Audit Report Global Standard Food Safety Issue 9

1. Audit Summary			
Company name	Neimenggu Fufeng Biotechnologies Co., Ltd.	Site code	5686713
Site name	Neimenggu Fufeng Biotechnologies Co., Ltd.		
Scope of audit	Production (fermentation, neutralization, crystallization and drying) of Monosodium Glutamate (MSG) and production (fermentation, extraction and drying) of Xanthan Gum, packed into plastic bags.		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit start date	2024-04-15	Audit finish date	2024-04-18
Re-audit due date	2025-05-21	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 programme	Unannounced – mandatory 1 in 3 years
Previous audit grade	A		Previous audit date	2023-05-04	
Certificate issue date	2024-05-24		Certificate expiry date	2025-07-02	
Number of non-conformities			Fundamental	0	
			Critical	0	
			Major	0	

2. Audit Results

	Minor	13

3. Company Details

Site address	Jing Er Road, Jinchuan District Adm. Committee, Industrial Economic Development Zone, Hohhot City, Inner Mongolia Autonomous Region, 010070		
Country	P. R. China	Site telephone number	008604715661210
Commercial representative name	Mr. Li Xingchao	Email	nmgffpgb@163.com
Technical representative name	Mr. Meng Lingjie	Email	cherry@fufeng-group.com

4. Company Profile

Plant size (metres square)	>25K sq.m s	No. of employees	501-1500	No. of HACCP plans	1-3

Shift pattern	3 shifts x 8 hours (00:00-08:00-16:00-24:00) x 7 days per week	
Seasonal site	No	
Seasonal opening times (Start/end date)	Click or tap to enter a date.	Click or tap to enter a date.
Other certificates held	ISO9001, ISO22000, FSSC22000, FAMI-QS, HACCP, ISO14001, ISO45001, ISO5001, IP, Halal and Kosher	
Outsourced processes	No	
Outsourced process description	None	
Regions exported to	Asia North America Europe Oceania	

4. Company Profile	
	South America Africa
Company registration number	1500/17009
Major changes since last BRCGS audit	QA manager had changed from to Meng LJ. Replaced a starch separator. Currently undergoing renovation of the alcohol distillation tower.

Company Description

The factory was established in 2006 and located at Jing Er Road, Jinchuan District Adm. Committee, Industrial Economic Development Zone, Hohhot City, Inner Mongolia Autonomous Region, 010070 P.R. China.

The site covered 3000mu, of which the building covered 35000m2 and focus on MSG and xanthan gum products. In the site, one xanthan gum process line with capacity 45000 tons and produced 30000 tons in 2023. Two MSG process lines with 600000 tons and produced 400000 tons in 2023. Staffs number was 510. About 70% xanthan gum and 40% MSG were exported to other countries. The mainly clients were trades and manufacturers.

Some finished xanthan gums were used for petrol industrial. It was manufactured in a separated workshop.

No redundant, off-site warehousing on site. The key equipment included ferment tank, centrifuge, frame filter, evaporator, packer, sieves, metal detector.

The staffs divided to 4 shifts and operated with 3 shifts (00:00-08:00-16:00-24:00).

The factory was granted the ISO 9001, ISO 22000, FSSC 22000, FAMI-QS, HACCP, ISO 14001, ISO 45001, ISO 5001, IP, Halal and Kosher certification that are valid.

The Customs registration No. 1500/17009, FDA registration No. 12128489546.

This audit was unannounced 1 in 3 and met the BRCGS audit requirements.

5. Product Characteristics	
Product categories	15 - Dried food and ingredients Category Category
Finished product safety rationale	Monosodium glutamate (MSG): pH 6.7~7.5, moisture less than 0.5%, Aw lower than 0.7, crystallized at 75-80℃ about 10h, shelf life was at least 3 years. xanthan gum: drying at 60℃ to the moisture less than 15%, Aw lower than 0.3, shelf life was 2 years. ambient stable

5. Product Characteristics					
High care	No	High risk	No	Ambient high care	No

Justification for area	Low Aw and not support pathogen grow, ambient stable. Low risk area: The finish product does not support pathogen growth even at ambient temperature. Enclosed area: warehouse for finished product
Allergens handled on site	Sulphur dioxide and Sulphites Soya Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	IP
Product recalls in last 12 months	No
Products in production at the time of the audit	MSG and xanthan gum.

6. Audit Duration Details			
Total audit duration	30 man hours	Duration of production facility inspection	15 man hours
Reasons for deviation from typical or expected audit duration	No deviation		
Combined audits	None		
Next audit type selected	Announced		

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

Meng Ling Jie	Management representative /QA Manager	On-site			On-site
Li Xinchao	QA supervisor	On-site	On-site	On-site	On-site
Xu Huixia	MSG dept. supervisor	On-site	On-site	On-site	On-site
Han Yujie	Xanthan gum dept. supervisor	On-site	On-site	On-site	On-site
Liu Qianyu	Supply dept.	On-site	On-site	On-site	
Bai bin	Supply dept.	On-site	On-site	On-site	
Li Baofeng	QA	On-site	On-site	On-site	On-site
Zhang Yan	QA	On-site	On-site	On-site	On-site

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/Unannounced	Pass/Fail
2021-09-23	FSSC22000 5.0	Unannounced	pass
2021-06-19	BRCGS food issue 8	Announced	pass
2022-09-22	FSSC22000 5.1	Announced	pass
2022-05-21	BRCGS food issue 8	Announced	pass
2023-09-28	FSSC22000 5.1	Announced	pass
2023-05-04	BRCGS Food Issue 9	Announced	Pass

Document control			
CB Report number	AF/BJS245819		
Template name	F908 Food Safety Audit Report Template		
Standard issue	9	*Template issue date*	2022-12-16
Directory allocation	Food	*Version*	1.1

Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements			
Clause	Detail	Critical or Major	Re-audit date

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1.1.12	In this audit, non-conformities were still issued under clauses 4.4.1, 4.4.7, and 4.11.1, although the previous non-conformities were closed.	Strengthen attention to infrastructure in daily work activities such as team meetings and GMP inspections, and guide employees to pay attention to infrastructure.	Conduct periodic GMP training to enhance employee awareness.	Employees feel that the damage to local facilities does not have a significant impact, and gradually forget the relevant requirements in their daily work, with insufficient attention paid to the condition of equipment and facilities.	2024-05-09	Catherine Li
3.3.1	The usage record of MSG export packaging materials on 2024-04-14 were not recorded.	The batch usage record of export packaging bags on April 14th has been completed.	1.Provide training on document and record filling requirements for personnel. 2.Shift leaders check the record filling each shift, and the process specialist verifies and promptly rectifies if any problems found.	The work records of the person in charge of recording were not filled out in a timely manner, and the supervision of shift leader was not sufficient, resulting in missing records.	2024-05-09	Catherine Li
3.5.1.2	The supplier survey questionnaire of NMGXMT did not cover topics such as HACCP, GMP, food defence and food fraud.	the supplier survey questionnaire has been updated to cover topics such as HACCP, GMP, food protection, and food fraud.	1.Send the updated supplier survey questionnaire to the supplier for filling out. 2.Every year, the supply department personnel are responsible for	The system responsible personnel have insufficient knowledge mastery, and the supplier survey questionnaire has	2024-05-09	Catherine Li

Minor						
			collecting survey questionnaires, which are confirmed by the quality control department, supply department, and user department.	not been updated in a timely manner.		
3.5.1.4	The supplier of filtration fabric, TTJJ was not included in the approved supplier list, although the supplier's qualifications and approval evidence had been provided.	The list of qualified suppliers has been revised and the filter cloth supplier has been added to the list of qualified suppliers.	1.Require timely updating of the qualified supplier list after supplier changes. 2.Review the list of qualified suppliers every month and update them promptly if any omissions or deficiencies are found.	Negligence in personnel work and failure to update the qualified supplier list in a timely manner.	2024-05-09	Catherine Li
3.9.3	Traceability practice from raw materials to finished products for xanthan gum was conducted on 2023-07-15. The batch of Soybean（batch no. 20221219-01）were received in total of 73780 kg, but the traceability record showed that only 1300 kg were traced.	The soybeans batch no. 20221219-01, quantity 73780kg have been re traced.	1.Provide training on personnel identification and traceability knowledge. 2.After each traceability test, the workshop quality manager confirms the traceability content.	Inadequate understanding of identification and traceability knowledge by personnel.	2024-05-09	Catherine Li

Minor						
4.2.1	The door connected to the outside world next to the feeding port of the MSG fermentation process was not closed, and the feeding port was not locked when not in use.	The feeding port has been locked and it is required to close the door when the equipment opens.	1.Provide training on food safety protection requirements for feeding personnel. 2.Through the pre shift meeting, the feeding personnel are required to close the door when feeding, and the feeding port must be locked after each feeding. 3.Shift leader confirmed the completeness of the lock each shift.	Personnel have insufficient requirements for food safety protection.	2024-05-09	Catherine Li
4.4.1	During on-site audit, it was found that some ceramic tiles on the floors of the xanthan gum extraction workshop were damaged	The damaged tiles on the floors of the extraction workshop have been replaced.	1.Provide training on equipment and facility maintenance requirements for personnel and clarify maintenance requirements. 2.Every day, the process specialist confirms the condition of equipment and facilities, and promptly corrects if any problems found.	Failure to maintain facilities in a timely manner leading to damaged walls and floors.	2024-05-09	Catherine Li
4.4.2	During on-site audit, it was found that some ceramic tiles on the	The damaged tiles on the walls of the extraction	1.Provide training on equipment and facility maintenance	Failure to maintain facilities in a timely manner leading to	2024-05-09	Catherine Li

Minor						
	walls of the xanthan gum extraction workshop were damaged.	workshop have been replaced.	requirements for personnel and clarify maintenance requirements. 2.Every day, the process specialist confirms the condition of equipment and facilities, and promptly corrects if any problems found.	damaged walls and floors.		
4.4.4	There are signs of water leakage on the second-floor ceiling of the MSG drying workshop.。	1、 1. The leakage point has been sealed off; 2、 2. The wall has been repaired.	1.Provide training on equipment and facility maintenance for personnel. 2.Every week, the system specialist inspects the equipment and facilities, and promptly rectifies any problems found.	Inadequate maintenance of infrastructure leading to roof leakage	2024-05-09	Catherine Li
4.4.7	The insect proof net of the ventilation fan near the yeast feeding area on the third floor of the xanthan gum workshop was damaged.	The insect proof mesh of the damaged ventilation fan in the yeast feeding area on the third floor has been replaced.	1.Provide training on equipment and facility maintenance for personnel. 2.Every day, the process specialist confirms the condition of the facilities and promptly corrects if any problems found.	Inadequate maintenance of infrastructure, resulting in failure to replace damaged equipment in a timely manner.	2024-05-09	Catherine Li

Minor						
4.9.6.3	During the on-site audit, it was found that the tray of semi-finished xanthan gum in the temporary storage room was damaged. This semi-finished product will be feeding in the mixing process in the future, and there was a risk of foreign objects.	All pallets for semi-finished xanthan gum have been replaced with new ones.	1.Provide training on equipment and facility maintenance for personnel. 2.Every day, the process specialist confirms the condition of the facilities and promptly corrects any problems found.	Inadequate maintenance of infrastructure, resulting in failure to replace damaged equipment in a timely manner; Insufficient food safety awareness among personnel.	2024-05-09	Catherine Li
4.11.1	Splashing material was found on the baffle above the opening of the extraction tank, which was not cleaned thoroughly.	The material on the baffle above the extraction tank has been cleaned.	1.Provide training on equipment cleaning, disinfection, and hygiene requirements for personnel. 2. After each production, the on-duty team leader shall verify the cleanliness status.	Inadequate implementation of personnel and equipment cleaning, disinfection, and hygiene requirements, failure to clean in a timely manner.	2024-05-09	Catherine Li
4.11.2	The pre-treatment process of MSG requires the use of hot water above 90 ℃ for disinfection, but the water temperature was not recorded in the cleaning and	Water temperature has been added in the cleaning and disinfection record.	1.Provide training on record filling requirements for relevant personnel, and strictly follow the prescribed requirements to write records.	The insulation tank is equipped with a continuous temperature detector to measure the water temperature, so it is not reflected in the record.	2024-05-09	Catherine Li

Minor						
	disinfection process on 2024-01.		2.Each shift is checked by the team leader and spot checked by the process specialist.			

Comments on non-conformities
None

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Lead auditor		
Auditor number	**First name**	**Second name**
25770	Catherine	Li

Audit team				Attendance (YYYY/MM/DD, 24hr: MM)			Presence	
First name	Second name	Auditor number	Role	Audit Date	Start time	End time	Remote or physical	Professional recognition number
Catherine	Li	25770	Lead Auditor	2024-04-15	09:00	17:30	Physical	
Catherine	Li	25770	Lead Auditor	2024-04-16	08:00	18:00	Physical	
Catherine	Li	25770	Lead Auditor	2024-04-17	08:00	18:00	Physical	
Catherine	Li	25770	Lead Auditor	2024-04-18	08:00	11:00	Physical	

1. Senior management commitment

Documented Policy

Documented policy issued in BRCGS manual NF/PG-GL-2023-01-01 and authorized by GM on 2023-11-10. Policy given the commitment to produce safe, legal and authentic products, Policy communicated through meeting, training course and bulletin board displayed.

Policy：Improve quality reputation, ensure food safety, and ensure the satisfaction of relevant parties.

Product safety and quality culture plan

By site communication with management person and worker, review detail actions of the food safety and quality culture, the food quality and safety culture level were total satisfactory. Documented food safety and quality culture plan was established, detail action scale time also been defined. Detail action such as training, communication, feedback and effective evaluation were complete. last review of food safety and quality culture had been happened on 2023-12-06 on management review meeting, the GM Mr. Zhao had involved the discuss of food safety and quality culture.

Food safety and legality objectives

The Food Safety Objectives was issued, it was precise, measurable and coherent with this quality policy, and divided to each department, detailed as following:

No quality, food safety accident.

Objectives for relevant dept. were monitored and report to senior management monthly, review of results from 2022-12 to 2023-11 objectives monitoring on 2023-12-06, all objectives had been attached, site had concerned the Outline key results or significant trends and used for objective improvement.

Management review

Internal audit and Management review procedure NF/PG-CX-2023-01-05 had been established to ensure the management review process; The company planed and implemented the management review annual and last on 2023-12-06, held by GM Zhao Lankun, all senior management had attendee management review meeting, evaluation covered all requirement of Global Standard for Food Safety, management review result showed the food safety system was effective, the report had and delivery to relevant department, total 6 documented CAP had been released.

Regular meetings

The company had a monthly meeting programme, the meeting is about food safety, authenticity, legality and quality issues, last monthly meeting records on 2024-04-05 and 2024-03-05 were available, the meeting result and delivery to relevant by meeting records and defined the corrective actions requirement.

Confidential reporting system

The factory has established a system of confidentiality reporting. the way of confidentiality reporting included mailbox and telephone. Confidentiality reporting information had been treatment by special person.

External scientific, practice, risk and legislation information informed.

Quality department in charge of collecting and updating the regulation and get information from the internet, clients and national government.

Current standard and change

Site have the current electric version of issue 9 BRCGS standards with Chinese version, Site was aware of any changes to the Standard or protocol by review of BRCGS Global Standards website.

Certification maintained

The Re-certification due date was to 2024-05-21 and the actual audit happened on 2024-04-15 to 2024-04-18, the certification maintained well.

Previous non-conformities

Total 9 Minor NCs released at previous audit had been corrected well, the corrective action and based on root causes analysis. But in this audit, non-conformities were still issued under clauses 4.4.1, 4.4.7 and 4.11.1.

Others

Adequate resources for BRCGS development and implementation provided by senior management.

QA manager Mr. Meng and department manager attend the opening and closing meeting. Due to this audit was an unannounced audit, the GM was on a business trip and not present at the factory.

The factory was registered in China customs with No. 150017009 (MSG). In USA FDA, the register No. 12128489546.

Organisational structure, responsibilities, and management authority

A current comprehensive organisational structure indicating job functions and lines of communication has been established and was demonstrated by an organogram. The senior management team is detailed in an organisation chart and includes General Manager, logistics manager, Production Managers, Quality Assurance Manager, Engineer Manager, Supply Manager and Office Manager. Trade was managed by the head office in Qingdao. The responsibilities for the management of activities were clearly allocated.

Replace personal management control procedure was in place. The sampled production staffs knew their responsibilities.

Job responsibilities of each department were specified, including managers and supervisors as well as workers, by interview staff were aware of their responsibilities.

No external product safety expertise used in the development or maintenance of food safety systems.

Reporting food safety issues

In the position responsibility, the reporting requirement for food safety issues had been defined, Once founding of food safety risks, concerns or non-conforming product issues, the relevant person shall report to designated person.

1 minor CAR was raised here under the clause 1.1.12.
Detail, please see the CAR FORM.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
1.2.4	No external product safety expertise used in the development or maintenance of food safety systems

2. The Food Safety Plan – HACCP

HACCP Team

HACCP team was established, the team members were from each department including production, quality, laboratory, purchase, sales, engineering and logistics. Vice-GM Mr. Zhao CX was appointed as HACCP team leader, Leader has the following HACCP training and more than 10 years working experience on food factory whole management.

All team members had got HACCP principal training, such as Li XZ and Xu HX got BRCGS Site Training by SGS course on 2023-05-09. Internal HACCP training was conducted for HACCP team member by trained personnel on 2024-02-26.

Site had established the HACCP plan for MSG NF/PG-JH-2023-01-12 and HACCP plan for xanthan gum NF/PG-JH-2023-01-10 based on HACCP principle.

PRPs

Documented PRPs were developed and implemented, all control measures and monitoring procedures for the PRP were clearly documented and included within the development and reviews of the HACCP, such as pest control, cleaning and disinfecting, personal hygiene, maintenance, training purchasing, transportation and allergen control.

PRPs had been reviewed during management review and HACCP plan review.

Scope of HACCP, Production description and intended using

MSG description:
Raw material: corn
Physical and chemical character: assay≥99.00%, moisture≤0.5%, pH 6.7-7.5, specific rotation +24.9~+25.3, As≤0.05mg/kg, Pb≤1mg/kg
Shelf life: 3 years in ambient
Store condition: ambient
Intended use: food ingredient for further process

Xanthan gum description:
Raw material: corn and soybean
Physical and chemical character: moisture≤15%, Pb≤2mg/kg, salmonella: ND
Shelf life: 24 months in ambient
Store condition: ambient
Intended use: food additive
By site verification the audit scope was accurately reflects all products on site.

Process flow diagram

The diagram of all products was similar as following:

MSG flow diagrams:

Corn received---store---soak---crushed--- centrifugation ---liquidation--- saccharification ---filtration---sterilization---fermentation---concentration---neutralization and discolouration---panel filtering---active carbon pole filtration---iron exchange---bag filtering--- concentrate to crystallization---centrifuge---magnetic sorting---fluid bed drying--sieving---metal detecting ---magnetic bar selecting---packing----metal detecting/CCP---finished product inspection---stored---transportation.

Xanthan gum flow diagrams:

Corn received---store---soak---broken---separation--- sterilization---fermentation---extraction--- extrusion---drying--- magnetic selecting---milling---sieving--- magnetic selecting---blending---sieving---packing----metal detecting/CCP---stored---transportation.

The flow diagram of MSG was verified on 2024-03-15 and Xanthan gum on 2023-07-16 by the HACCP team members.

The information used for hazard analysis was collected, maintained and updated in place. Include regulation of food safety, relevant code of practice, recognised.

By site verification the flow diagram basically accurately reflects the production processes.

Hazard analysis

All hazards (Microbiological, chemical, physical, allergen, adulteration) that was contaminated from or intake form raw material, water, processing and work conditional, reworking and waste control were identified and analysed based on risk assessment. Significant hazards have been identification, relevant control methods were established. During the hazard analysis, the likely occurrence of hazard and severity of the effects considered fully. Hazard degree=Likelihood (1-5) * severity (1-5). Score 15-25 was identified as High risk and controlled by CCP.

Critical Control Points, limits and controls

CCPs were identified as below,

CCP1 for MSG: metal detecor, control foreign matter.

- CL: 2# workshop: Fe φ2.0 mm, Non-Feφ2.5 mm, SUSφ2.5 mm; 3# workshop: Fe φ1.5 mm, Non-Feφ2.0 mm, SUSφ2.0 mm.
- Monitoring action: metal detection verification with standard items by site worker at start production, end of production, and every two hours during production.
- Corrective action: impacted products segregated and evaluation; pass the metal detector again and find out the metal or repair the metal detector. if the detected product was more than 1%, total batch of the products were separated, evaluation the contamination. If necessary, the product will down grade.

CCP2 for Xanthan gum: metal detection, control foreign matter

- CL: Fe φ1.5 mm, Non-Feφ2.0 mm, SUSφ2.0 and the detected product ≤1%

- Monitoring action: metal detection verification with standard items by site worker at start production, end of production, and every two hours during production.
- Corrective action: impacted products segregated and evaluation; pass the metal detector again and find out the metal or repair the metal detector. if the detected product was more than 1%, total batch of the products were separated, evaluation the contamination. If necessary, the product will down grade.

OPRP for MSG:

- OPRP1 Sulfite concentration in soaking solution 0.16%~0.30%; SO2 content observable action criteria SO2 below 0.007g/100ml, monitored every tank/ every shift.
- OPRP2 sterilization observable action criteria 121-125℃, flow speed 70-100m3/h, glucose 105~109℃, 60~100m3/h，monitored 3 times a batch.
- OPRP3 sieves integrity observable action criteria no broken, every shift every 8 hours
- OPRP4 Pipeline metal detection for MSG observable action criteria Fe φ1.0 mm, Non-Feφ1.2 mm, SUSφ1.5mm, monitored twice a shift.

OPRP for Xanthan gum:

- OPRP1 Sulfite concentration in soaking solution 0.16%~0.30%; SO2 content observable action criteria SO2 below 0.007g/100ml, monitored every tank/ every shift.
- OPRP2 sterilization(fermentation) observable action criteria 123-125℃, flow speed below 50 m3/h, monitored every 30 min.
- OPRP3 sieves integrity observable action criteria no broken, monitored every batch.

The rationale for these and the validation method:

CCP metal detection: FDA CHAPTER - 5 SUB CHAPTER – 555, SECTION 555.425 -Foods - Adulteration Involving Hard or Sharp Foreign Objects.

OPRP according to final products testing and experience data.

The procedures for CCP identify the corrective action to be taken when the limits are exceeded. Records are kept of adjustments made and any actions taken. Once exceeded limited, raw materials rejected.

CCP control were verified by internal audit, records review and review of external feedback.

On-site view the production of xanthan gum,

OPRP1 Sulfite concentration in soaking solution 0.211~0.217%; SO2 content 0.0059%,OK.

OPRP2 sterilization(fermentation), batch 24040756, 8:50 124.2℃/41.2 m3/h；9:20 124.5℃/ 13.6m3/h, OK

OPRP3 Sieves 80mesh, no broken, OK.

CCP Metal detector test, OK;

On-site view the production of MSG:

OPRP1 same as xanthan gum.

OPRP2 sterilization: The sterilization process has been completed during the on-site audit, and no parameters were observed on site.

OPRP3 1# sieve, 22mesh, no broken. OK.

OPRP4 Pipeline metal detection test OK.

Sampled CCP and OPRP monitoring checking record such as: Xanthan gum, batch no.: HH202401080351; Xanthan gum,batch no.: HH202403200221; MSG, batch no.: M24020802-08/308. All above records were available for review.

Validation, verification, and review

HACCP plan had been validated yearly and once relevant change happened, last yearly validation were conducted on 2023-08-22 for MSG and 2023-08-18 for xanthan gum.

HACCP verification procedure was established and implemented and is addressed in the HACCP study. The latest verification record of 2023-4-22~25. was viewed on site audit. Verification activities included:

- internal audit-- current internal audits.
- review of CCP records.
- review of customer complaints and product withdraw/recall in the annual management review, the factory declared that no actual recall is happened until now.

The controlling result of HACCP plan established was demonstrated to keep the product safety risk within acceptable limit level.

HACCP plan and PRP review was conducted yearly. The last review was conducted on 2023-08-22 for MSG and 2023-08-18 for xanthan gum.

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, 3.2 Document control, 3.3 Record completion and maintenance

Food safety and quality manual

Documented policy issued in BRCGS manual NF/PG-GL-2023-01-01 and authorized by GM on 2023-11-10.

The copies of Quality manual are distributed to each department. Key staff could access the up-to-date version of Manual.

Working methods and practices are documented within food safety and quality control system, the manual was comprehensive and covered all BRCGS food standard requirements.

Document control

Document and record control procedure (NF/PG-CX-2023-01-01) was established. The controlled document list was established and indicated the latest version number. Sampled documents had got suitable identified and approval.

Relevant procedure and SOP files issued including documented and records control procedure, internal audit control procedure, corrective action procedure, recall control procedure and so on. Records of documents delivery and retrieval are available.

The document control procedure had described how document control is communicated to key staff and how access is controlled.

The electronic form is stored with authorised access, control of amendments and password protection, it is backed up to prevent loss.

Record completion and maintenance

Document and record control procedure (NF/PG-CX-2023-01-01) is established and implemented.

The requirement of collation, review, maintenance, storage and retrieval of records are defined.

The retention of the quality record was required at least 5 years, the shelf life of the finished product was 3 years for MSG and 2 years for xanthan gum, and detailed record retention time was defined in procedure.

The electronic form is stored with authorised access, control of amendments and password protection, it is backed up to prevent loss.

1 minor CAR was raised here under the clause 3.3.1
Detail, please see the CAR FORM.

3.4 Internal audits

Documented Internal audit and Management review procedure NF/PG-CX-2023-01-05 was established and implemented.

Internal audit was conducted according to the agreed plan. Scope and frequency were defined by risk analysis, on site reviewed internal audit plan of 2023 and 2024, arrangement planned was in 4 different date covering whole year. In 2023, the internal audit was conducted on 2023-03-27~30, 2023-06-18~26, 2023-08-27~30, 2023-12-18~21. Total 17 NCs were released on whole internal audit of 2023 and all NCs had got verification to be closed. Related management was responsible for it. Reports given to related management responsible for the section and correction had validation.

The internal was conducted by qualified auditors and Internal auditors did not audit their own works.

Sampling BRCGS audit report on 2023-12-18~21, total 3 NCs released.

Sampling BRCGS audit report on 2024-03-27~30, total 3 NCs released.

The factory GMP was inspected daily, and the inspection and check record were in place. The processing equipment in the workshop was inspected and checked. Sampling GMP checking records on Apr 1~30, 2024, records were available.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Purchase evaluate procedure NF/GY-CX-2023-01-01 was established. The documented risk assessment of each raw materials included allergen contamination, foreign body risks, microbiological contamination, chemical contamination, variety or species cross-contamination, substitution and any risk associated with raw materials were subject to legislative or customer, it was updated and reviewed annually. The last assessment was conducted 2024-02-23 by group QA and the records were maintained. Packing materials were identified as high-risk and control measures were in place.
All suppliers must be evaluated at first before input supply chain. Evaluation is based on the risk to product. Risk assessment of product and supplier is conducted at first and then management according to new supplier and regular annual management:

For high-risk supplier, the approval could be conducted by GFSI certificate or on-site audit. For medium and low-risk supplier, the approval could be conducted by questionnaire, the site audit or questionnaire should include products safety, traceability, HACCP review, food defence plan, food authenticity plan and GMP, an approval list was established. Onsite audit should be conducted once a year or two years based on the supplier performance.

Total 71 suppliers base were approval on list, updated list issued on 2024-01-01. Sampling supplier approval information as following:

Corn was mainly from Inner Mongolia, Hebei, Shanxi Province. The site sent samples to 3rd party lab for testing half a year for different plant areas and test every truck during incoming inspection. Corn suppliers were low risk and approval based on document questionnaire.

Corn-NMGXMT, business licence and permit cert were in valid. 3rd party lab testing report was in place and test item including heavy metal, toxin, and pesticides, which complying with GB 2761, GB 2762 and GB 2763. Low risk, supplier Approval based on document questionnaire on 2023-04-10 and result was approved.

PP/PE composite bag –JNHD, business licence and product permit cert in valid, 3rd party lab testing report was in place and comply with GB9683 and plasticizer ND. High risk. Supplier approval based on on-site audit, audit on 2023-04-25 and result was approved.

filtration fabric-TTJJ, business licence was in valid, 3rd party lab testing report was in place and comply with GB4806.7 and plasticizer ND. Low risk, supplier approval base on document questionnaire on 2023-12-01 and result was approved.

Container bag (PE)- JNBG, business licence and product permit cert in valid, 3rd party lab testing report was in place and comply with GB4806.7 and plasticizer ND. High risk supplier Approval based on on-site audit, audit on 2023-07-31.

Supplier traceability system was verified annually through mock test, the results met the requirements.

The purchase control procedure defined how exceptions to handle for raw material suppliers that are prescribed by a customer.

Site had defined the exceptions purchasing requirement in purchasing control procedure, no exceptions condition for supplier approval.

2 minor CARs were raised here under the clause 3.5.1.2 and 3.5.1.4
Detail, please see the CAR FORM.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

The raw material, chemical and packaging materials acceptance and inspection standards were in place, the inspection records sampled onsite verification were compliant with the requirements.

Raw material and packing material specification NF/PG-BZ-2021-01-27; container bag specification FF-GL-ZL-08-2023.

For raw materials, site verify supplier externals COA yearly and conduct internal test each batch according to inspection plan.

Sampled the records of the raw materials corn, batch no. 2024-03-03; Glucoamylase, MFG: 2024-01-19; α-amylase, MFG: 2023-10-27; container bag, batch no. 20240312-03; PE bag, batch no. 20240317-01, above receiving records were reviewed and conformity.

Any change for receiving standard, the incoming testing person will be communicated by document files, only correct version receiving standard could be used on site.

3.5.3 Management of suppliers of services

A documented service supplier approval policy was established, site service supplier included waste service, calibration service, transportation service and lab service.

The service servicers approval by collecting of qualified certificates, evaluated its performance annual.

All services suppliers had signed service contract and defined relevant service requirement.

For example:
Hazard waste treatment service supplier was KLQJYDM, contract valid from 2024-02-26 to 2025-02-25. Treatment quantity was available.

Transport: SXWL , business license, road transportation operation permit were both in valid, contract valid from 2024-03-01 to 2024-12-31, All requirements about food safety was listed in contracts.

3.5.4 Management of Outsourced processing

No outsourced processing and packing.

3.6 Specifications

The documented specification of raw material, ingredient and packing material is defined in “spec list”, the specification defined the limits for relevant chemical, microbiological, physical and allergens standards, such as detailed refer standard is below:
Raw materials: Raw material and packing material specification NF/PG-BZ-2021-01-27.

Packing materials: container bag specification FF-GL-ZL-08-2023.

The specifications of the finished products such as GB 1886.41-2015 for xanthan gum, and GB 2720-2015 for MSG. For export products, the specification considered the GB, EU, USP requirements.
The review record of specification/ recipe is kept on files. The review frequency is once at least every three years or changed, the latest review was conducted on 2023-12-29. Some special customers specifications were also reviewed, such as TIC customer for Xanthan gum on 2022-02-16, sample the finished product test report of batch no. HH202402080281, comply with the specification.

Raw materials and finished product specifications were agreed with relevant party such as customer

through document contract.

3.7 Corrective and preventive actions

Documented corrective & preventive action procedure NF/AB-CX-2023-01-01 was developed, the root cause analysis and corrective action for the non-conformity were followed and implemented.

For example, the cause of CAR raised in the internal audit was analyzed, corrective and preventive actions were conducted by the relative employees, and verified by internal auditor leader, more details please refer to internal audit.

3.8 Control of non-conforming product

Documented non-compliance control procedure NF/PG-CX-2023-01-04 is defined and implemented. QC dept has authority for releasing product.

The non-conforming product is handled as following:

- For incoming material: rejection in time, responsibility is QA receiver.
- For semi-finished product: production operator must be isolated and label non-conforming product, QA responsible for access and evaluation.
- For finished product: lab test finished products and isolate/evaluate the non-conformity, QA responsible for evaluation and handling and making a loss.
- For product returned to the site: after products testing or isolate/evaluate the non-conformity, QA responsible for treatment method such as rework or as waste.

Clear process well understood by staff that is interviewed during the audit. Labelled containers or areas for non-conforming products are provided. Non-conforming products handling reports are raised for review. Root analysis is analysed and CAs are adopted.

No major trends for non-conforming product, the typical incidence of non-conformity in process occurs occasionally such as foreign bodies, packing.

e.g., non-conforming product treatment records on 2024-02-24 for xanthan gum, the NC items was Alcohol residue exceed the customer requirements (special customer requirements) and the products was degrade to normal food products.

There was not any NC products had been hold during current audit.

3.9 Traceability

Documented product code and traceability control procedure NF/PG-CX-2023-01-03 is in place to enable complete traceability from finished product back to raw materials and packages, and from raw materials forward to the customer though paper records and computer system.

Traceability path: finished product batch no – production date –receiving date and supplier and verso, it is performed through paper records.

The original batch number of the ingredient as the batch number was checked and registered; for the finished product, production date code and order code were defined for the batch number of the finished product.

Auditor chose a batch of finished product to verify the traceability, the detail as bellow:
Final product xanthan gum, batch no. HH202401080351, MFG:2024-01-23/24, quantity 800bag*25kg, packed in plastic bag, could traced to raw material and package material, such as: strach batch no.

202401032105028, quantity 8.2t, soybean batch no. 20231208-01, 1300kg, yeast batch no. 21231108-01, defoamer batch no.20211106-11, PE bag batch no. 20240102-01, The material mass balance for the relative ingredient and product were counted and checked; all concerned products are located within 4 hours; The mass balance was calculated and reasonable.
The traceabiltiy of vertical audit was within 120 mins and been completed in required time, all information including batches and quantity could been traced completely, the traceability system was effect by vertical audit testing.

Traceability test carried out to cover both directions (raw material to finished product and vice versa) at least 2 times per year for MSG and xanthan gum separately. Traceability testing had been completed in required time, all information including batches and quantity could been traced completely, The mass balance was calculated and reasonable. The traceability system was effective by testing.

For MSG
From finished products to raw materials:
Traceability test was conducted on 2024-02-26, finished product MSG batch no. M23120302-04/20232817, traced to all materials and ingredient, such as fermentation broth batch no.2023123100102/00203/00301/00402, NaOH batch 20231230-01, Active carbon batch no. 20231229091,PE bag batch no.20240104-04. plastic woven bag, batch no. 2023-12-24-02.

For Xanthan gum
From raw material to finished products
Traceability test was conducted on 2023-07-15, raw material: soybean, batch:20221219-01, 1300kg. Could traced to the finished products xanthan gum such as HH202306080131. The batch of Soybean （batch no. 20221219-01）were received in total of 73780 kg, but only 1300 kg were traced.

Rework processing also kept traceability by using batches monitoring.

1 minor CAR was raised here under the clause 3.9.3.
Detail, please see the CAR FORM.

3.10 Complaint-handling

Documented customer compliant handling procedure was established and implemented.

Sales department collects complaints from clients and deliver it to QA department. The root of cause is analysed by QA. And related person will take actions.

Total 4 client complaint happened in 2023, and 0 complaint in 2024. The main issues include foreign objects, abnormal colours, and transportation issues. The complaint was analysed and treatment effectively.

Sample:

2023-05-07, MSG, during sea transportation, water ingress leads to mold growth.

Complaint trend analysis and summary was conducted at least one year, the any significant trends in complaint was used for corrective action taken.

3.11 Management of incidents, product withdrawal and product recall

Documented emergency preparedness and response control procedure NF/PG-CX-2023-01-12 is in place, taking into account the equipment break down, water, energy, fire, chemical leakage, malicious contamination or sabotage and disease.

It was tested on 2023-06-20 in xanthan gum workshop and 2023-05-15 in MSG workshop, metal detector broke down in Xanthan gum workshop, report was completed.

Documented identification, traceability and product withdrawal and recall procedure was in place NF/JX-CX-2023-01-02. Recall team was established, the up-to-date list of key contacts and responsibility were collected,

Mock recall was specified to be carried out by risk analysis, at least once per year. and Last was conducted on 2024-02-04~05, mocked recall product was finished product MSG batch number M20230302-04/2817, all products information was reached within defined timing. Mocked recall result showed that the recall procedure was effect.

Recall procedure defined that factory would inform CB within three working days of the decision to issue a recall, furthermore detail recall information will be provided to CB for evaluation. No actual recall or withdrawal has occurred.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.4	No processes were outsourced.

4. Site standards

4.1 External standards

The factory locates in economic development zone, the boundary of now site was clearly defined. The potential contamination had been considered and prevented well such as adequately segregated and closed.

The outside of factory was maintained in good condition, the road surface is flatted, and the lawn was maintained well.

The dormitories, canteens and power plants are segregated from working areas of workshop and storages, there are not any pollution to products.

The site had security gates to register visitor and contractor, CCTV was installed at key area and products opening area, employee only could enter designated area with authority.
All person had got food defence training on 2023-07-18.

Site had not external storage or external tanks or intake pipes.

4.2 Site security and food defence

Site had established the food defence plan NF/PG-FF-2023-01-16, the food defence plan team had got training yearly and had appropriate knowledge, last training on 2023-07-18. The food defence plan defined

the control of security to prevent access of unauthorised persons to production and storage areas, responsible was by Admin Dept.

The detailed food defence plan measure included the gate guard at the factory gate, the access control at the entrance of the workshop, the visitor registration, the CCTV at key areas and the password protection of the office computer.

Food defence plan was evaluation yearly and last on 2023-07-25.

Food defence was tested on 2023-09-20, Foreign personnel trying to enter into the plant and production area, report was completed.

Process and storage areas were identified restricted areas. Contractors and visitors were asked to register by security guard at factory entrance, was required to answer health questionnaire before entering.

1 minor CAR was raised here under the clause 4.2.1

Detail, please see the CAR FORM.

4.3 Layout, product flow and segregation

Site had updated factory map, there was effective segregation in place to minimise the risk of the product contamination and it was identified as different risk areas:

Low risk area: starch workshop, glucose workshop, pre-treat area and packing area.

enclosed areas including, outer packing room, warehouse.

Most processing steps were occurred in enclosed tank. The final products were ambient storage and not support pathogen grow.

Detailed plan of the site including access points for personnel and travel routes, location of staff facilities and routes to the facilities from places of work, production process flow, routes for the removal of waste was in place.

All contractor, visitor or driver had been information the site hygiene requirement in different area.

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

During site visit, not any ongoing refurbishment work or temporary structures was noted.

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

The floor and walls of the workshop were covered with tiles and composited rock, the doors and some walls were covered with composite plates, warehouse wall was composited and tiles, the processing and filling workshops have suspended ceilings.

On site verification, the fabrication of the buildings and facilities such as the wall and floor are suitable for the intended purpose.

The workshop drainages were provided adequately and were designed and maintained well. The in-house laboratory with its own drain separated from those of production areas.

The company had inspected the suspended ceilings regularly.

The windows were designed to meet the demands of the process. The windows in process and warehouse were shielded with film to avoid the contamination with the food when the windows are broken.

The doors maintained in good condition.

Site had not elevated walkway.

There were adequate quantity and luminance of lighting for all work areas, especially at operation station and inspection station.
The ventilation was adequate in the produce area by air-condition.
No excessive dust surface was found.

The condition of plastic strip curtains at person flowing door and products flowing window was maintained well.

4 minor CARs were raised here under the clause 4.4.1, 4.4.2, 4.4.4 and 4.4.7.
Detail, please see the CAR FORM.

4.5 Utilities – water, ice, air and other gases

The municipal water is used at reaction area and purify water used at refining area. The municipal water and purified water will be tested by government lab or qualified third party at least annually.

The water distribution plan is established in place.

The municipal water testing report from SGS is in place, issue date 2023-04-12, total 37 testing items including TPC, Coli form, As, Cr, Pb, Hg, PH, visual matter and others, the testing result complied with GB 5749-2022.

Internal testing of the municipal water will be performed by internal lab daily, the testing of sensory, Residual chlorine and TPC once a week, sampling testing records on 2024-01-04/2024-01-11/2024-01-18.

Air was directly contract with products during powder transportation, the filter was used, checking and changing were available. Sample, xanthan gum workshop, checked every 2 months, changed no more than every 6 months, 2023-12-29, 303 filter, changed; 2024-02-17, 303 filter, checked.

Compressed air was not directly contract with products.

No other gas and ice were used.

4.6 Equipment

Site mainly equipment included ferment tank, centrifuge, frame filter, evaporator, packer, sieves, metal detector, all most equipment was built with stainless steel and met to food equipment using, all requirements had defined in equipment purchasing contract.

The building and designing were based on food safety risk, the potential contamination of food safety hazard could be avoided.

The new equipment should be test and commissioned prior to use. Equipment is positioned well to facilitate cleaning and service. Suitable evidence was available for the equipment in direct contact with food. Sample: 2024-02-28, starch separator, the equipment acceptance report was provided.
Equipment management rule had defined the requirement of moving static equipment detailing potential risks to food safety are prevented and equipment integrity maintained.

The storage of equipment that is not in use was in good condition.

Mobile equipment such as battery-charging equipment was used use and no potential risk to the production.

The battery charging equipment for forklift trucks on site is closed.

4.7 Maintenance

Maintenance procedure has been established to ensure the safety and legality of products are not jeopardised, It includes preventative plan which established once a year to cover all equipment and emergency maintenance including daily activities, the equipment maintenance were conducted monthly, quarterly or yearly based on risk assessment.

Sample:

Xanthan gum workshop Fermented tank, 1st extract tank, dryer, once a month, record: 2024-01-15, 2024-02-15

Xanthan gum workshop dryer, once a month, record: 2024-01-14, 2024-02-14

MSG workshop crystallizing pot, every 6 months, 2024-03-24.

7 in-house engineers for xanthan gum and 10 in-house engineers for MSG report to engineering responsibility person who operates computerised maintenance plan.

No temporary found on site, once temporary repairing, permanently repairing will be required in defined timescale.

Maintenance site was protected well to prevent contamination risk to product when maintenance activities happened, production can't continue if maintenance activities not performed and clearance is done, maintenance tools and parts are counted before maintenance and after maintenance, hygiene is performed after maintenance, the maintenance record is signed by production and QC and it shows that the production and clearance has been performed.

Documented hygiene inspection on maintenance start-up and completed by QC employees, production only could be carried out after checking and approved by QC.

The food grade lubricating oil with NSF H1 registration is used and stored, such as ATOX 220 NSF H1, No.025685. MSDS and instructions are kept on files. It doesn't contain allergens at all.

Engineering workshop is kept clean and tidy, measures such as person training and checking was performed to prevent transfer of engineering debris to production or storage areas.

4.8 Staff facilities

In the processing zone and packing zone, the dedicated protective clothing was used, and the designated employee checked the hygiene policy.
Site had provided personal items storage cabinet for all employees.
Personal items and protective clothing were stored segregated, the cleaned protective clothing and dirt protective clothing was stored segregated.
Sufficient hand-washing facilities are provided at the entrance of workshops.

- Hand washing station provided at each processing workshops entrances;
- Taps are hand-free;
- Tempered running water is provided
- Liquid soap
- Air drying device
- Disinfection is realized 75% alcohol.
- Hand washing policy is defined and posted.

Toilets are adequately segregated and do not open directly into production area and storage area.
The hand cleaning chemical and hand drying devices are provided for the toilet for operators in processing areas.
Personal items are stored in small closet in changing- room, no food is permitted in production and store area. Food is provided in canteen only.

Smoking was allowed at designated room away from workshop.

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

4.9.1 Chemical control

Chemical management procedure was established to be used as guidelines for preventing chemical contamination risk.

List of chemicals was available including HCL, NaOH, liquid hand soap, alcohol, lubrication oil and so on.

Label and MSDS of chemical were in place.

Site had confirmed of suitability for using ad no strongly scented products used.

Special locked room was provided for chemicals. Control person got training.

chemical spill was as incident items and defined the incident control procedure.

Chemical procedure had defined the safety, legal disposal or return of obsolete or out-of-date chemical and empty chemical containers.

While strongly scented or taint-forming material have to be used, site will take protective measure and adequately segregated. No actual issue happened.

4.9.2 Metal control

Documented policy for the control of the use of sharp metal implements including scissors, knives was in place and there was daily inspection record for damage and the investigation of any lost items.

Needles clips and staples were not allowed in the production area.

Snap off blade was not permitted to be used on site.

Filter, and magnet (⩾8000 Gs) were set for foreign matter control. Metal detector was in place as CCP and OPRP to minimize the risk of metal. Control measures was effective.

Records were remained on files and verified on 2024-01.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Documented foreign bodies control procedures for handling glass, brittle or hard plastic, ceramic or other materials include the check requirement and frequency. Glass items were registered and numbered properly. The map of brittle materials including location and number were available. The status of brittle materials was checked daily and recorded.

Brittle items broken treatment requirement had been defined in the procedure, treatment flow including site segregated, production stopping, checking and so on. No actual glass broken incident happened.

Site window glass and lights had been protected while risk present according to assessment.

Sampled the inspection record on xanthan gum extract process, alcohol meter, thermometer, observation window, 2024-01-09~25.

4.9.4 Products packed into glass or other brittle containers

N/A no products packed in glass or other brittle containers.

4.9.5 Wood
Documented wooden control procedure is developed and implemented, the wooden tools were prohibited to use in opened product area; the wooden pallets were used in raw materials storage and finished product storage, those were well maintained.
4.9.6 Other physical contaminants
The site had a segregated room for external packing materials moving for raw materials inputting and finished products packing. But during the on-site audit, it was found that the semi-finished products pallets to be used for feeding in the mixed process were damaged. The pen used on site was special pen without small parts and detectable, It was met the standard requirement, others necessary tools such as mobile phones and similar portable items was also control well such as checking and registration. In the foreign bodies control procedure, site had defined other types of foreign bodies contamination control requirement based on risk assessment. **1 minor CAR was raised here under the clause 4.9.6.3** **Detail, please see the CAR FORM.**
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment
A documented assessment in association with the HACCP study had been carried out on to identify the potential use of equipment to detect or remove foreign-body contamination. Filtering and metal detection were used to remove foreign body for finished products. Relevant requirement for foreign-body detection had been defied including location, type, testing and checking requirement, correction action once failed testing. Any unexpected materials was detected or removed by equipment, site will carried out investigated and take necessary preventive action to reduce occurrences happened.
4.10.2 Filters and sieves
Sieves were used to ensure its product was not contaminated by foreign bodies. The filter size of the sieve is 80, 200, 30, 50, 60 meshes. The sieves were checked once per shift and the records were in place. The affected materials would be assessed in case of defective sieves are identified and the potential for contamination of products investigated.
4.10.3 Metal detectors and X-ray equipment
The company had established the metal detection machine management rule defined in operated to allow effective segregation of the affected product. Based on risk assessment, the metal detector was used. The WI for operation and calibration of the metal detector was established and implemented. Metal detection has been determined as one CCP and OPRP. Testing blocks used to ensure the metal detector can work normally. All products pass the metal detector and detected products to be stopped on the belt and audible alarm (in its packaging line) or rejected in special container.

Metal detector demonstrated effectively by staff who was aware of failure process – isolation of stock and retesting. And the non-conformity products were properly disposed and the metal foreign body had been found and kept it in the record.

Corrective action and reporting in the event of the testing procedure identifying any failure of the foreign body detector was defined.

X-ray detection device wasn't applied in the production.

During site audit the bovine collagen peptide was processing, auditor carried out site verification for metal detection operation, the result was met.

4.10.4 Magnets

Magnet bars above 8000 Gs were in place for metal foreign body control and were installed in the outlets of packer, sieves and drier.
The strength of magnet bar was verified at least once a month, sample: 2024-01-01, 2024-02-01, 2024-03-01, all above 8000 Gs.

4.10.5 Optical sorting equipment

N/A due to optical sorting equipment not used.

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

N/A, no products filled in brittle containers.

4.10.7 Other foreign-body detection and removal equipment

During the audit, the fluid bed was using on site, it didn't exist the risk, the operator obeyed the WI and rule for it. During the audit, 4 destone machine was found using for corn raw material, they run well as the procedure required.

4.11 Housekeeping and hygiene

By site verification the cleaning condition of building, facility and equipment, tools and condition were maintained well.
Documented cleaning rule was defined in SSOP were described including food contacted and non-food contact surfaces to ensure appropriate standards of hygiene are maintained and the risk of contamination is minimised. The cleaning rule included responsibility for cleaning, area/equipment/ utensils, frequency, method of cleaning and disinfecting, cleaner and disinfector, check method and corrective actions in case of deviation.

The cleaning plan were performed by internal employees who are trained at least annually.

The cleaning equipment was fit for food process areas and with suitably identified. Equipment cleaning used as purified water and disinfection used boiling water. No disinfection chemical water.

Verification of the cleaning and disinfection by visually and swab testing, check and testing had been conducted per cleaning completed. Review of 2024-03-19, extract process, every batch, steam and alcohol, visually check ok；2024-1-30, tools in packing room, every 4 hours, 75% alcohol, visually check ok. 2024-03-06/12/18， fluid bed, hot water, every 8 day, visually check ok.
2024-02-01 and 2024-03-01, swab test, test TPC，comply with the requirements.

During the on-site audit, most of the walls, floors, ceilings and other areas of the production workshop and warehouse were cleaned in good condition and met the requirements, but splashing material was found on the baffle above the opening of the extraction tank, which was not cleaned thoroughly.

2 minor CARs were raised here under the clause 4.11.1 and 4.11.2.
Detail, please see the CAR FORM.

4.11.7 Cleaning in place (CIP)

The CIP procedure was in place for cleaning the filter and followed. CIP layout was available and clear to show the process piping circuits. The cleaning effectiveness was validated by test rinsing fluid /pH 7.5-8.5 and product residue. The CIP operates with purity water and NaOH and HCL. The CIP cleaning record was in place. The record dated on 2024-02 were checked.
The clean effectiveness was checked once a month by testing PH.

4.11.8 Environmental monitoring

Environment monitoring programme NF/CJC-0108 had been established based on risk assessment, the scope included air outlet, food contract surface, worker hands and clothes at the finished products filling and packing room, inner packing materials, etc.
Detailed EMP as following:

- Typical sampling areas: air of inner packing area, food contract surface, tools, worker hands at the finished products filling room.
- Organisms: TPC, Coliform, Mould and yeast, Salmonella.
- Limits: For air of packing area TPC≤30 cfu/9cm^2， Mould and yeast≤3 cfu/9cm^2. For food contact surface, TPC≤20 cfu/cm^2， coliforms ND, Mould and yeast≤2 cfu/cm^2. For surrounding area of the product contact surface, TPC≤20 cfu/cm^2， coliforms ND, Mould and yeast≤2 cfu/cm^2. Salmonella ND.
- Frequency of testing: once a month
- out of specification results: segregation of products, investigation of source, cleaning& disinfection and swab testing again.

Review of testing records for xanthan gum workshop and MSG workshop on 2024-01-01, 2024-02-01,2024-03-01 and 2024-04-01, the testing point was processing area of filling room were available. The result was met to limit. Once the monitoring result was out of specification, site will re-evaluation monitoring plan and the products safety risk. Trend analysis was provided, and the results showed the control was effective.

HACCP team had reviewed the Environment monitoring programme at least yearly, while under the following, the EMP will be re-evaluation:

- Major change in processing condition and processing flow;
- New development in externa relevant l information.
- Significant issue about regulatory or products safety.
- Products non-conformity.
- Consistently negative result.

Last assessment of EMP was on 2023-12-28, the assessment result was suitable.

4.12 Waste and waste disposal

Waste control procedure is implemented. Site had established wastewater facility, delivery had been monitored by government depart online, permit license was in valid.

Hazard waste treatment service supplier was KLQJYDM, contract valid from 2024-02-26 to 2025-02-25. Treatment quantity was available.

External waste collection containers were managed well to minimise risk.

The factory would handle unsafe products or substandard trademarked materials themselves, and the dealing record was completed.

4.13 Management of surplus food and products for animal feed

Client brand product will be treatment after got client agreement otherwise move the client package and label before treatment.

Surplus products handling should confirm with contractor.

Corn husk, corn protein powder, glutamic acid residue could be used as feed raw materials and was stored separately and in good condition.

4.14 Pest management

Pest control procedure (NF/PG-CX-2023-01-10) was established. The pest control daily work also conducted by the site in-house staff. The in-house PCO was trained and competent. For example, Xu HX , Wei WJ, joined pest control training on 2019-06-17 in a 3rd party institute.

Main pests were flies and rodents. Sticky EFK, glued board, cages, sound expeller and baffles were used for pest control. The EFK were checked once a week in summer (May to Oct) and once a month in winter (Nov to Apr), the mouse control facilities were checked every day. The EFK records of 2023-11-01 and 2023-12-01 were reviewed. The mouse control facilities inspection record of 2024-01 were reviewed.

The pest control device's location map was established and current updated on 2024-03-28 for MSG workshop and on 2024-01-01 for Xanthan gum workshop.

EFK and sticky board were used inside of workshop and warehouse, no mechanical devices/toxin bait stations used in plant.

The regular inspection and treatment of the site to deter eradicate infestation was conducted by inner PCO. The target organisms including: flies, mouse, mosquito, moths and other pests. And the pesticide and toxin baits use record were retained.

The trend analysis for pest control result was conducted monthly based on checking result and reviewed the analysis on 2023-10-25.

The current depth pest control survey was conducted on 2023-12-10~13 by own PCO expert. The frequency was defined as yearly in documented file based on risk. In the survey report done by expert, the follows contents were reviewed: the pest control proofing, trend analysis report, pest control plan, fabric of the building, equipment and machinery. The PCO reviewed the survey report and necessary measures were taken.

The site carried out bird infestation risk assessment and take some measures to prevent bird entry building including screen installed for opened window and door closed and bird repellents provided.

No evidence of infestation was found or had recently been reported. No issues highlighted through trending reports.

All the operators were trained for pest control awareness and record were kept on site.

4.15 Storage facilities

The company had established the storage and transport management procedure.

The finished and semi-finished products are stored in the room temperature storage separately and identified clearly.

Raw materials, packaging materials and finished products are stored in different area. Separated storages are painted in walls and established with marble or cement in floor and door sealed well. Label cards are stick at separated products in storages. Products storage was away from wall and floor.

Site had solo for corn storage which condition was well. Sampled the corn silo temperature monitoring record on 2024-04-05~14, met the requirements.

The amylase store was controlled under 0-25℃, during the audit, the store was 17℃.

All products were identified properly. Stock rotation of raw materials was based on FIFO or FEFO, production arranged according to order.

No controlled atmosphere storage.

No outside storage on site.

4.16 Dispatch and transport

The company had established the storage and transport management procedure, across the supply chain from raw materials dispatch to finished product delivery was considered to be able to minimise the risk of contamination and damage, batches number was printed on the finished product containers. Records of dispatch and receipt of goods had recorded the manufacturing date of the product and transport containers number.

The site had designated loading area at the entrance of warehouse, during loading and unloading operation the products was closed condition, so there was not contamination risk. Site had considered the products protective during loading and unloading.

During site visit there was not loading and unloading processing, by review of vehicle checking records, the download operation was suitable.

The transport control rule had defined vehicle control requirement. Sampling the vehicles clean inspection records for finished products vehicle on 2024-02-12, vehicle no. Meng A87409 was available; other samples: 2024-03-01~17. The finished products vehicle checking had been conducted per batches. the clean requirements defined in the transport contracts.

Transport of finished products was under normal temperature.

Site production transport was conducted by contracted transport service supplier, the transport requirement including products safety and protection had been defined in contracted.
Supplier: SXWL , business license, road transportation operation permit were both in valid, contract valid from 2024-03-01 to 2024-12-31, All requirements about food safety was listed in contracts.

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

4.3.6	No temporary structures constructed
4.4.5	No suspended ceilings or roof voids present
4.9.1.2	No such chemical used on site.
4.9.4	No products packed in glass or other brittle containers.
4.10.3.5	Site had not X-ray machine used
4.10.5	No optional equipment used.
4 10.6	No products filled in glass jars, cans or other rigid containers.
4.12.4	No unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal.
4.15.4	No controlled atmosphere storage
4.15.5	No outside storage.
4.16.3	No temperature control requirement during transport.

5. Product control

5.1 Product design/development

Documented product development control Procedure NF/GCYF-01-06-2022 is established.

Head office R&D was in charge of product development, which incorporates the hazard analysis principles in accordance with HACCP system, in R&D activities, process or packaging/label is linked into HACCP review, approved by HACCP team director. Plant activities was controlled by change control procedure.

Shelf-life test procedure was established and implemented. Shelf- life trails records for its products are retained on file. For MSG, test items include sensory, assay, specific rotate, PH, Fe, moisture. For xanthan gum, test items include moisture, viscosity, PH. Sample the record of MSG, MFG:20200102, tested half a year, the latest tested was conducted on 2024-01-12, qualified.

Procedures to confirm product packaging conforms to relevant food safety legislation and specification is in place.

The product formulation and production process was fully validated to meet the stated claim.

5.2 Product labelling

Correction of labelling was verified against destination country and Chinese legal.

All label sample and design of products was provided and designed and approved by head office R&D and QA team and approved by the clients finally. All communication mail was in place for review.

No nutritional claim was on the label, No cooking method on the label.

5.3 Management of allergens

Documented allergen procedure (NF/PG-CX-2023-01-08) was established and implemented. According to the requirement of the regulations of national, USA and EU such as 2003/89/EC, allergen risk assessment of the incoming materials and ingredient were performed.

Updated allergen ingredient list based on assessment was issued on 2024-10-10, the allergen containing materials has been identified including soybean and SO2(only xanthan gum). All workshops were separated well, so there was no risk of allergen cross contamination.

In warehouse and workshop, all allergens were basically segregated and labelled, the dedicated schedule to handle the different allergen material according to daily production plan.

Possible allergen contained in products was analysed and no allergen was contained in products. Sampled allergen testing report of MSG and Xanthan gum, soybean and SO2 results were ND.

The restaurant was inside factory located in a segregated area. it was segregated well from warehouse and workshop, All the allergen including wheat flour, soybean, milk shrimp, peanut, egg and fish used in plant restaurant were managed to prevent access workshop.

Employees could not take any food to factory, also could not take any food to outside of canteen.

5.4 Product authenticity, claims and chain of custody

Site had established the products authenticity and custody control procedure; the authenticity and custody control team had got training yearly and had appropriate knowledge.

Risk assessment about products authenticity and custody had been undertaken by the team yearly and last on 2024-01-01, evaluation items included historical, economic, ease of access, testing sophistication and nature of raw material according to standard requirement. evaluation Information collected from internet and official website. Corn was identified as high-risk materials. Other materials were identified as low risk about authenticity.

Mass balance test of the two products was conducted at least twice one a year. Last test of MSG was conducted on 2024-02-26. Based on production records, the mass balance was calculated and conformed.

IP certificate was valid to 2024-07-01.

MUI HALAL cert was in valid 2027-02-28.

Kosher cert was in valid to 2025-02-28

5.5 Product packaging

Product inner packaging PE bag appropriate for the intended use of the finished product.

Third testing report could be provided as:

PP/PE composite bag –JNHD, 3rd party lab testing report was in place and comply with GB9683 and plasticizer ND.

Container bag (PE)- JNBG, 3rd party lab testing report was in place and comply with GB4806.7 and plasticizer ND.

Inner packaging and outer packaging were stored separately. The inner packaging materials were protected and labelled properly in the warehouse.

In SSOP defined the treatment requirement for obsolete packaging and label, the obsolete packaging and label had been segregated stored and broken printing information before treatment as waste.

5.6 Product inspection, on-site product testing and laboratory analysis

Lab inspection rules were in place for all materials, finished products and environment sampling.

Raw materials had been sampled per receiving and carried out incoming testing according to rule.

The final product was tested in internal lab per batches, test items included sensory, physical and chemical, heavy metal and microbiological items. The mandatory inspection by third qualified lab to confirm product safety, legality and quality, test items according to the relevant standards.

For Xanthan gum, food safety test items including sensory, Pb, TPC, coliforms, mould and yeast, salmonella.

For MSG, food safety test items including sensory, pH, Fe, Chlorides, sulphates.

Sampling finished products testing report in internal lab:

Xanthan gum, MFG:2024-02-09, qualified.

MSG, MFG: 2024-02-06, qualified.

MSG, MFG: 2024-04-09, qualified.

Final products were sent to external qualified lab for testing yearly. The reports of 2024 were in testing, review test report as following:
Sampling:
COA of xanthan gum, issued on 2024-01-19 by SGS based on GB 1886.41; testing items: sensory, viscosity, shear ratio, loss on drying, ash, pyruvic acid, lead, nitrogen, CNAS L 2274.

COA of MSG issued on 2024-01-23 by SGS based on GB/T 8967; testing items: sensory, sodium glutamate, transmittance, specific optical, rotation,pH, chloride, loss on dry, sulphate, lead, iron, arsenic. CNAS L 2774.

Inspection result trend analysis was done quarterly, the analysis of result trend was used for necessary corrective action established.

Ongoing shelf-life assessment system is in place and implemented, testing records of MSG, MFG:20200102, tested half a year, the latest tested was conducted on 2024-01-12, qualified.

The lab of the company is physically separated from the production workshop and warehouse, visitor can't access until visitor is permitted, there is no potential hazard from lab.

The testing device was calibrated according as the legal requirement, and the calibration certificate was reviewed.

The external lab was accredited by CMA or CNAS such as SGS lab, and the accredited number was registered in the product testing report.

The internal lab got CNAS certificated, CNAS L5525. Total 112 lab person and all lab persons got suitable training. The factory lab had capability verification with DLZS LAB (CNAS PT0035) yearly and sampled the report on 2023-08-18, test item: ash, moisture; report on 2023-06-25, test item: Pb, Cd, All the results were satisfied.
5.7 Product release
Documented product release procedure is established and implemented. QA/QC report is screen and results are compliance with the specification. Finished products normally approved by its QA director or his representative before the loading. No products were held off site.
5.8 Pet food and animal feed
No pet food and animal feed products.
5.9 Animal primary conversion
N/A, no animal primary conversion processing on site.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.4	No cooking method in the label.
5.3.6	No allergen cross contamination risks
5.3.7	No claim of claim suitability of a food for allergy or food sensitivity sufferers,
5.3.8	No allergen cross contamination risks
5.5.2	No liners used
5.8	No pet food and animal feed products.
5.9	no animal primary conversion processing on site.

6. Process control

6.1 Control of operations

HACCP plan, process monitoring SOP and check records were available.

Operating procedure was established and implemented to control all parameters. For the scoped product were conducted including below:

- Raw material inspection (per batch, such as the sense, moisture, PH, and supplier COA).
- Fermentation (checking sterilization temperature and flow, per batch).
- Filtering (check filter facility complete per batches.).
- weight control (one by one).
- metal detection (testing with standard testing items at start production, end of production, and every two hours during production)
- label checks (per batch).
- date coding checks (per batch).

Key equipment settings were completed by authorised trained personnel only such as reaction processing and spray machine.

Start-up check control procedure is established. All right packaging and correct label with information must be checked before start-up. Start-up checking record is kept on file, checking indicator includes hygiene, equipment, ingredients, label including weight, code of batch, packaging.

In the case of equipment failure or deviation of the process from specification, procedures are in place to determine the action to be taken.

Site did not handle products or materials that were outside of scope of audit.

6.2 Labelling and pack control

Documented procedure was developed in place to ensure that products are packed into the correct packaging and correctly labelled including changing batches of packaging material and the checking was carried out.

The procedure requires quality personnel, production personnel and warehouse personnel to jointly confirm the correctness of finished product labels.

The visual checking was done before the production started up, the checking items are as follows: status of food contract surface, the hygiene of operation environment, the remaining issues from last production shift. All the materials and packaging were removed out before next shift or next products.

During the onsite audit, the product changeover was witnessed. The works removed all products and packages and cleaned the lines, including the equipment and tools.

Site had not on-line equipment for labelling and pack checking.

6.3 Quantity, weight, volume and number control

The company has stipulated product weight standards according to customer requirements and the laws of the selling country. During the production process, the factory staff must strictly implement it.

The frequency and methodology of quantity checking was documented. In process, the workers check the net weight every bag. Sample： 2024-03-10, MSG, batch no. 20240302312/0310, 24.10~25.30kg, 20 samples, 25.17kg on average.

The frequency and methodology of quantity checking meets the requirement. The weight was monitored by each bag when production period. The internal calibration for the used scales was conducted every day with the standard weight which had been calibrated by external institute.

The product packaging specification includes 25kg/800kg/900kg/1000kg, inner pack: PE bag.

No bulk products without packing weighing requirement.

6.4 Calibration and control of measuring and monitoring devices

All Measuring equipment used to monitor CCP and product safety and legality shall be identified. The identified measuring equipment was calibrated to a recognised national standard. The monitoring and measure equipment list was in place.

Sampling the calibration report as following:

flowmeter of sterilization, LDG-80S, calibration date 2023-04-26

thermometer of sterilization, SWP-C904, calibration date 2024-03-01.

Electronic scale used at xanthan gum filling room, defender-150-3k, calibration date 2023-04-26.

Electronic scale used at MSG filling room, C1200-100, calibration date 2023-04-26.

electronic truck scale, SCS-150, calibration date 2023-05-05.

Incubator used at LAB, spx-250, calibration date 2023-04-23.

Vertical pressure steam sterilizer used at LAB, TMQ.R-3870, calibration date 2023-04-23..

All reference measuring equipment calibrated by third qualified lab. Once the prescribed measuring and monitoring devices are found not to be operating within specified limits. The actions included products identification, segregation and treatment, measuring and monitoring devices re-adjusted to ensure accuracy unauthorized adjustment of measuring and monitoring devices was prohibited.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
6.1.7	Site did not handle products or materials that were outside of scope of audit.
6.2.4	No online verification equipment (e.g. bar code scanners) is used.
6.3.2	No bulk products without packing weighing requirement.

7. Personnel

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

The company HR control procedure NF/RL-CX-2023-01-01to describe the staff training and the requirement of work experience or qualification.

The company ensured all employees were properly trained, instructed and supervised and were competent in conducting their tasks.

2023 training plan and 2024 training plan were available, sampling training records as following:

BRCGS V9 training on 2024-03-20~21

Pest control training 2023-05-17

CCP training on 2023-05-24/2024-05-08

Pest control training 2024-03-20~23

Packing Lable management training on 2024-03-20~23

Allergen training on 2023-07-10~12

Food defence training on 2023-07-18

Foreign matter control training on 2023-06-24

Cleaning and sanitation training on 2023-08-20

GMP training on 2024-03-31~2024-04-02

The effectiveness of the training through orally, paper exam or on-site operation. Relevant training records were available.
By site interview with workshop worker CCP control person and department manager, sampled person had adequately competence.
Site had concerned the ongoing training requirement based on person competency and updated the training plan.

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

The company had established personnel hygiene rule in GMP requirements. The personal hygiene was detailed described. Hand washing and disinfecting requirement was defined in personnel hygiene rule, staff washed their hands before commencing work, after visiting toilet, becoming soiled.

There were hand washing sinks at entrances to processing areas, or appropriate areas convenient to staff for washing hands when they became soiled. Operators were aware of washing their hands prior to entering the processing areas during the audit.

Blue metal plaster was used once person finger small cut. Personnel hygiene rule required the relevant content, using records were available. Every batch of blue metal plaster had been tested with metal detector, sampled the testing report on 2023-12-13/2024-01-01/2024-01-15.

The personal medical control rule was established.

7.3 Medical screening

The company had established personnel hygiene rule in GMP requirements; employees would be medically examined prior to employment and yearly during employment. Sampled 4 workers as following: Wu DY，Wang H，Wei WJ， Di LL, all health certificates were available for review during the inspection. Medical examination institutions: HHHTSZYBYY.

Personnel hygiene rule describe the relevant content, if any employee or contractors and visitor was noted with infectious disease, they would be excluded from the processing areas. The factory required the auditor to fill in the health statement when entering the workshop during the on-site audit.
7.4 Protective clothing: employees or visitors to production areas
Personnel health and hygiene management requirement defined in GMP requirements. The company had provided adequate protective clothes for all persons in the processing areas including formal workers, temporary workers, contractor and visitor. The auditor was also required to wear the visiting clothing to enter food processing areas. The protective clothing was sufficient and suitable designed. Filling processing area protective cleaning was conducted by internal laundry, at this area the protective clothing was cleaned daily. After cleaning, use a UV lamp for disinfection. Sampling protective clothing cleaning records of 2024-03, for pre-treatment areas was low area, the protective clothing was not contacted with food, at this area the protective clothing was cleaned by worker themselves, the protective checking also carried out daily. One off food grade glove used on site. Mask was disposable and changed every time.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
7.4.6	No items of personal protective clothing that were not suitable for laundering were provided.

8. Production risk zones – 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
Based on decision tree, the products stored under normal temperature, do not support the growth of pathogens or the survival of pathogens. Production workshops are all low-risk area.
8.2 Building fabric in high-risk and high-care zones
Site do not have high care area, high risk area, ambient high care area, section 8.2 is not applicable.
8.3 Equipment and maintenance in high-risk and high-care zones
Site do not have high care area, high risk area, ambient high care area, section 8.3 is not applicable.
8.4 Staff facilities for high-risk and high-care zones
Site do not have high care area, high risk area, ambient high care area, section 8.4 is not applicable.
8.5 Housekeeping and hygiene in the high-risk high-care zones
Site do not have high care area, high risk area, ambient high care area, section 8.5 is not applicable.
8.6 Waste/Waste disposal in high risk, high care zones
Site do not have high care area, high risk area, ambient high care area, section 8.6 is not applicable.
8.7 Protective clothing in the high-risk high-care zones
Site do not have high care area, high risk area, ambient high care area, section 8.7 is not applicable.

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

8.1.2-8.1.4	Site do not have high care area, high risk area, ambient high care area,
8.2~8.7	Site do not have high care area, high risk area, ambient high care area.

9. Requirements for traded products
9.1 The food safety plan - HACCP
Not applicable
9.2 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.3 Specifications
Not applicable
9.4 Product inspection and laboratory testing
Not applicable
9.5 Product legality
Not applicable
9.6 Traceability
Not applicable

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	

Click or tap here to enter text.
11.3 Raw material receipt and inspection
Click or tap here to enter text.
11.4 Management of cross-contamination between species
Click or tap here to enter text.
11.5 Product testing
Click or tap here to enter text.
11.6 Training
Click or tap here to enter text.

Module 13: Meeting FSMA Requirements for Food – July 2022
Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33)
Click or tap here to enter text.
Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)
Click or tap here to enter text.
Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)
Click or tap here to enter text.
Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)
Click or tap here to enter text.
Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)
Click or tap here to enter text.

14.1 Additional Specifier Requirements
14.1 Traceability
Click or tap here to enter text.
14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.