.

It was identified as CCP, relevant information refers to Chapter II.

4.10.4 Magnets

N/A. No magnets used in the site.

4.10.5 Optical sorting equipment

4.10.5 Not Applicable, as no optical sorting equipment.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

Marked as NA due to no containers such as glass, jars, cans and other rigid containers used for products package.

4.11 Housekeeping and hygiene

The cleaning and disinfection plan is part of XR-PRP-2019 & XR-OPRP-2019 was available for review including responsible employee, cleaning items, cleaning frequency, cleaning method, cleaning criteria.

Cleaning and housekeeping was conducted with records describing the method, equipment and area.

The training record of cleaning and housekeeping was available.

Cleaning and disinfection chemicals were suitably labelled, secured in the designated area and used in accordance with chemical work instructions.

Visual check daily; swab test for food contact surface including TPC, coli form, weekly; air settlement micro-biological test in workshop monthly, checking records were available for review and the results were considered satisfactory.

Cleaning equipment for high care are is segregated from other area.

4.11.7 Cleaning in place (CIP)

4.11.7 Not Applicable, as no CIP system

4.11.8 Environmental monitoring

Documented environmental monitoring was established, refers to XR-QP-53-2019.
The aim of the environmental monitoring was to identify any potential risks in the production and open-product areas so that they can be appropriately managed and prevented from becoming the source of product contamination. The environmental monitoring was for pathogens or spoilage organisms.
These were based on risk and considered sampling protocol, identification of locations, frequency of tests, target organism, test methods and recording and evaluation of result. Test item included TPC and coliform which is test in factory.
Control limits were defined environmental monitoring, and the actions to be taken if these were exceeded or when there was a trend towards increasingly positive results. Factory provided 2020 record and it acceptable.

Review of the environmental monitoring program was conducted annually. The last done on 2020-12-03, refers to XR-PRP-005.

4.12 Waste

External and internal waste collection containers are managed well to minimise risk. The waste of the product disposed was conducted by local waste control private.

The waste water was treated. Disposal was well managed. Local private-Mr. Lin BL collect waste.

External waste collection container is clean in time.

Disposal record of September to December of 2020 was showed to auditor.

Requirements for the disposal of trademarked waste are defined within a contract with the waste disposal contractor and include the need for records of destruction or disposal to be maintained. They ensure that waste products do not re-enter the food supply chain once sent for disposal.

If unsafe products are transferred to a third party for destruction, the waste disposal and provide records which include the quantity of waste will be collected.

4.13 Management of surplus food and products for animal feed

Documented surplus customer-branded products were established.
The release of surplus product to alternative customers were taken place in accordance with the original brand owner's specific requirements.
Staff shops and donations of products to charity which do not meet specifications, this was with the prior consent of the brand owner. All products were still be safe, legal and fit for consumption.
4.13.3. Not Applicable, as no food for animal feed.

4.14 Pest management

Documented pest management was established.

Procedure where pest activity is identified by staff, actions were taken to ensure the risk of contamination of products, raw materials or packaging is avoided. This will include identifying and quarantining any potentially affected product so that it can be evaluated in accordance with the site's non-conforming product procedures. Action included steps to protect other products and inspection by the external pest management specialist.

The site was contracted external pest company Zhangzhou Lijing Biological Technical Co., Ltd, the contract was dated from 2020-07-01 to 2022-01-01. The frequency of inspections was determined by risk assessment, at least twice per month. The scope of the service was included rodent, fly, cockroach and mosquito.

The up-to date map of pest control devices was in place. EFKs were placed inside of workshop and warehouse, sticky rat devices were placed on site, bait stations were placed on outside workshop. These devices were appropriately designed, located and maintained to limit the potential for contamination of products. The sticky-board technology insect-killing devices installed correctly. Bulbs on insect-killing devices were changed annually or in accordance with the manufacturer's instructions.

The pest management inspections records of January 2020 ~ November 2020 were reviewed. All relevant recommendations made by the pest management specialist are carried out within a suitable timescale and

verified for effectiveness by the site. All relevant recommendations made by the external pest management specialist are carried out within a suitable timescale and verified for effectiveness by the site. The analysis of results of pest management inspections and trends were done quarterly, the last done 2020-12-31. It was included results from trapping and monitoring devices to identify problem areas and used as a basis for improving the pest management procedures. All member of staff on the site were trained to report of pest activity, the last done 2020-12-13.

Pest management survey was conducted annually by external pest company, but factory did not provided this report in time.

Major CAR 1 on 4.14.10 was provided.

4.15 Storage facilities

Documented storage facilities-controlled policy was established.
The facilities used for the storage of raw materials, packaging, in-process products and finished products were suitable for purpose. These do not pose a risk to products. Also, these included segregations of products where necessary to avoid cross-contamination, storing materials off the floor and away from walls, specific handling or stacking requirements to prevent product damage. Storage of packaging was stored separately from raw materials and finished product.
The traceability of packaging was retained, for example the coding was retained on the outer packs on return to storage. For Finished frozen product in frozen storehouse is control under -18 C, it has automatic recorder, the temperature check record is in place, and the alarm device of the cold storage is in good manner; it is also monitor and record by engineer once per two hours. For V-F finished product in ambient storehouse.
4.15.4. Not Applicable, as no in controlled atmosphere for storage.
4.15.5. Not Applicable, as no outside storage. Stock rotation in storage was operated on a FIFO basis, and in relation to the materials' manufacturing date and within shelf life.

4.16 Dispatch and transport

Documented dispatch and transport were established. Finish products transport subcontracted to Xiamen Minchengxing Logistic Company contract was showed to auditor.
The site was considered the potential risks to product safety and quality that may develop during dispatch and transport, the use of covered bays for vehicle loading or unloading, securing loads on pallets, inspection of loads prior to dispatch.
The vehicles or containers used for the transport of raw materials and the dispatch of products were controlled.
The inspection covered whether vehicles have the correct levels of cleanliness and are free from evidence of pests and strong odours and have been maintained to prevent product damage during transit. Records of inspections were maintained.
Raw material and packaging transport arranged by suppliers.
Vehicle temperature control policy was in place, the control of temperature under every load. Records can be achieved.
Vehicle maintenance and hygiene procedure was in place, included method of cleaning, the frequency of cleaning and records of cleaning.
Transport procedures were considered any restriction on the use of mixed loads, security requirement of product during transit and vehicle breakdown.
Third-party contractors were in place.
No loading process was observed during audit. Some loading supervision report are sampled: Container number: BMOU9230639, seal number: EMCDVS42595, it was loaded on 2020-04-24. Related records are provided.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.4.6	No elevated walkways are adjacent to or pass over production lines
4.9.4	No applicable.
4.10.4	No applicable.
4.10.5	No optical sorting
4.10.6	No applicable.
4.11.7	No CIP
4.13.2	Customer-branded products which do not meet specification were not sold to staff or passed on to charities or other organisations
4.13.3	No by-products and downgraded/surplus products intended for animal feed
4.15.4	No controlled atmosphere storage.
4.15.5	No outside storage

5. Product control

5.1 Product design/development

The R&D procedure was established, and the R&D activities were responsible by QA department. The R&D procedure provided clear guidelines on any restrictions to the scope of new product developments to control the introduction of hazards which would be unacceptable to the site or customers.

Shelf control Procedure XR-WI-2019-18 is established. Little new product variations other than change of raw materials since last BRCGS audit. Full development procedure documented.

Shelf life of product were taken reference to the legality, customer requirement and CN GB. Shelf-life trials was in place for frozen pea pod on January 1, 2018 to now, and checking items including organic items and microbiological.

The HACCP plan will be reviewed for update once a new product design and production and any change of recipe, package type or process technology must be approved by HACCP team leader.

5.2 Product labelling

Documented product labelling was established, refer to XR-QP-34-2019.
Legality of labels were in according with destination country standard.
On site audit assessed the site's processes for ensuring the accuracy of labelling and verified that the systems were operating correctly.
Label review was conducted whenever a change occurs to the product, its formulation or the ingredients to ensure it remains correct and up to date.
5.2.3. Not Applicable, as no claims made to satisfy a consumer group (no nutritional claims).
Where the label information was the responsibility of a customer or a nominated third party, the relevant initial information was provided.
5.2.5 Not Applicable, as no cooking instruction for these products.

5.3 Management of allergens

Documented allergens management was established, refers to XR-QP-32-2019
The allergen ingredient list is collected, and the allergen containing materials has been identified including soybean in produce line, and shrimp, wheat, egg, fish, and soybean in factory restaurant. Allergens based on FDA regulation and allergen of Australian Food and Grocery Council.
The documented risk assessment is carried out for handling raw materials, intermediate and finished products.
The allergen control of rework operations was established.
Documented procedure is established to prevent allergen cross-contamination, it also included the restriction on food brought onto site by staff, visitors, and contractors and for catering purposes.
In the raw material storage, different products were stored separated and marked clearly.
All relative ingredients are printed on the label of the product.
Risk assessment for allergen cross-contamination was conducted annually, the last was conducted 2020-06-18.
Allergen training was conducted on 2020-07-10, record was provided.
5.3.5~7 is not Applicable due to not such activity.

5.4 Product authenticity, claims and chain of custody

Documented product authenticity claims, and chain of custody was established.
It maintained up-to-date knowledge of relevant scientific and technical developments, emerging issues and known risks relating to the authenticity of the raw materials it purchases and the potential for food fraud in the supply chain.
A vulnerability assessment was a search for potential weaknesses in the supply chain in order to prevent the adulteration or substitution of raw materials before they arrived at the site. It was defined four levels of risk included very high, high, low and negligible grade.
Vulnerability assessment was conducted annually, last was done 2020-03-09 to identify those raw materials that was at particular risk of adulteration or substitution..
Output from the vulnerability assessment all materials ranked and scored as negligible grade, and no further action required as the material was extremely unlikely to be a target for food fraud.
5.4.4. Not Applicable, as no claims made on finished products which are dependent on a status of the raw material.

Kosher product was processed, and certificate is not yet issue. Facility Initial-Inspection Form from ORGANIZED KASHRUS LABORATORIES was provided, it was audited on 2020-11-30.
Halal was certificated by Halal Foundation Center Hong Kong, certificate number: 32563926376176, validate from 2020-06-08 to 2023-06-08.
Non-GMO declaration from the supplier and testing report was in place,
The documented mass balance test was done at least every 12 months, refer to 3.9.

5.5 Product packaging

Documented product packaging for the intended use and stored under condition to prevent contamination and minimise deterioration were established.

COC or COA was available for product packaging to confirm it complies with applicable food safety legislation and was suitable for its intended use.

For example: Test report of plastic bag from Longhai City Minghua Plastic packing Co., Ltd, it was test by Technology center of Xiamen Customs. Report number is 2120009060.

5.5.2. Not Applicable, as no contact liner use.

Documented obsolete packaging was established. Effective management of packaging materials, particularly those that were printed, can minimise the risk of these product recall incidents.

Physical segregation in storage areas, clear ‘do not use’ labelling was identified.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Laboratory management procedure was established, XR-HYS001.

The company had an in-house laboratory to undertake analyses and testing or contracted out to outside independent body to confirm product safety, legality and quality, using appropriate procedures, facilities and standards.

In-house laboratory conducted physical/chemical/microbiological tests, such as visual, net weight, aerobic plate count, coliforms and so on.

Approved outside companies conducted the tests of heavy metal and pathogenic bacteria (e.g. SGS, CTI, local government).

Testing and inspection schedule for finished product, raw material and packaging materials were established and implemented. Each batch of finished products were tested for organoleptic test, physical and chemical quality and microorganism level. Test reports were available for review and considered adequate. It was reviewed regulated to identified trend, frequency is quarterly.

Internal laboratory located separated from the production room and warehouse and did not pose a product safety risk.

There was 1 QC in the laboratory who had relevant education and experiences. Such as the QC named “Chen MR”, she had gained food test certificate and provided for check.

5.6.2 Laboratory testing

Pathogen testing is carried out externally, the lab facility was fully segregated from the production and storage area. Design of laboratory facility was considered to eliminate potential risks to product safety. Analyses critical to safety and legality by the external lab. The external lab was accredited by CMA and CNAS, and the accredited number was registered in the product testing report. The requirement of management of tests not critical to safety and legality was in place. Ring test and proficiency testing were reviewed. The review of laboratory results was recorded, noting the name of the person undertaking the review and a record of any actions taken.
5.7 Product release
Product release procedure is established and implemented. COA of final product was seen and results are compliance with the specification. Finished products approved by QA manager before the releasing and the QC report was adhered on product dispatch record.
5.8 Pet Food
N/A. No pet food was processed in the facility.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.1	Label design is the responsibility of client
5.2.2	Label design is the responsibility of client
5.2.3	No product is designed to enable a claim to be made to satisfy a consumer group
5.3.6	No that situation: nature of the production process is such that cross-contamination (cross-contact) from an allergen cannot be prevented
5.3.7	No allergen Claims
5.4.4	No applicable.
5.5.2	No contact liner used
5.8	No pet food

6. Process control

6.1 Control of operations

Process monitoring checks conducted include: blanching temperature and time checks (every hour), cooling temperature checks (every batch), metal detection sensitivity checks (every hour), scale tare checks (daily), weight control (as below), label checks (every batch), and date coding checks (every batch).
For example, CCP2 Blanching record: Date on 2020-01-08, time 0811~1713, 99.0C blanching time 60 seconds; audit on site.
Date on 2020-02-23, CCP3 Metal detection monitoring record, time 0830~1729, testing pieces of Fe, Non-Fe, Sus, the sensitivity of the metal detection is satisfaction.
The corrective action was documented for each process monitoring, the corrective action would be taken in the case of the equipment failure or deviation from specification and ensure the product in safety condition.

6.2 Labelling and pack control

Documented procedure was clearly established to ensure that products are packed in correct packaging and correctly label at the start, when changing batches of packaging, every batch and at the end of packing.
The visual checking was done before the production start-up, the checking items are as follows: status of food contract surface, the hygiene of operation environment, and the remaining issues from last production shift. All the materials and packaging were cleaned out before next shift or next products.
No on-line vision equipment's were used to checking product label and printing.
Documented checks of the production line are carried out before commencing production and following changes of product.
During on-site audit, packing and coding for frozen vegetable were verified. Staff was interviewed and could demonstrate the understanding for product packing control.

6.3 Quantity, weight, volume and number control

Documented quantity control – legislative requirements was established.
Average weights, minimum weight or count were determined by the company in conjunction with the requirements of the customer. Adequate records were kept.
6.3.2. Not Applicable, as no bulk quantities packed.
6.3.3. Not Applicable, as no online check weighers.

6.4 Calibration and control of measuring and monitoring devices

Documented calibration and control of measuring and monitoring devices was established, refers to XR-QP-08-2019.
Calibration device list was in place, these were detailed the location of each item of equipment, an identification code and calibration due date. Procedure was defined prevention from adjustment by unauthorised staff, protection from damage, deterioration or misuse.
Key equipment was calibrated annually by external company, others equipment was calibrated in house based on risk assessment.
Calibration method refer to recognised national or international standard.
Calibration certification and calibration records were in place.
Oven, factory number: 3589, calibration date: 2021-01-07, certificate number: (FJHJ)RG-JZ/21-00311.
Digital balance, factory number: 4105, calibration date: 2021-01-07, certificate number: (FJHJ)ZL-JD/21-00205.

Pressure gauge, calibration date: 2021-01-07, certificate number: (FJHJ)YL-JD/21-0086
All reference equipment (for example master thermometer, counterweight) were calibrated and traceable to a national or international standard.
The uncertainty of calibration was considered when equipment was used to assess critical limits.
Documented equipment outside specified limits was established, this details the action to be taken when equipment if found to be outside specified limits.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.2.4	No on-line vision equipment is used to check product labels and printing.
6.3.2	No bulk quantities packed.
6.3.3	No on line check weigher.

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

Employee training management procedure is developed.
Annual training provided to each staffs and current training plan was issued and covered all key positions.
The training plan for temporary staffs were also developed and including the WI, hygiene and rules of site.
Some training records were reviewed:
CCP training was conducted on 2020-02-16 and production staffs covered in the training.
Packing and label control training was conducted on 2020-07-04.
Allergen training was held annually for all staffs, and last training was conducted on 2020-05-22.
SSOP training was conducted on 2020-08-22.
The name of the trainee and confirmation of attendance, training objects, training provider, date and duration of the training were all recorded.
The examination and operation assessment methods were used for training result evaluation.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

Documented personal hygiene requirement was established and implemented defined in its GMP
Compliance with the requirement was daily checked and recorded. False nail was not allowed.
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 spraying and washing instruction with appropriate language/Chinese was sufficiency provided at every access point.
Staff who had cuts which affect to product safety was removed from processing area to perform another task. Blue plaster was used on site and test reports on 2019-11-13 were provided. Batch of blue plaster: 20190821.

Personal medicines were allowed to be kept in locker only.

7.3 Medical screening

There was documented healthy control procedure.
Staffs were made aware of their responsibilities regarding notification of illness/risks of food borne disease (per prescribed list of diseases).
Healthy certificate for sampled staffs were available, for example:

Mrs. Huang BM, checking date: 2020-09-14. Register number: 闽 (2020)5301-011703.

Mrs. Gan YR, checking date: 2020-09-14. Register number: 闽 (2020)5301-011687

Mrs. Su XL, checking date: 2020-09-14. Register number: 闽 (2020)5301-011726

Visitor will be asked to fill a health questionnaire while entered workshop. Sampled staffs knew how to response if got infection, disease or negative condition. Only full recovery then the staff could return to work.

7.4 Protective clothing: employees or visitors to production areas

Company provided 2 sets of clothing, white caps, upper clothing, mask and shoes for the operator Change Procedure: caps, coat, mask, boots and hands washed and sanitised. Visitor/contractor/temporary worker was also asked to follow the procedure. Protective clothing was removed on leaving the production areas. Gloves were changes once broken. Laundering of protective clothing was carried out by special in-house cleaning person. Protective clothing laundering process. QC was responsible for check the effectiveness of cleaning through swab test.

The gloves are blue disposable gloves and must be replaced when damaged or entering the workshop.

Clause 7.4.6 was marked as “N/A” due to no items of personal protective clothing that are not suitable for laundering. No items of personal protective clothing that are not suitable for laundering are provided.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
7.4.6	No applicable.

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones

8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones

The map of designation of production risk zones was established.
The final products stored frozen condition, the product support the growth of pathogens or the survival of pathogens which could subsequently grow use of the product unless stored frozen, products required fully cooking before consumption, but known alternative use includes ready to heat for Japan. So IQF room and packed room identified as high care.
8.1.2 Not Applicable, as no high-risk area.
This was effectively achieved through full physical segregation by means of walls which separate the high-care area from other factory areas.
Segregation was considered the flow of product, the nature of materials (including packaging), the equipment, the personnel, the disposal of waste, the flow of air, the air quality, and the provision of utilities (including drains).
8.1.4 Not Applicable, as no ambient high-care areas.

8.2 Building fabric in high-risk and high-care zones

The flow of drains was not present a risk of contamination of the high-care areas.
There was a plan of the drains for these areas which shows the direction of flow and location of any equipment fitted to prevent the back-up of waste water.
8.2.2 Not Applicable, as no high-risk areas.

8.3 Maintenance in high-risk and high-care zones

Maintenance in high-care areas do not result in microbiocidal contamination of this areas.
Tools in the areas were dedicated and not removed from the area.
Where specialist tools or equipment need to be brought into an area for a specific task, then mechanisms were in place to ensure that this does not result in contamination.
Equipment was moved from place to place to be used in different areas. Where this occurs, the site was taken steps to ensure that re-introduction to those areas does not compromise the conditions.
Records of acceptance back into the area were maintained.
Systems ensure that the use or transportation of small portable equipment, such as hand-held devices, cannot become the source of pathogen contamination.

8.4 Staff facilities for high-risk and high-care zones

High-care area changing facilities were sufficient provided.
The changing facilities were incorporated the following:
1). The clear instructions for the order of changing into and dedicated protective clothes.
2). The protective clothing for high care was visually distinct from that worn in other areas and which not be worn outside the area.
3). The hand-washing routine during the changing procedure to prevent contamination of the clean clothing.
4). Provision and use of hand-washing and disinfection facilities.
5). Dedicated site footwear that was provided by the site and which was not worn outside the factory.
6). An effective control of footwear to prevent the introduction of pathogens into the area, a programme of environmental monitoring was used to assess the effectiveness of footwear controls.

8.5 Housekeeping and hygiene in the high-risk high-care zones
Documented cleaning procedures in high-care was established. It was considered the responsibility for cleaning, item to be cleaned, frequency of cleaning, method of cleaning, cleaning chemicals and concentrations, cleaning materials to be used, cleaning records and responsibility for verification. The frequency and methods of cleaning was based on risk, and the procedures were implemented to ensure that appropriate standards of cleaning were achieved. Limits of acceptable and unacceptable cleaning performance were defined for environmental cleaning (i.e. the factory environment) in high-care areas. Acceptable limits may be based on visual inspection, ATP monitoring or specific analysis such as microbiological testing. Equipment used for cleaning high-care were dedicated for use in that area, and therefore retained in the area.
8.6 Waste/Waste disposal in high risk, high care zones
Waste disposal procedure was established and implemented. The waste from high risk area were stored in designated area and specific waste bins which only used in this area, and removed every shift by designated staffs. The waste storage area was clean and external waste collection containers were managed in normal to minimise risk.
8.7 Protective clothing in the high-risk high-care zones
Protective clothing for high care was cleaned by laundering in-house. In-house laundering carried out on the company premises was controlled. It was considered the following: 1). Dirty and clean clothing is adequately segregated to ensure that recently laundered items are not re-contaminated. 2). The protective clothing is effectively cleaned (e.g. by the completion of microbiological validation and verification tests). 3). Clothing is commercially sterile following the washing and drying process. 4). Cleaned clothes are protected from contamination (e.g. through the use of covers or bags) until delivered to the appropriate area of the site. The company assessed and monitored the laundry (e.g. through visual inspection, regular audits and a complaints procedure) to ensure that the processes in place for the cleaning of high-care clothing were maintained and kept consistently under control. The audits of the laundry can be completed directly. The frequency of the audits was based on risk, the audits done annually. Protective clothing worn in high-care areas were changed at least daily and hairnets changed daily or whenever removed (e.g. when leaving the area).

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

8.1.2	No high risk area.
8.1.4	No ambient high care area.

9 - Traded Products

9.1 Approval and performance monitoring of manufacturers/packers of traded food products

N/A

9.2 Specifications

N/A

9.3 Product inspection and laboratory testing

N/A

9.4 Product legality

N/A

9.5 Traceability

N/A

Module 11: Meat supply chain assurance

Scope	Click or tap here to enter text.

11.1 Traceability

Click or tap here to enter text.

11.2 Approval of meat supply chain

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11.3 Raw material receipt and inspection

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11.4 Management of cross-contamination between species
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11.5 Product testing
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11.6 Training
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Module 12: AOECS Gluten-free Foods

Scope	Click or tap here to enter text.
12.1 Senior management	
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12.2 Management of suppliers of raw materials and packaging	
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12.3 Outsourced production	
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12.4 Specifications	
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12.5 Management of gluten cross-contamination	

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12.6 Management of incidents, product withdrawal and product recall
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12.7 Labelling
Click or tap here to enter text.
12.8 Product inspection and laboratory testing
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Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018			
Clause	Module item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant.		

	Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to		

	the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine “hazards requiring a preventive control” (i.e., significant hazards).		
13.1.8	Establish one or more preventive control(s) for each identified “hazard requiring a preventive control” (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and		

	responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		
13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRCGS section 2.10.		
13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRCGS sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).		
13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon		

	changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method		

	• Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
13.1.16	Devices used to verify preventive controls must be calibrated.		
13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		

13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
13.1.21	Where a hazard requiring a supply-chain-		

	applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.		
13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use		

	as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation		

	strategies at actionable process steps.		
13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum): • Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of		

	an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.		
13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.		
13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.		
13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The		

	procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		
13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense		

	plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities		
13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		
13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review		

	• Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		
13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe		

	cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier.		

	Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating		

	temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper		
13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier		
13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.		
13.4.9	The recordkeeping policy shall ensure all sanitary design		

	requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.		
13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job		
13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest		

	containers or equipment		
13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.		
13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.		
13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.		
13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable		

	hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.		
13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.		
13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.		
13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or		

	food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.		
13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), ‘‘Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007),’’ December, 2009 or equivalent method.		
13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water		

	used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.		
13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.		
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.		
13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes		

	used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: • Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and		

	testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).		
13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive surfaces and the surrounding area to determine the extent of contamination • Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate		

	• Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		