



# SQF Food Safety Audit Edition 9

JSL Foods Inc. - 58795

## Summary

**Audit Decision**

Certified

**Certificate Number**

58795

**Audit Rating****Decision Date**

May 3, 2025

**Audit Type**

Recertification

**Recertification Date**

April 14, 2026

**On-Site Audit Dates**

March 18, 2025 - March 19, 2025

**Expiration Date**

June 28, 2026

**ICT Dates**

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Excellent

**Issue Date**

May 3, 2025

## Facility and Scope

**JSL Foods Inc. - 58795**

1219 Carpenter Rd  
Humble, 77396 United States

**Products**

Noodles and Chow Mein.

**Food Sector Categories**

13. Bakery and Snack Food Processing  
20. Recipe Meals Manufacturing

**Scope of Certification**

The receiving, storing, mixing, rolling, slitting, steaming, cutting, cooling, freezing, packing of Noodles into plastic bags and stored in freezer. The proofing, baking, cooling, and packing of Baked Chow

## Certification Body and Audit Team

**Safe Food Certifications, LLC**

710 Striker Ave  
Sacramento, CA 95834-1112 United States

**CB#:** 42261

**Accreditation Body:** ANAB

**Accreditation Number:** 1225

**Lead Auditor:** Jeff Nelson (C-423812)

**Technical Reviewer:** Shawnil Guiles-Pelcastre (C-363109)

**Hours Spent on Site:** 16

**Hours of ICT Activities:** 0

**Hours Spent Writing Report:** 8

Mein stored in cooler. The receiving, storing of raw materials, boiling, cooling, vacuum packing, heating, and cooling of brown rice stored in cooler. The receiving and staging of ingredients and packaging for assembling meal kits into a sleeve, master case and stored in a refrigerator.

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## Section Responses

### Audit Statement - Audit

**SQF Practitioner Name** - Name the designated SQF Practitioner

**Response:** Jonathan Gonzalez

**SQF Practitioner Email** - Email of the designated SQF Practitioner

**Response:** jonathang@jslfoods.com

**Opening Meeting** - People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas)

**Response:** Jonathan Gonzalez: QC Manager, Gregorio Torres: Production Plant Manager, Martin Torres: Corporate Director, QA/QC, Huiying Hu: QA Technical Manager, Merced Sanchez: Production Supervisor, Jeff Nelson: Lead Food Safety Auditor (Safe Food Certifications, LLC).

**Facility Description** - Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details)

**Response:** The Site started operations in this facility in January of 2021. Eighty-two employees operate the 60,000 Sq. ft. building. The employees are divided into two manufacturing shifts and one sanitation shift. The plant typically manufactures products from 7:30 am to 11:00 pm, followed by sanitation. The Site receives ingredients from processing facilities and creates heat-treated, ready-to-cook noodles. The site is surrounded by gravel and paved parking. There are no alternative sites, warehouses, or separate buildings. The facility is made of steel and concrete walls. The ceiling is made of corrugated steel. Paved roads and interstate highways service the site, and it is located in a commercial area of the Houston greater metropolitan area. The site has five HACCP plans and one CCP (metal detection plus X-ray for customer 1 products). The FDA and the local health department regulate the plant. The estimated audit duration was 2 days (16 hours) and audit was completed in 16 hours. The time spent for the site inspection of 6 hours was adequate to review production activities (observation and interviews, plant exterior and interior, employee GMPs, etc.). Moreover, the site only had two lines running during the audit and is relatively compact in size, so all areas were easily accessible. The site has been assessed to SQF designated customer specific requirements where noted.

**Closing Meeting** - People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas)

**Response:** Jonathan Gonzalez: QC Manager, Gregorio Torres: Production Plant Manager, Martin Torres: Corporate Director, QA/QC, Huiying Hu: QA Technical Manager, Merced Sanchez: Production Supervisor, Merced Sanchez: Production Supervisor, Jeff Nelson: Lead Food Safety Auditor (Safe Food Certifications, LLC)

**Auditor Recommendation** - Auditor Recommendation

**Response:** Recertification upon completion and acceptance of nonconformity corrective actions.

### 2.1.1 - Management Responsibility (Mandatory)

**2.1.1.1** - Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to: i. Supply safe food; ii. Establish and maintain a food safety culture within the site; iii. Establish and continually improve the site's food safety management system; and iv. Comply with

customer and regulatory requirements to supply safe food. The policy statement shall be: v. Signed by the senior site manager and displayed in prominent positions; and vi. Effectively communicated to all site personnel in the language(s) understood by all site personnel

**Response: Compliant**

**Evidence:** • The site had a food safety policy statement, “Quality Policy” (SQF.002, revision #005, revision Date 08/06/2023 signed by the Company President, the Director of Quality and Food Safety, and the VP of Operations) which covers management commitment to supply safe food, establish and maintain a food safety culture, establish and continually improve the food safety management system, and comply with all customer and regulatory requirements. The Policy is communicated to the facility's staff by way of internal training and public posting (i.e. in the main hallway prior to production area entry, hallway where offices and alternate team member entrance is located, and in the breakroom) and is in languages (English and Spanish) used in the site. “We strive to meet or exceed company expectations through the four pillar strategy: innovation, quality and performance, customer service, and family spirit, in accordance with food safety culture, we look to diligently minimize food risks within all of the plant while complying with the latest regulatory requirements, pledges to supply safe, quality foods that meet our customer needs” The company management commitment policy (Procedure PL.003, revision date 02/10/2025, Revision 003) includes the company commitment to Safe Quality Food, by methods including: - Establish and maintain a food safety culture with all company facilities - Manufacture package and deliver products that meet the highest food safety and quality standards including meeting or exceeding all statutory and regulatory requirements for quality and food safety, - Communicate food safety expectations and requirements to suppliers, contractors, customers, external auditing agencies, etc. Signed by the company president in English and Spanish The site has a specific quality and food safety management policy (SQF.003, revision date 06/05/2024, revision number 002) which includes the requirement to set an annual measurable review for food safety and quality objectives. This was signed by the plant manager and the director of QA/QC. In addition, the site continuous improvement policy (GMP.060, revision date 03/11/2022, revision #001) – provides an overview for the site and company commitment to continuous improvement.

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**2.1.1.2** - Senior site management shall lead and support a food safety culture within the site that ensures at a minimum: i. The establishment, documentation, and communication to all relevant staff of food safety objectives and performance measures; ii. Adequate resources are available to meet food safety objectives; iii. Food safety practices and all applicable requirements of the SQF System are adopted and maintained; iv. Employees are informed and held accountable for their food safety and regulatory responsibilities; v. Employees are positively encouraged and required to notify management about actual or potential food safety issues; and vi. Employees are empowered to act to resolve food safety issues within their scope of work.

**Response: Compliant**

**Evidence:** • Food Safety culture is defined and communicated to team members and there is a summary sheet posted in the break room and in meetings rooms. In addition, the policy (PL.005, revision date 06/21/2024, revision 001, captures the same information in Spanish and English, Food Safety Culture is broken down into 5 areas: 1) Strong leadership (Senior leaders show the way and openly commit to making safe food the top priority throughout the Company by regular meetings to discuss food safety performance and reviewing food safety performance with work teams monthly). 2) Committed managers (area managers, supervisors, etc.) showing commitment to foods safety through dedicating time and effort – by using team meetings to discuss and solve food safety challenges, encourage and require notifying management about actual or potential food safety issues. 3) Everyone contributes (everyone at the Company believes making safe food is important and everyone plays a part). 4) Everyone is accountable (everyone understands that they are held responsible for ensuring food is safe and meets regulations). 5) Knowing and acting – all people at all levels at the Company

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making sure everyone knows the risks and does the right thing every time. The site has a suggestion box at the site entrance to allow team members to (anonymously, if desired) to leave suggestions related to food safety or other matters that could improve the site. The company four pillars and the food safety culture overview are on a website (for internal and external viewing).

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**2.1.1.3** - The reporting structure shall identify and describe site personnel with specific responsibilities for tasks within the food safety management system and identify a backup for the absence of key personnel. Job descriptions for the key personnel shall be documented. Site management shall ensure departments and operations are appropriately staffed and organizationally aligned to meet food safety objectives.

**Response:** Compliant

**Evidence:** • The site had Job Descriptions for all site positions. Examples reviewed included: - QC Manager (#HR.021, revision date 09/13/2024, revision 002) - QC Supervisor (#HR.032, revision date 09/13/2024 revision 005) - Noodle shaker operator (#PDC.JD.007, Revision 001, Revised 01/13/2022) includes general expectations, responsibilities, key food safety requirements (GMPs, PPE, Food Defense, HACCP, and SQF). - Sanitation team member (#SJD.001, Revision 001, revised 02/26/2020) includes key functions, qualifications, key food safety requirements, physical requirements, etc. - QC Packaging Inspector (#JD.QC.002 Revision 004, revision date 03/10/2022) - Production team member (#PDC.JD.0011, Revision 002, last revised 04/22/2020). An organizational chart, dated 06/10/2024, outlines the structure of staff having responsibility for food safety as well as backups for key personnel and includes the corporate reporting structure (as examples, the corporate director of quality and food safety has direct reports listed for each site) and specific indications of the SQF practitioner at each site.

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**2.1.1.4** - Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review, and maintenance of the SQF System; ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

**Response:** Compliant

**Evidence:** • The site has designated individuals as SQF Practitioner (QA Manager) and Substitute SQF Practitioner (Plant Manager). In addition, the company Director of Food Safety and quality is a SQF practitioner. This is outlined in the Policy "Management Responsibility, Safe Quality Food Practitioner" (PL.002, revision date 04/30/2021, revision 001) which includes the contact information for the Corporate SQF Practitioner), as well as the site "management responsibility, safe quality food practitioner" (PL.004, revision date 02/29/2024, revision 002). Training for the site SQF practitioners included: - QA Manager (SQF Practitioner) – HACCP Alliance Systemic Approach to Food Safety 04/05/2022, FSPCA FSVP – 10/12/2024 (Cert # dc292aa6); FSPCA preventive controls for human food (PCQI) – 06/15/2024 (Cert #22fc9eb5); - Plant Manager (substitute SQF Practitioner) – Advanced HACCP (IHA Accredited) 12/26/2023.

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**2.1.1.5** - The primary and substitute SQF practitioner shall: i. Be employed by the site; ii. Hold a position of responsibility related to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code: Food Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification

**Response:** Compliant

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**2.1.1.6** - Senior site management shall ensure the training needs of the site are resourced, implemented, and meet the requirements outlined in system elements 2.9 and that site personnel meet the required competencies to carry out those functions affecting the legality and safety of food products.

**Response:** Compliant

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**2.1.1.7** - Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities.

**Response:** Compliant

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**2.1.1.8** - Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed-upon unannounced audit.

**Response:** Compliant

**Evidence:** • This was an announced audit.

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#### Summary -

**Response:** The site objectives have been communicated to all team members via monthly employee meetings. Performance of defined food safety objectives is reviewed during monthly Senior Management Meetings. Plant staff is required to report food safety issues to management, as evidenced by the Food Safety Culture policy and supported during interviews with team members throughout the site. The SQF Practitioner (QA Manager) is responsible for developing, implementing, and maintaining the SQF System. A substitute SQF Practitioner (Plant Manager) has been identified as competent to maintain the SQF system in the absence of a designated SQF Practitioner. There is also a management responsibility, safe quality food practitioner policy (PL.004, revision 004, revision date 02/14/2025) that includes the contact information for both the site practitioner and back up practitioner, as well as roles and responsibilities for both positions. The site conducts several activities to drive food safety culture, including a “reverse service day” where management changes places with workers in the production area to learn what it is like to work in the team members shoes, periodic celebrations of team members observed performing safe food activities, etc. Interviews with team members demonstrated that team members understand the importance of notifying management of food safety and food defense related issues and that there is a commitment to providing a food safe, high-quality product. The site uses employee suggestion boxes and presents employee of the month recognition to aid in engaging team member at all levels. The site verbally conveyed methods of capturing team member satisfaction with how they are being engaged in site food safety activities, understanding and being made aware of how they directly impact site food safety objectives, and how they are able to be included in messaging related to food safety objectives for the site. This is not currently being documented.

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### 2.1.2 - Management Review (Mandatory)

**2.1.2.1** - The SQF System shall be reviewed by senior site management at least annually and include: i. Changes to food safety management system documentation (policies, procedures, specifications, food safety plan); ii. Food safety culture performance; iii. Food safety objectives and performance measures; iv. Corrective and preventative actions and trends in findings from internal and external audits, customer complaints, and verification and validation activities; v. Hazard and risk management system; and vi. Follow-up action items from previous management reviews. Records of all management reviews and updates shall be maintained.

**Response:** Compliant

**Evidence:** • The site conducts an annual review meeting for senior management where the SQF System is reviewed and trends relevant food safety results are discussed. The last Management review was conducted 02/21/2025 and topics included: - GMP internal audit results 2024. Scores ranged from 96% (Feb and August

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2024) to 100% (April and May 2024). Yearly average was 95.3% (above KPI goal of 95%). - ATP Swab trends – actual failures are captured ranged from 7 fails (December 2024) to 35 fails of 368 total (August 2024) - Listeria positives (no positives in 2024. No positive results since the last SQF audit) - Salmonella positives (no positives in 2024. No positive results since the last SQF audit) - Customer Complaints (These were trend charted by customer (Pareto chart) and by month (August, September, and December had zero complaints to May which had four complaints, which was below both the quality and food safety complaint thresholds. - Food Safety culture Survey summary results for 2024 survey – 15 questions The lowest response was a 78% response of strongly agree to “if I make a suggestion that will improve food safety, I know it will be taken seriously”. The site is working on some ways to improve communication with team members and listening to help team members to feel like they are being heard. This will be fleshed out and more specific measures will be identified by the end of April. The management review was attended and signed by the corporate director QA/QC, plant manager, production manager maintenance manager, warehouse supervisor, sanitation lead and the site QA manager Review of 2023-2024 Food Safety Goals included: Food Safety related customer complaints (goal <25 complaints – actual complaints received at the time of the meeting: 2) Quality related customer complaints (goal <25 complaints – actual quality complaints received: 6) Micro results out of specification (goal <12 out of specification events – actual events 1) Third Party Annual Average audit results (goal >85% - actual 97%).

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**2.1.2.2** - The SQF practitioner(s) shall update senior site management on at least a monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented.

**Response:** Minor

**Evidence:** • Food safety plans, good manufacturing practices, and the SQF system are reviewed by management when any potential changes are made in products and processes. The SQF Practitioner updates senior site management every week during the “managers’ weekly meetings” on any matters that impact the site’s SQF System. Examples reviewed included: 02/21/2025 – Review follow up items from the prior meeting (examples improve oil flow, new placement for stretch wrap plus more than 30 items for follow up); SQF audit production schedule, pest control program; status of customer complaints (below YTD goal); discussion of annual SQF goals. Discussion of sanitation process for egg allergens. Also reviewed 12/05/2024 – high coliform on for all lines – discussion and next steps. Sanitation of aging conveyors (deep cleaning is needed). Repair issue follow up from internal GMP audits.

**Root Cause:** In 2024, the facility underwent management transition starting from the sudden exit of the QC Manager and absence of plant manager. During this gap, the continuity of the management meetings were not carried out.

**Corrective Action:** New QA manager assigned as SQF practitioner and new plant manager was assigned to the facility as SQF substitute practitioner. (Evidence 1.1) Meetings will continue to be held monthly and in the event that there is an event that may cause an interruption in the continuity of the meetings, the corporate QA team will step in to make sure that the continuity remains until this interruption is resolved.

**Verification Of Closeout:** The auditor reviewed the following documents: • (Evidence 1.1) Policy PL.004 Manager responsibility, Safe Quality Food Practitioner Revised 02/14/2025, Revision 004. Change history on document shows revision from 6/21/2024, Revision 003 shows that the 2 SQF practitioners were assigned.

**Completion Date:** April 7, 2025

**Closeout Date:** April 7, 2025

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**Summary -**

**Response:** The site had one measurable 2024-2025 food safety related goal: - Third party annual audit goal

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results - >95% - Achieved The site has had a lot of management turnover during the past 12 months and has elected to wait until April 1 to establish goals for 2025-26.

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### 2.1.3 - Complaint Management (Mandatory)

**2.1.3.1** - The methods and responsibility for handling, investigating, and resolving food safety complaints from commercial customers, consumers, and authorities, arising from products manufactured or handled on-site or co-manufactured, shall be documented and implemented.

**Response:** Compliant

**Evidence:** • There were three significant food safety complaints for 2024 – - 03/12/2024 - Metal in customer 1 product – Issue with metal nail in a finished product kit of which the noodles are a component. The site investigation could not determine that the nail came from the site and as there were several other components in the kit, there was no clear indication that the issue occurred at the site. A response was provided 03/14/2024 and it was closed out on this date.. - 10/23/2024 – Udon 4 oz. nests. Customer found a large piece of plastic on the frozen noodle nest. The site conducted an investigation and the complainant send a picture of the plastic. It was an intact cup from the Udon conveyance line (the cups are not attached to the line so it was likely dumped into the box with the nest and missed by the personnel removing the noodles and the team member that received the noodle in the box.). Corrective actions : o Add an adjustable bar to prevent the cups from crossing into a finished product case. o Meeting with team members to be more observant about watching in the event cups pass through the bar. There have been no complaints for this issue since the corrective actions were implemented. Closed out 01/12/2025 (after the restrictor bar was installed). - 11/22/2024 - A plastic shard was found in Ramen noodle nests use by March 13 2025 AC. Pictures sent by the customer to the site showed white plastic 2.3 cm in length. The site investigation showed that this was likely a broken cup and review of records showed that, while there were no missing of broken cups noted during the time the product was manufactured, the second shift did note that several cups were missing. There have been issues historically with the cup that was likely to have been the cause of the issue. The most probably cause was that a piece of the cup broke off and 100% of the cup was not retrieved. Corrective action includes: o working with the manufacturer to create a reinforced cup to minimize potential breakage. o team members were also retrained to enhance attentiveness. The site has hourly documentation of cup condition by QA. Closed 11/27/2024. 5 complaints were related to COA (either not correctly filled out or not providing the COA) during March through May (1 issue each month). This was reacted to upon receipt of the third complaint in May. Two solutions – One issue was that the results were being transcribed correctly as the handwritten information was in a different sequence than the information inputted into the computer, so the form was changed to match the computer listing. In addition, there has been increased communication between quality and the warehouse so prior to orders being filled, a COA is generated. No issues since July 2024.

**2.1.3.2** - Adverse trends of customer complaint data shall be investigated and analyzed and the root cause established by personnel knowledgeable about the incidents.

**Response:** Compliant

**2.1.3.3** - Corrective and preventative action shall be implemented based on the seriousness of the incident and the root cause analysis as outlined in 2.5.3. Records of customer complaints, their investigation, and resolution shall be maintained.

**Response:** Compliant

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**Summary** -



**Response:** The “Complaint program” (GMP.023, revision 008, revision date 11/03/2023), includes the initial notification process for complaints. Initial complaints are received by the customer service team. The corporate Director of QA/QC shall be notified of all complaints. The consumer makes the initial communication through the company website, email, letter, or phone. The Sales Department initiates the investigation and routes the form to the QA department. Complaints are captured on a log. The log headers include: Customer company name, product name, created date, date of complaint, Item #, Lot #, affected qty, status, Site location, detail of complaint, attachments (pictures, etc.), if customer returned the sample, plus any additional information on investigation corrections, closeout, etc. A cross-functional team will perform a root cause investigation when necessary. An investigation should be completed in no more than ten working days. If a sample needs to be sent to an outside lab, additional days may be needed. If the complaint is related to a food safety issues, resources will be made available to reconcile the issue within 24 hours, if possible. When necessary, a root cause analysis will be conducted as part of the complaint investigation. All information will be captured in a complaint report and recorded on a complaint log. Information included in the investigation includes review of; in process control sheets, finished product evaluation, production work sheet/downtime turnover, review of retention samples if lot code information has been provided, review of outside lab findings. Corrective actions will be implemented, as necessary, and will be followed up to confirm that the correction was effectively addressed. Complaints are reviewed during management meetings. Any trends will be included and discussed if needed. (there were 23 complaints in 2024). No trends were noted for 2023. At the time of the audit there were eight complaints for 2025. The site has increased both customers and volume in 2024 and 2025 which has accounted for the relative increase in complaints (i.e. the company does not currently normalize complaints by number of lbs. produced or cases sold, etc.).

## 2.2.1 - Food Safety Management (Mandatory)

**2.2.1.1** - The methods and procedures the site uses to meet the requirements of the SQF Food Safety Code: Food Manufacturing shall be maintained in electronic and/or hard copy documentation. They will be made available to relevant staff and include i. A summary of the organization’s food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The processes and products included in the scope of certification; iv. Food safety regulations that apply to the manufacturing site and the country(ies) of sale (if known); v. Raw material, ingredient, packaging, and finished product specifications; vi. Food safety procedures, prerequisite programs, food safety plans; vii. Process controls that impact product safety; and viii. Other documentation necessary to support the development, implementation, maintenance, and control of the SQF System.

**Response:** Compliant

**Evidence:** • The site food safety plan (Procedure# GMP.005, Revision # 003, Revision Date 02/26/2024) outlines that the Director of QA/QC will have responsibility to ensure the food safety plan is followed. A site PCQI will supervise or conduct the preparation of the food safety plan. Elements of the Plan include: Current HACCP plans (including hazard analysis, monitoring procedures, corrective action procedures, verification procedures, etc.) and FSMA preventive controls (process, allergen, sanitation, supply chain preventive controls), plus recall, environmental monitoring, and other controls, as appropriate. The food safety plan must be reanalyzed in its entirety every three years, but the individual components will be analyzed annually.

**2.2.1.2** - Food safety plans, Good Manufacturing Practices, and all relevant aspects of the SQF System shall be reviewed, updated, and communicated as needed when any changes implemented have an impact on the site's ability to deliver safe food. All changes to food safety plans, Good Manufacturing Practices, and other aspects of the SQF System shall be validated or justified prior to their implementation. The reasons for the change shall be

documented.

**Response:** Compliant

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#### Summary -

**Response:** A quality and food safety systems manual (SQF.004 revision 004, revision date 06/25/2024 - removed location from the logo) has been developed and is maintained in hard copy and electronic form. The hard copy form is contained in the "SQF binder - Carpenter" The manual is maintained by the site SQF Practitioner. The food safety manual contains: the scope of the certification, a list of products in the scope, the organizational chart and food safety policies, and programs and procedures that make up the site's SQF System. It is made available to all relevant staff by means of hard copy access in the QA Office. The manual is updated whenever there is a significant change to the food safety program, and changes are documented in the manual register. The "Scope of the Safe Quality Food Certification" (SQF.006, revision 003, last revision 06/26/2024 - removed location from the logo) indicates that the certification program will provide that the programs comply with international and domestic food safety regulations, and that the program covers SQF Food Sector 13, bakery and snack food processing and category 20 - Recipe meals, manufacture). All changes made to food safety plans, Good Manufacturing Practices, and other aspects of the SQF System are validated or justified by the Corporate Director, QC/QA Director and the site QA manager. A history of changes is documented at the end of each document and includes the description of the change, validation date, and author's name. The system is made available to all relevant staff for review and the hard copy of the program is kept in the QA office.

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### 2.2.2 Document Control (Mandatory)

**2.2.2.1** - The methods and responsibility for maintaining document control and ensuring staff have access to current requirements and instructions shall be documented and implemented. Current SQF System documents and amendments to documents shall be maintained.

**Response:** Compliant

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#### Summary -

**Response:** The site documented control program is outlined in control of documents and records (Doc #GMP.011, revision 013, last revised 08/04/2023 - last change revised to change record destruction), which defines the methods and responsibilities for document control. The program is managed by the corporate document control coordinator (responsible for all documents controlled throughout the company). Records must be kept for at least 3 years after product expiration date. Records were found during the audit to be readily accessible and adequately stored. A current list of all SQF documents is maintained, and documents were observed to be securely stored and accessible. The food safety and quality manual table of contents" - (Form #Q.208, revision 6, Revision Date 09/06/2022)- last updated electronically 03/03/2023) included all food safety related documents that the site uses. The form included the Document #, Name of document, additional information, date issued, and date reviewed. The site also had the "Document Preparation and Revision Procedure" ( Doc #GMP.012, Revision 003, last revised 02/23/2024) which outlined instructions for making uniform preparation and/or revision of company and site procedures. Each department head is responsible for maintaining documents specific to their department. As defined in this procedure, documents are reviewed and approved for adequacy by each department head and then submitted to the Document Control Coordinator before issue. Changes to identified documents may be made by the document owner and submitted to the Document Control Coordinator for review. An Example of documents reviewed: - The complaint program (GMP.023, Revision 008, revision date 11/03/2023), - finished goods list (Doc #SQF.056.TX,

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### 2.2.3 - Records (Mandatory)

**2.2.3.1** - The methods, frequency, and responsibility for verifying, maintaining, and retaining records shall be documented and implemented.

**Response:** Compliant

**2.2.3.2** - All records shall be legible and confirmed by those undertaking monitoring activities that demonstrate inspections, analyses, and other essential activities that have been completed.

**Response:** Compliant

**Evidence:** • The nonconformity in this element from the previous audit was corrected and the effectiveness of the corrective action was confirmed during this audit.

**2.2.3.3** - Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Retention periods shall be in accordance with customer, legal, and regulatory requirements, at minimum the product shelf-life or established by the site if no shelf-life exists.

**Response:** Compliant

**Evidence:** • Documents were reviewed that represented aspects of the entire food safety system, including: - Production Report that includes the amount used and lot numbers - Bio-security Truck Inspection Report - 08/08/2024, 08/12/2024, 10/09/2024, 11/07/2024, 12/16/2024, 01/17/2025, 01/20/2025 - Packing Report - 01/23/2025 - Finished Foods transfer form - 01/23/2025 - Daily Packing Report - 01/23/2025 - Transfer of pallets into production - 1/23/2025 - Final Count of Packaged Product - 1/23/2025 - Mixer Sheet - Total Liquid - 01/20/2025 (A & B shift). - Mixer batch sheet - 01/20/2025 (A & B shift). - Product in racks 01/20/2025. - Heating and Cooling Log (Form FD.051, Revision Date 08/26/2024, Revision 004) - 01/20/2025. - Preoperational Inspection Noodle Room - 01/20/2025 - X-Ray Detection log - 01/20/2025 - Sanitation Records - Daily Sanitation Checklist - 01/01-31.2025 Other documents reviewed are captured in the relevant sections of this audit.

#### Summary -

**Response:** The control of documents and records program (Doc #GMP.011, revision 013, last revised 08/04/2023 - last change revised to change record destruction), outlines the site policy for verifying and retaining records. Records are retained for three years for refrigerated, frozen, preserved or shelf stable products and 5 years for organic products. Off-site record storage is allowed after six months, so long as records can be retrieved within 24 hours. All written records are to be made in ink and must be legible (labels are not an acceptable replacement). If there are errors, a single line is made through the error, along with initials of the person making the correction. The facility procedures for recording production and correcting and initialing errors are based on customer, company, and regulatory requirements. Records were observed to be readily accessible, legibly filled out, securely stored to prevent damage, and have documented retention times. All quality and process control records shall be stored in a clean, dry environment that prevents damage and deterioration. Records are accessible to those individuals who have been granted access to the computer file.

### 2.3.1 - Specification, Formulation, and Realization

**2.3.1.1** - The methods and responsibility for designing and developing new product formulations and converting

product concepts to commercial realization shall be documented and implemented.

**Response:** N/A

**Evidence:** • N/A: Product formulation is not carried out at this site (new product was developed and tested at a sister site in southern California. The processes are basically the same, so the procedure was migrated to the site and product was scaled up rather than going through bench testing.

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**2.3.1.2** - New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure product safety. Product formulations shall be developed by authorized persons to ensure that they meet the intended use. Where necessary, shelf life trials shall be conducted to validate and verify a new product's: i. Pre-consumer handling and storage requirements, including the establishment of "use by," "best before dates," or equivalent terminology; ii. Microbiological criteria, where applicable; and iii. Consumer preparation, where applicable, and storage and handling requirements.

**Response:** N/A

**Evidence:** • N/A: Product formulation is not carried out at this site.

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**2.3.1.3** - A food safety plan shall be validated and verified by the site food safety team for each new product and its associated process through conversion to commercial production and distribution or where a change to ingredients, process, or packaging occurs that may impact food safety.

**Response:** Compliant

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**2.3.1.4** - Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment.

**Response:** Compliant

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**2.3.1.5** - The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination.

**Response:** Compliant

**Evidence:** • Processes reviewed and observed were designed to minimize or eliminate cross contamination.

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**2.3.1.6** - Records of product design, formulations, label compliance, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.

**Response:** Compliant

**Evidence:** • Records of new product scale introduction and scale up were reviewed: An example of commercialization development: Extra wavy ramen noodles (using an existing formula but creating a wavier noodle) was initially developed at a sister plant. Since the equipment is the same at both sites, the site conducted a trial run on 02/24/2025 to determine if there would be any product variability between products made at the two sites. The site used the same formula as the original site product, and the company specific equipment settings with a special cutter to create the extra wavy appearance. The information was documented on the R&D NPD Preliminary Form (Form RD.066, revision date 10/15/2014, revision 005), which included all settings including pasteurization settings and comments about specific equipment used, any other product or formula variants (there were none), etc. The product was able to match the sister site product, but the customer was seeking a lighter color noodle, so the sister site is reformulating and running additional tests. If these are approved by the customer, then this site will use the final formula and settings to attempt to produce a matched product.

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## Summary -

**Response:** Product development is not carried out at this site, however plant trials and commercialization will occur at the site. Sales and Marketing is typically responsible for generating or receiving customer ideas. These initial ideas are created as benchtop samples by the R & D team. If the samples are deemed acceptable then a meeting is held with Operations, Quality, R & D and other key team members to discuss if there are any new ingredients or equipment needed, if the process will be different from existing processes, if there are any food safety concerns, etc. If new material or suppliers are used, the procedures for approval of new ingredients and suppliers will be followed. Shelf life studies are conducted as needed. As an example were conducted on noodles From 07/20/2018 to 08/31/2018 to determine that the product shelf life could be met when refrigerated appropriately or when the refrigeration temperature could be elevated as high as 45 F. The site had a corporate developed "Product Development" program (Number SQF.009, Revision 004, last revised 06/26/2024 – change title of SOP approver), which outlined the processes for developing and approving new products While this is not typically conducted at this site, if product were to be developed at the time: once a raw material is approved, the site will use it to create a pilot sample on the production line. This sample will be used to confirm process requirements, review any changes made to the food safety program, and confirm performance of the raw material or process. These samples are submitted to the customer (if any) for approval or internally reviewed (if there is no customer). If it is determined that the product is okay the product is commercialized (via production line scale up) and supporting documentation for the scale up is captured. Formulation variations may be incorporated into final recipes due to differences in heat and humidity at this site, but any changes would require customer approval.

### 2.3.2 - Specifications (Raw Material, Packaging, Finished Product, and Services)

**2.3.2.1** - The methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications shall be documented.

**Response:** Compliant

**2.3.2.2** - Specifications for all raw materials and packaging, including, but not limited to, ingredients, additives, hazardous chemicals, processing aids, and packaging that impact finished product safety shall be documented and kept current.

**Response:** Compliant

**Evidence:** • Raw material specifications reviewed included: Soybean Oil (last updated 01/02/2020)– 100% refined, bleached, and deodorized soybean oil - Color (Lovibond) – Red=2.0, max. Yellow = 15 max - Smoke Point 45 F max - Cold test at 32 F – 20 hours max. - Chemical properties (FFA - 0.05 max; PV - 1.0 Max; Moisture - 0.09 Max; Iodine Value – 117-140) - Microbiological SPC - 5,000 cfu/g max; Yeast - 50 cfu/g max; Mold - 50 cfu/g max; Coliforms - 10 cfu/g max; E. coli – neg/25 g; Salmonella – neg/25 g) - 12 months max shelf life at 50 to 8- F and <50% RH Hi Grade 50 lb. Salt - Calcium/Magnesium - 0 to 0.3000% - NaCl – 99.70% to 100.00% - Surface Moisture – 0 to 0.1000% - Water insoluble – 0 to 0.0200% - Retained on US 30 mesh screen – 0 to 50% Vital wheat gluten (last updated 09/01/2024) – Appearance and color – Light yellow color - Odor and taste – normal taste-grain, sweet smell - Protein – Min. 82% (Nx6.25 on dry basis) - Ash – Max 1.0% (dry basis) - Moisture – Max. 9% - Water absorption rate – Min 150% (dry basis) - Mesh size – minimum 5% retained on 80 mesh screen. - Lead - <0.05 mg/kg - DDT - <0.1 mg/kg - BHC - <0.1 Mg/kg - Yeast - <35 cfu/g - Mold - <50 cfu/g - E. coli - <3 MPN/g - Salmonella – Negative/25 g - Staphylococcus - <8 MPN/g

**2.3.2.3** - All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation in the country of

manufacture and country(ies) of destination if known.

**Response:** Compliant

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**2.3.2.4** - Raw materials, packaging, and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose.

**Response:** Compliant

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**2.3.2.5** - Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may vary by crop or by season).

**Response:** Compliant

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**2.3.2.6** - Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

**Response:** Compliant

**Evidence:** • Packaging specifications reviewed included: Roll film: (Clear) – PA/PE coextruded film for non-thermo forming applications. 62 micrometer; Nominal seal strength - > 20 /15 mm. Bonding strength - >1.2 / 15 mm. Width 482.5 mm +/- 1 mm Thickness - 0.056 to 0.068 mm C.O.F (dynamic) - <0.4 Residual solvent - <5 mg/m<sup>2</sup> Tensile Strength - >30/30 mpa Elongation at the break - 40-100% Continuing letter of guarantee – Not adulterated or misbranded withing the meaning of FDCA of 06/25/21938 or produced in violation of Sections 4040 or 2301(d) of the act. Certificate of conformance, signed on 9/16/21, indicating that it does not risk chemical migration to food products.

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**2.3.2.7** - Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel.

**Response:** N/A

**Evidence:** • N/A - The Site manufactures a commercial bulk product, and no retail labels are used. Bulk labels identifying the product, net contents, ingredients, code dates, and allergens are applied to master cases.

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**2.3.2.8** - Description of services for contract service providers that have an impact on product safety shall be documented, current, include a full description of the services to be provided, and detail relevant training requirements of all contract personnel.

**Response:** Compliant

**Evidence:** • The contract service providers procedure (GMP.00 Revision Date 02/26/2024, Revision # 003) included the requirement that contract service providers provide, Cert of liability, scope of work, relevant food safety training, current accreditations, etc. Contract suppliers must review and sign the site GMP policy and follow all GMP practices. Documentation will be reviewed every two years. An example reviewed: - Laundry/smock provider. Contract (dated 08/14/2020) which include the usage and price of the materials provided and the guaranty to resolve any issue withing 10 working days of notification receipt. Documentation included the company HACCP program (01/03/2023) which identifies the company as a HACCP conscious uniform rental service. Materials used in the uniforms, separation of clean and soiled garments, and process descriptions of the wash cycle, ATP testing, random testing of garments for APC, Listeria, Salmonella Yeast and

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Mold, along with redundant testing quarterly at a second lab. The provider identified 3 CCPs (Wash, Steam tunnel/dryer (must be 240 to 280F), and garment delivery (including clean and dirty garment separation on the truck), Monitoring program for CCPs and a flow diagram outlining the process steps were included in the HACCP program. Other SOP's included disinfecting garment folding tables, cleaning/removing debris from the dryer area, and washer loading and unloading. A cross check against the log showed that the service providers checked on the list matched the service providers that were in use at the site.

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**2.3.2.9** - Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable: i. Microbiological, chemical, and physical limits; ii. Composition to meet label claims; iii. Labeling and packaging requirements; and iv. Storage conditions.

**Response:** Compliant

**Evidence:** • The site had a finished goods list (Doc #SQF.056.TX, Revision 004, Last revised date 12/23/2024, supersedes 07/27/2023) which contained 24 product skus. The list captures the production line, the item #, the product, whether it is pasteurized or not (and, if so, the pasteurization time, units/case. Weight/case, cases/pallet. Specifications were available for all products. Examples reviewed included: Product # 01-01-1040 Chow Mein (No Bake) 3 lbs. refrigerated (Revision 002, last revision date 11/29/2024) Ingredients: Enriched wheat flour (wheat flour, niacin, reduced iron, thiamine mononitrate riboflavin, folic acid), water, highly refined soybean oil, vital wheat gluten, salt, potassium sorbate, sodium benzoate, potassium carbonate, sodium carbonate, riboflavin). Allergens: Wheat – Manufactured on equipment that also processes egg and soy (Note the site no longer has any products that contain soy). Spec (Noodle length: 15" +/-4"; Noodle thickness: 2.20 +/- 0.3 mm; Noodle width: 2.20 +/- 0.3 mm); package weight 2.90 to 3.30 lbs. Physiochemical (Moisture: 49% +/-2%; pH: 6.6 +/- 0.4) Net wt.: target 3.1 lbs. – 2.7 to 3.3 oz. Microbiological (TPC: <50,000 cfu/g (AOAC 990.12); Coliform: <100 cfu/g (AOAC 991.14);E. coli: <10 cfu/g (AOAC 991.14); Yeast: <300 cfu/g (AOAC 2014.05) ; Mold: <300 cfu/g (AOAC 2014.05); S. aureus (Coag +): <100 cfu/g (AOAC 2003.07); B. cereus: <100 cfu/g (AOAC980.31)) Shelf life – 31 days under refrigeration (37 to 43F). Label examples included the product name, item number, lot code, best by date, keep refrigerated designation, ingredient statement, the allergens (wheat), net weight (30 lbs.), count/case, and the requirement to keep frozen. Product # 01-01-5036-01 and 01-01-5036-04 Precooked Noodles, 28 x 16 oz pasteurized. (Revision 012, last revision date 09/05/2023) Ingredients: Water, wheat flour, highly refined soybean oil, vital wheat gluten, salt, potassium carbonate, sodium carbonate, riboflavin) Allergens: Wheat – manufactured ion equipment that also processes eggs. Spec (Noodle length: 12" +/-6"; Noodle thickness: 2.2 +/- 0.3 mm; Noodle width: 2.2 +/- 0.3 mm)l package weight 16 oz. +/- 0.7 oz. Microbiological (TPC: <25,000 cfu/g (AOAC 990.12); Coliform: <100 cfu/g (AOAC 991.14);E. coli: <10 cfu/g (AOAC 991.14); Yeast: <300 cfu/g (AOAC 2014.05) ; Mold: <300 cfu/g (AOAC 2014.05). Shelf Life – 3 months under refrigeration (37 to 43 F). Label examples included the product name, item number, customer 1 item #, Pack date, use before date, , keep refrigerated 40 F or below, ingredient statement, allergens (wheat), nonmanufactured on equipment that also processes eggs, net weight (28 lbs.)

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**2.3.2.10** - Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained. A list of all the above specifications shall be maintained and kept current.

**Response:** Compliant

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**Summary -**

**Response:** Specifications for raw materials, packaging, ingredients, additives, chemicals, finished products, processing aids, and contract services have been documented. A policy defining the methods and responsibilities for developing and maintaining specifications has been documented and implemented in

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“RD.001 New Product Development Procedure” and “GMP.021 Sites and Materials Approval Process.” Raw and packaging materials are validated to ensure product safety, regulatory requirements, and fit-for-purpose requirements are met. These are done by receiving and reviewing the certificate of insurance and maintaining letters of guarantee. The shipping personnel and QA technician responsibility is to verify raw materials and packaging upon receipt. Inspection of pre-printed packaging shall be conducted at receipt of packaging. A minimum of five samples are inspected from each inbound load to verify that all required information is present, accurate, and legible for reading. Review of packaging shall be recorded in the packaging verification log. There is a register of raw material, ingredients, and packaging specifications, called “Approved Sites and Ingredients” that was current. All contract service providers’ services impacting food safety are documented in the “contract service providers log,” (Form #QA.0546, Date of origin 03/09/2023, revision 1) which included providers of services, including: sanitation chemicals and sanitizers, third party laboratory, lien and garment service, pest control provider, Scale calibration service, Waste management, Boiler service, Metal detector calibration service, and SQF certifying body. He site also has a Contract Service Providers SOP (Doc # GMP.008, revision 003, revision date 02/26/2024) that outlines the procedure for how service providers are selected, required training (e.g. site visitor GMPs every two years, and reasons and methodology for revoking access rights). Finished product specifications were current, documented, and approved by the site’s customers. Specifications include description, allergen statement, ingredients, standard composition, physical and chemical attributes, storage conditions, shelf life, microbiological standards, GMO status, sampling criteria, nutritional facts, packaging information, pictures, and pallet labeling.

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### 2.3.3 - Contract Manufacturers

**2.3.3.1** - The methods and responsibility for ensuring all agreements with contract manufacturers relating to food safety, customer product requirements, their realization, and delivery shall be documented and implemented.

**Response:** N/A

**Evidence:** • N/A - The site does not use contract manufacturers.

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**2.3.3.2** - The site shall establish a method to determine the food safety risk level of contract manufactured product and shall document the risk. The site shall ensure that: i. Products and processes of co-manufacturers that are considered high-risk have undergone an audit by the site or third-party agency to confirm compliance with the SQF Food Safety Code: Food Manufacturing and regulatory and customer requirements; ii. Products and processes of co-manufacturers that are considered low-risk meet the requirements of the SQF Food Safety Code: Food Manufacturing, or other GFSI benchmarked certification programs, and regulatory and customer requirements; and iii. Changes to contractual agreements are approved by both parties and communicated to relevant personnel.

**Response:** N/A

**Evidence:** • N/A - The site does not use contract manufacturers.

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**2.3.3.3** - Contractual agreements with third party storage and distribution businesses shall include requirements relating to customer product requirements and compliance with clause 2.3.3.2 of the SQF Food Safety Code: Food Manufacturing. Contractual agreements shall be approved by both parties and communicated to relevant personnel. The site shall verify compliance with the SQF Code and ensure that customer and regulatory requirements are being met at all times.

**Response:** N/A

**Evidence:** • N/A - The site does not use contract manufacturers.

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**2.3.3.4** - Records of audits, contracts, and changes to contractual agreements and their approvals shall be



maintained.

**Response:** N/A

**Evidence:** • N/A - The site does not use contract manufacturers.

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**Summary -**

**Response:** N/A - The site does not use contract manufacturers.

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### 2.3.4 - Approved Supplier Program (Mandatory)

**2.3.4.1** - The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier shall be documented and implemented. A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained. Code Amendment #2 Approved supplier registers shall include supplier contact details. All approved and emergency suppliers shall be registered.

**Response:** Compliant

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**2.3.4.2** - The approved supplier program shall be based on the past performance of a supplier and the risk level of the raw materials, ingredients, processing aids, packaging, and services supplied, and shall contain at a minimum: i. Agreed specifications (refer to 2.3.2); ii. Reference to the level of risk applied to raw materials, ingredients, packaging, and services from the approved supplier; iii. A summary of the food safety controls implemented by the approved supplier; iv. Methods for granting approved supplier status; v. Methods and frequency of monitoring approved suppliers; vi. Details of the certificates of conformance, if required; and vii. Methods and frequency of reviewing approved supplier performance and status.

**Response:** Minor

**Evidence:** • Once approved, the supplier will be reviewed annually. If there are any complaints or materials are out of specification, a supplier complaint or incident report will be submitted to the supplier. The policy includes a review of the specifications of products, the supplier's food safety controls, procedures for granting and monitoring approved suppliers, the level of risk of products to the site and details of requirements for Certificate of Conformance, Certificates of Analysis, and testing. A register is maintained of all current approved suppliers, which was reviewed during the audit and found to be acceptable. A separate register with a risk analysis of all raw materials was in place. Risk considered included Biological, Chemical and Physical risks and the severity and likelihood of hazards. Packaging materials were all deemed low risk for each type of hazards. Risks for raw materials had low to medium low risks (none were deemed significant). If the supplier is not GFSI certified, the vendor must provide: a product specification sheet, Kosher Certification, 100 g Nutritional Information, Letter of Guarantee, Certification of Insurance, GMO Letter, Country of Origin, MOQ and Lead Time, Pricing, Organic Certificate, and 3rd Party Audit. Upon approval, purchasing assigns an item number that triggers an R&D team member to place ingredient documents into the ingredient. For certain ingredients, the company reserves the right to audit vendors. Minor NC: The site has not conducted risk analyses on suppliers of services or the services themselves. In addition, the site did not have any documentation that service providers for waste management and laundering had signed and acknowledged the site visitor GMPs within the past 2 years (site program requirement).

**Root Cause:** Unclear responsibility in the GMP.008 Revision 003 of conducting risk analysis. Lack of adherence to the SQF version 9, 2.3.4.2

**Corrective Action:** Review and update new version of GMP.008 Revision 003 to be in accordance to SQF Version 9, 2.3. (Evidence 2.1) New version will include clear responsibilities in GMP.008 to develop risk analysis of service providers. (Evidence 2.2)

**Verification Of Closeout:** The auditor reviewed the following documents: • (Evidence 2.1) New version of GMP.008, revision 004. • (Evidence 2.2) Risk Analysis of Contract Service Providers

**Completion Date:** April 7, 2025

**Closeout Date:** April 7, 2025

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**2.3.4.3** - Verification of raw materials shall include certificates of conformance, certificates of analysis, or sampling, and testing. The verification frequency shall be identified by the site.

**Response:** Compliant

**Evidence:** • There was an approved suppliers/ingredients register for all raw materials and the plant had a matrix of approved suppliers that included: Item#, Ingredient name, Supplier Name; allergens, GFSI certification, whether a Food Safety questionnaire was required (the corporate protocol is to require current GFSI certification or a completed food safety questionnaire to be completed and on file at the corporate office and electronically). Also required: Letter of Guarantee, product specification; organic status, nonGMO, kosher, vegan, and gluten free status (and relevant certification cert if those claims are made). Examples reviewed: Flour and oil supplier (low risk) – No issues last three years – SQF audit on file expires 06/27/2025. Egg supplier (powder) (low risk) – No third party issues in the past three - SQF certificate on file 04/23/2025 Packaging provider (low risk) – No third part issues in the past three years – FSSC22000 certificate expires 11/22/2027.

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**2.3.4.4** - The receipt of raw materials, ingredients, processing aids, and packaging from nonapproved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use.

**Response:** Compliant

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**2.3.4.5** - Raw materials, ingredients, and packaging received from other sites under the same corporate ownership shall be subject to the same specification requirements (refer to 2.3.2), approved supplier requirements, and receiving inspections as all other material providers.

**Response:** Compliant

**Evidence:** • Vendors are included in the corporate approved supplier register and each site that is allowed to use the vendor and raw material is listed on the register. The site register also includes the "Supplier Risk Assessment" (Form QA.005C, revision date 03/19/2024, supersedes 10/19/2023, revision 002). The list is managed by the Manager of Corporate procurement. The list includes: Supplier name/manufacturer, 3rd party audit certificate, Any FDA recall in 3 years, Any FDA warning in the last 3 years? Notes, and overall risk (all were deemed "low" risk). The risk assessment also includes the type of 3rd party audit certificate (i.e. SQF, BRCGS, FSSC 22000, HACCP, etc. and expiration date). Packaging for both food contact and nonfood contact packaging risks have been assessed (all risks were low). Supplier risk assessment is conducted separately, and included: supplier name, 3rd party audit certificate, any FDA recalls or warnings in the past 3 years, any additional notes, and overall risk. A certificate of analysis is requested from each supplier for each ingredient lot provided. The Certificates of Analysis contain, as applicable: microanalytical data, Chemical data, protein level, moisture, and Lot code. There was a separate risk analysis of packaging material (preprinted films, non-preprinted films, and nonfood contact materials such as cases, bags etc.) – all were deemed to be low risk for Biological, Chemical, and Physical hazards, along with a justification for the determination of the level of risk. After approval of a new ingredient, the Director of QA/QC uses the suppliers specification as a source of physical, chemical, or microbiological tolerances. Information gathered during plant trials conducted by R&D will also be used. Attributes to be included will depend on the use and risk to the finished product. Packaging Materials Potential vendors are selected for review by the R&D team via several sources; vendor's reputation in the industry, trade Journals, etc. An annual review is completed for all Sites that generated a Material Deviation by the JSL Management Team, those ingredients deemed "high risk," and all flours. Conforming

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Sites are reviewed every three years. The procedures for emergency use of non-approved Sites have been documented. Per the Site approval policy, incoming materials from sister sites are subject to specifications and Site approval requirements. All approved Sites are maintained, reviewed during the audit, and found acceptable. Raw materials used to manufacture the Customer 1 product traced during the audit salt, potassium carbonate, riboflavin, unenriched flour, and vital wheat were verified from Sites on the Approved Site List.

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**2.3.4.6** - Supplier audits shall be based on risk (as determined in 2.3.4.2) and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

**Response:** Compliant

**Evidence:** • N/A - Although it was marked compliant, the clause is not applicable. The Site does not require second party vendor audits and relies on third-party food safety audit certificates and reports.

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#### Summary -

**Response:** The site has a written "Supplier Approval Procedure" (GMP.021, revision 006, last revised 04/08/2024 – last revision was a change in the procedures section ) which covers the procedures for approving the sites of raw materials, ingredients, packaging materials, and services. The policy includes a review of the specifications of products, the supplier food safety controls, procedures for granting and monitoring approved Sites, the level of risk of products to the site, and details of requirements for Certificate of Conformance, Certificates of Analysis, and testing. The program is managed at the corporate level and the Director of QA/QC is responsible for ensuring that this procedure is followed. Potential vendors are selected for review by the corporate R&D team via several sources, including: the vendor's reputation in the industry, trade Journals, etc. The R&D team initiates the first contact and discussion with the prospective vendor. New suppliers require the endorsements of the PCQI from two of three R& D, Purchasing, or QA. Responsibilities are defined for members of each of the three departments. During the approval process, risk assessments are conducted for each raw material and supplier being reviewed and will include considerations for "inherent risk of the ingredient determined by its category and functionality, supplier recall history and performance, the likelihood of physical contaminants to occur in the product. Suppliers must agree to allow the site to perform second party audits or to have third party audits conducted by accredited auditing companies. There is a general scorecard that includes components of food safety (i.e. the number of food safety and non-food safety incidents that have occurred by the supplier). The customer 1 requirement that raw materials operate under a food management system that meets all applicable regulatory requirements is met, based on site supplier approval criteria. The approved supplier program was compliant with customer 1 requirements.

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### 2.4.1 - Food Legislation (Mandatory)

**2.4.1.1** - The site shall ensure that at the time of delivery to customers finished products shall comply with food safety legislation applicable in the country of manufacture and sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice.

**Response:** Compliant

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**2.4.1.2** - The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented.

**Response:** Compliant

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**2.4.1.3** - SQFI and the certification body shall be notified in writing within twenty-four (24) hours as a result of a regulatory warning or event. Notification to SQFI shall be by email to [foodsafetycrisis@sqfi.com](mailto:foodsafetycrisis@sqfi.com).

**Response:** Compliant

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#### Summary -

**Response:** The auditor reviewed "Food Legislation" (SQF.008, Revision #003, Date of Origin/last revised 08/06/2024 – revised to change contact information). The site has ensured that products delivered to its customers comply with regulatory requirements in the country of use. Regulatory compliance for this operation includes FDA, Texas State Health Department, and Kosher Certification. The site keeps updated about changes in relevant legislation, technical developments, and industry codes of practice in their specific industry, by means of FDA Updates and Outside 3rd Party Training, as well as subscriptions to industry related newsletters and periodicals. The site has a written provision that the certification body, and SQFI will be notified within 24 hours if a food safety event requiring public notification occurs. The Corporate Director QA/QC is responsible for obtaining relevant regulatory information from sources such as FDA, USDA, trade organizations, etc. and sharing any relevant information with the senior team. Resources used for determining food safety related protocols included: 21CFR Parts 100 to 169 (inclusive of part 117); FDA "A Food Labeling Guide" January 2013; "Allergen Management in the Food Industry" (Boye, and Godefroy 2010); annex to "Control of Salmonella in Low moisture foods" (GMA – February 2009); "Recall Procedures" (USDA – August 2018); "Checking of Net Content of Packaged Goods" (NIST 2018); "Control of L. monocytogenes in RTE Foods: Guidance for industry" FDA 01/2017; Food Safety Magazine (ongoing); "Pasta and Noodle Technology" (Kruger, Matsuo, and Dick 1996), etc. Resources available are outlined in "Resources (SQF.007 – Date of origin 03/10/2022 revision 001) includes a listing of key documents used to help guide the site in food safety practices (as examples 21 CFR part 100 to 169, AFDA Food labeling guide, etc. The site has registered with the FDA to comply with FDA bioterrorism registration requirements. FDA Registry (# xxxxxxx9612). Expires 12/31/2026. This complies with customer 1 requirements.

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## 2.4.2 - Good Production Practices (Mandatory)

**2.4.2.1** - The site shall ensure the applicable Good Manufacturing Practices described in Module 11 of this Food Safety Code are applied or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures that ensure food safety is not compromised.

**Response:** Compliant

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**2.4.2.2** - The Good Manufacturing Practices applicable to the scope of certification outlining how food safety is controlled and assured shall be documented and implemented.

**Response:** Compliant

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#### Summary -

**Response:** The site has several relevant GMP documents (example: "Employee Practices and Hygiene" (Procedure GMP.001, revision # 010, Revision Date 08/05/2024 in English and Spanish – revised change glove policy to add usage clarification) which outlines the policies that the team members are expected to follow to help make safe food. This includes a dress code (team members will wear smocks and also have clean outer garments). Smocks and aprons are not allowed to be worn outside of the plant, in restrooms, or in breakrooms. The site glove policy indicates that production team members will wear colored (the site used blue gloves at the time of the audit) vinyl disposable gloves . Gloves with tears and holes are unacceptable and

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must be changed out. If a team member is reassigned to a different area, then the old gloves must be discarded and new gloves worn. Maintenance, Janitorial, pasteurized rack handling, and frozen product handling will require the use of different color gloves than those of production team members. The property, buildings and equipment are located, constructed, and designed to ensure food is manufactured in a safe, hygienic environment. The site has written and implemented those Good Manufacturing Practices applicable to the scope of this certification. Food safety pre-requisite programs are based on those found in the SQF Module 11 Manual. Team members were observed to be following site GMP's and the site conditions were also GMP compliant. The property, buildings, and equipment are located, constructed, and designed to ensure food is manufactured in a safe, hygienic environment. The effectiveness of the pre-requisite programs are verified every month. The GMP and glove use policy are compliant with customer 1 requirements. All team members touching product and, in general all support team members, were observed to be wearing gloves during the site tours.

### 2.4.3 - Food Safety Plan (Mandatory)

**2.4.3.1** - A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented and maintained and shall outline how the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

**Response:** Compliant

**Evidence:** • The "Hazard Analysis Control Plan-HACCP Program" (revision 28, Program GMP.004, Revision date 01/29/2025 - revised to update with correct members) , includes the HACCP team for each site and the statement that the HACCP plan is produced in accordance with regulatory agencies such as Codex Alimentarius and/or NACMCF. Five HACCP Plans have been developed, implemented, and maintained by the site. The plans are identified as: HH.001 (revised 02/10/2025, supersedes 02/28/2024) "Noodles, Formed and Frozen" Plan Reassessment Change Form Showed plan reviewed on 02/10/2025. There is a checklist that indicates reassessment. Questions include: Product description changed? Formula change? Ingredients/packaging changed? Any new storage needs? Process flow diagram changed? (Yes); Personnel changed? (Yes). HH.002 (revised 02/11/2025, supersedes 02/29/2024) "Noodles, steamed/boiled" HH.003 (revised 02/12/2025, supersedes 02/29/2024) "Rehydrated Product" HH.004 (revised 02/13/2025, supersedes 05/14/2024) "Noodles, heat treated" HH.005 (revised 02/14/2025, supersedes 03/01/2024) "Skins and Wrappers NRTE"

**2.4.3.2** - The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant raw materials, packaging, processing aids, products, and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food safety team.

**Response:** Compliant

**Evidence:** • A multi-disciplinary Food Safety Team has been identified and trained, with documentation found in the "HACCP team assemble." (part of HH-001, Revised 02/10/2025, supersedes 02/28/2024) The document has the name, experiences, and certifications, including PCQI, HACCP, and FSVP. Team members included the Director of QA/QC, plant manager, QA Manager, Maintenance Manager, Production Manager, QA Technical Coordinator, Sanitation Lead, and Warehouse Supervisor). All team members have had either third party HACCP training or internal site HACCP training. The plans include a list of all products in the scope of the certification (as an example, Noodles, formed and frozen includes: Lo mein 1.3 oz nests, lo mein noodles 3.9

oz., ramen nests 1.5 oz., whole wheat yakisoba 2.06 oz nets, shanghai bricks 6 oz., and Udon 4. Oz nest. All products are identified as ready to cook. A complete product description, intended product use, including vulnerable populations, and flow diagrams for each process, including all input and output steps in the process. In addition, the assessment includes an evaluation of CCP critical limits, monitoring, corrective action, verification and record keeping that includes: Do the CCPs control the hazards? Are the CCP critical limits adequate? etc. The QA Manager/SQF Practitioner is the HACCP Team leader and has had formal HACCP training (HACCP Alliance Systemic Approach to Food Safety 04/05/2022). All HACCP team members have taken formal 16 hour HACCP training courses (i.e. HACCP: Developing and Implementing a Hazard Analysis and CCP plan (16 hours - ), FSPCA FSVP – 10/12/2024 (Cert # dc292aa6); FSPCA PC for Human Foods (PCQI) – 06/15/2024 (Cert #22fc9eb5); Plant Manager (substitute SQF Practitioner) – Advanced HACCP (IHA Accredited) 12/26/2023; Production Manager - 06/06/2021. The team also includes the corporate director of QA/QC, and the Corporate QA Technical Coordinator. The HACCP team signed off on the Plans and flow charts on 2/21/2025 and the walkthrough was included as part of the annual management review meeting (all flows). The team also was listed by title, name, industry experience and certifications. (example: QA Manager Experience: BS in Food science, Chemical Engineering; 2 years in food manufacturing 4 years in food microbiology research. Certifications: HACCP alliance; PCQI certification).

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**2.4.3.3** - The scope of each food safety plan shall be developed and documented including the start and endpoints of the processes under consideration and all relevant inputs and outputs.

**Response:** Compliant

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**2.4.3.4** - Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions.

**Response:** Compliant

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**2.4.3.5** - The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative uses of the product.

**Response:** Compliant

**Evidence:** • HACCP Product Description (example – Noodles, Formed and Frozen) Long noodles made from enriched wheat flour, cooked by either steaming or boiling, placed in a mold and quick frozen then cased in bulk. Shelf Life: Keep Frozen 0+/-10F. Shelf life is valid as long as the package remains sealed. Once the package has been opened, product should be used immediately. Lo Mein: 14 month shelf life; Chow Mein: 9 month shelf life; Ramen: 9 month shelf life; Yakisoba: 12 month shelf life. For institutional sales only. Further processing is required. Target Customer Group: General Public, except for vulnerable groups. Consumption by vulnerable group: Vulnerable groups may include any individual who is allergic to wheat, infants or elderly, also some consumers with preferences and recipes and/or special recipe/diet.. No potential alternative uses other than regular noodles. Do not ship if product temperature is over 20F. Ingredients (example 01-01-6005-04 Low Mein 1.3 oz. Water, Wheat Flour, Highly Refined Soybean Oil, Sodium Carbonate – Allergens: wheat). All products are considered ready to cook. HACCP Product Description (example – Skin wrapper) Asian style wrapper made from wheat flour that is paper thin and cut to size. It is then vacuum packed and cased. It can be frozen or refrigerated. Shelf Life: Keep 6 weeks to 2 months refrigerated (36 F +/- 3 F). 9 to 12 months frozen 0+/-10F. Shelf life is valid as long as the package remains sealed. Once the package has been opened, product should be used immediately. For institutional and retail sales. Further processing is required.

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Consumption by vulnerable group: Vulnerable groups may include any individual who is allergic to wheat and egg, infants or elderly, also some consumers with preferences and recipes and/or special recipe/diet.. Do not ship if refrigerated product temperature is over 40F or if frozen product temperature is over 20F. Ingredients (example 01-06-1000-04 Egg Roll 16 oz. Enriched Wheat Flour, Water, Salt, Whole Egg Powder, Sodium Propionate, Citric Acid, Sodium Benzoate, Calcium Sulfate, L-Cysteine, Tricalcium phosphate, dusted with corn starch.

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**2.4.3.6** - The food safety team shall develop and document a flow diagram covering the scope of each food safety plan The flow diagram shall include every step in the process, all raw materials, packaging, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation.

**Response:** Compliant

**Evidence:** • Flow Charts were reviewed: Example: Form HH.001 (noodle, formed and frozen) revised 02/10/2025 (Changes to personnel. Line reviewed with no changes to the flow chart). Inputs included Dry ingredients, water, receive flour in bulk or bag, nitrogen, oil application, packaging materials; Outputs included product shipped, and waste after weigh checking. Rework is not allowed at this site. All ingredients are dry and do not require temperature control . Example: Form HH.004 (Noodles, Heat treated) revised 02/10/2025 (Revised to include optional X-Ray for customer 1 on flow chart). Inputs included Dry ingredients, water, receive flour in bulk or bag, oil application, packaging materials. Outputs included product shipped, and waste at mixer, cutter, cool tank, and vertical filler/coder The nonconformity in this element from the previous audit was corrected and the effectiveness of the corrective action was confirmed during this audit.

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**2.4.3.7** - The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

**Response:** Compliant

**Evidence:** • The Hazard Analyses included considerations for : Biological – Yeast/Mold, Coliforms, E. coli, Listeria, Salmonella, Pathogenic E. coli, B. cereus, cockroach, small flies, rodents, cigarette beetles, snakes, mice. Chemical – Aflatoxin, mycotoxins (Nivalenol), heavy metal contamination (lead, mercury, arsenic, etc.), chemical contamination, ink migration, allergens Physical – Metal, wood, plastics, paper, rocks, Allergen – wheat and Egg (Wheat is uncontrolled. Egg is in Wrappers only) These were identified hazards for all five of the site HACCP plans.

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**2.4.3.8** - The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.

**Response:** Compliant

**Evidence:** • The site had a risk matrix to identify hazard significance: Likelihood: (1=Low-unlikely to occur – issues <1/year. 3=High -virtually certain to occur (could happen now); 2=Medium – somewhere between low and high Severity: 1=low-issue results in customer dissatisfaction. 2=medium-potential food quality issues; 3=high- reasonably likely that incident is food safety related resulting in injury, fatality, recall, etc. Overall score 1-3 – requires prerequisite program 4-6 - Preventive control point 9=CCP required.

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**2.4.3.9** - The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.

**Response: Compliant**

**Evidence:** • The Site had a risk matrix to identify hazard significance: Reviewed the hazard analysis for skin and wrappers, NRTE (HH.005 revision date 02/14/2025, supersedes 03/01/2024) Examples assessed: Step 1a Receive Dry Ingredients – Biological (Salmonella, Yeast/Mold, Coliforms, E. coli), Severity of Hazard (3 -high); Likelihood of occurrence (2-medium). Overall risk 6 (requires a Preventive Control). Justification: the dry ingredient has low risk of growth for microorganisms but still may have microbiological contamination endemic in the ingredient. Preventive control: Supply chain control – COA required upon receipt, and the incoming ingredients program. No CCP required for this step. Step 5 Mixer – Physical (metal). Severity and likelihood high. Overall Risk 9 (requires CCP) – Justification: Likelihood is high because of many moving machinery parts along the process line. It was noted that the process control point is at the metal detector, but it is not applied at this step (it is at the metal detector step, which is step 17 on the hazard analysis) Step 20 Case Code – Chemical (Allergen wheat and egg) Severity of Hazard (3 -high); Likelihood of occurrence (2-medium). Overall risk 6 (requires a Preventive Control). Justification: Mislabeling might cause illness for the customer if they are allergic to these items. Control measure: Allergen Control (PC) – label verification.

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**2.4.3.10** - Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

**Response: Compliant**

**2.4.3.11** - For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard(s) and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).

**Response: Compliant**

**Evidence:** • Skins and Wrappers - The site identified one CCP: Metal Detection – Critical Limits: 2.5 mm ferrous, 3.5 mm nonferrous, and 3.5 mm stainless steel. (metal detector is on and functioning). Monitoring Procedures, Frequency, and Responsibility – the metal detector is tested before production starts, every hour (+/- 30 minutes), and after production ends. The site passes each test sample through three times and this is recorded on the metal detection log QC.013. Wands are passed through three times each. Noodles, Heat treated The site identified one CCP: Metal Detection/X-Ray (X-Ray is only in use for customer 1 product and it is the CCP for the line in these events. When the X-Ray is not in use it is removed from the line and replaced by the metal detector, which is the CCP when it is in place). Critical Limits – Metal detector: 2.5 mm ferrous, 3.5 mm nonferrous, and 3.5 mm stainless steel. (metal detector is on and functioning). Critical Limits – X-Ray: 2.5 mm ferrous, 3.5 mm nonferrous, 3.5 mm stainless steel, 2.0 mm ceramic, and 2.0 mm quartz glass. (X-Ray is on and functioning). Monitoring Procedures, Frequency, and Responsibility – the metal detector or X-ray unit is tested before production starts, every hour (+/- 30 minutes), and after production ends. The site passes each test sample through three times and this is recorded on Metal detection log QC.013 (for Metal detection) or the X-Ray detection log. Wands are passed through three times each. Corrective Action: If the test sample is not detected or there is a deviation from the Critical Limit, the QA manager or designee is responsible for determining the root cause of the deviation and corrective actions to eliminate the deviation. Product held to the last good check, then product will be tested once control of the MD or Xray has been reestablished. Measures to prevent recurrence have been established. No product that is injurious to health or otherwise adulterated as a result of the deviation will be permitted to enter commerce.

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**2.4.3.12** - The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency.

**Response:** Compliant

**Evidence:** • The monitoring and documentation of the metal detection CCP was witnessed during the audit. The technician followed the protocol as outlined. All wands were observed to be rejected for each of the three passes for each wand (nine total passes) and the belt retraction system, lights, and alarms all functioned as intended. The quality control technician who conducted the testing was interviewed and was able to verbally indicate the process and why metal detection was important, as well as identifying what to do if the metal detector failed (i.e. stop the line, hold product to the last good check, confirm that the metal detector was fixed and operating, rerun impacted product through the metal detector). CCP (metal detection) records were reviewed for 07/24/2024, 10/12/2024, 01/20/2025, 02/24/2025, 03/18/2025 and were found to be complete, legible, and initialed by the staff undertaking the monitoring activity. No issues were noted. The records also had sign off by the QA manager that they were reviewed within 48 hours of document creation (Note: CCP checks must be reviewed within 24 hours of completion). No deviations were noted on the days reviewed. The plans were comprehensive and included all key elements of a HACCP plan, including flow charts, Hazard analysis (including raw materials and packaging hazard analyses), a severity/likelihood risk grid to help determine if the identified hazards were a significant risk, a model for determining if hazards of significance required CCPs or Preventive controls (PCs), monitoring protocols for CCP's and corrective actions in the event of a CCP deviation. Plans are kept on file in the QA Office and maintained by SQF Practitioner and QA Director. The auditor reviewed HACCP Records for Pre-operational inspection, CCP Logs (Metal Detection), Sanitation, Product testing, Positive Release, Sanitation, and Calibration records from 01/20/2025, 02/24/2025, and 03/18/2025, and these were found to be complete, legible, and initialed by the staff undertaking the monitoring activity. X-Ray – On and functioning – 2.5 mm Fe, 3.5 mm nonferrous, 3.5 mm Stainless Steel, 2.0 mm Ceramic, 2.0 Quartz Glass. Checks at start up, every hour (+/- 30 minutes) and at end of production. X-Ray check records were reviewed for 01/20/2025 and were found to be complete, legible, and initialed by the staff undertaking the monitoring activity. No issues were noted.

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**2.4.3.13** - The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.

**Response:** Compliant

**Evidence:** • Corrective Action: If the test sample is not detected during the metal or X-Ray detection process, or there is a deviation from the Critical Limit, the QA Manager or designee is responsible for determining the root cause of the deviation and corrective actions to eliminate the deviation. Product is held to the last good check, then product will be tested once control of the metal detector/X-Ray has been reestablished. Measures to prevent recurrence have been established. No product that is injurious to health or otherwise adulterated as a result of the deviation will be permitted to enter commerce. If product is rejected in a functioning metal detector, it will be analyzed for the source of metal and an attempt to eliminate the metal source will be made once it has been determined. The QA manager or designee will verify records on a weekly basis to assure documentation complies with internal and regulatory requirements. An example of a deviation and response for metal detection was reviewed for production date 02/24/2025: the product 01-01-1040-04 Chow Mein, 3 lbs. At the 13:17 check none of the test wands were successfully rejected by the metal detector; eight pallets were placed on hold, because the metal did not pass. The metal detector was repaired and then repassed through on the same day. No product was rejected, and the eight pallets were released.

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**2.4.3.14** - The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur.

**Response:** Compliant

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**2.4.3.15** - Procedures shall be in place to verify that critical control points are effectively monitored and appropriate corrective actions are applied. Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).

**Response:** Compliant

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**2.4.3.16** - Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used.

**Response:** Compliant

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**2.4.3.17** - Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.

**Response:** Compliant

**Evidence:** • FSMA preventive controls were identified on the hazard analysis including: Supply Chain Controls (ingredient approvals, ingredient testing, LOGs, COAs, visual inspection of ingredients upon receipt, and truck wash certificates) Process Control – (cooking noodles, silo screens check, cup mold inspection, metal detection prior to the CCP) Allergen Control (storage separately, labeling, temperature control) Sanitation Control (documented cleaning, weekly, after production) Other PRPs identified as controls included: Pest Control, G & BP program, Wooden Pallet program There were also similar summaries for sanitation PC (cleaning of bulk storage of the flour freezer tunnel, process PC (silo inspection, metal detection, cooking, cup mild inspection) and supply chain (receiving protocols, supplier approval program, and shipping protocols (i.e. temperature monitoring). The Noodles, Steamed/Boiled (last reviewed 02/13/2025) and Noodles, Heat Treated (last reviewed 02/10/2025) – The additional process PC is cooking which is a customer requirements rather than a food safety requirement (the site indicates that cooking is only for quality reasons and that the product requires further processing at the customer location in the form of cooking to 165F or above). The skins/wrappers (last reviewed 02/14/2025) also had a FSMA PC specific monitoring program, that followed the same frequency, type of testing, and records as the identified CCP (metal detection) for the HACCP program.

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#### **Summary -**

**Response:** The site last conducted a review of the plans from 02/10/2025 to 02/14/2025 using the “HACCP Reassessment Change Form”. Reviewed HACCP Plan Reassessment Change Form (QA.001, revision #000, Date of Origin 01/15/2015) for the 02/10/2025 review of Noodles, Formed and Frozen. The form included questions such as: Product description changed? Formula changed? Ingredient /packaging changed? New storage needs? New suppliers? Process flow diagram changed? Equipment changed? Personnel change? etc.. The one change noted was the HACCP team changed by removing the maintenance supervisor (no longer with the company). The programs identified personnel changes (new plant manager, new maintenance manager (who is the former plant manager), and new warehouse supervisor). Otherwise, no changes were made to the process or product categories. The food safety plans are kept on the HACCP binder and are maintained by the SQF Practitioner/QA Manager The program was developed in accordance with Codex Alimentarius and/or NACMCF guidance. The program is reviewed at least annually, or any time a change is made to a process or

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equipment used in that process. The only identified CCP is metal detection (test pieces used are 2.5 mm Fe (Ferrous) , 3.5 mm Nonferrous (NonFe), and 3.5 mm Stainless Steel (SS)) or, for heat treated noodles for customer 1, X-Ray. Responsibilities for corrective actions to critical deviations are defined: QA Dir/QC Manager – Determines deviations, places product in hold, determines disposition. Shipping and receiving manager – maintains product in-house. Production Manager – Isolated affected product Inventory Control – Isolates and maintains product in a status that prevents it from shipping Maintenance Manager - repairs affected machinery and maintains relevant records. If product is returned, it is immediately disposed of (i.e. not brought in house) to minimize potential cross contamination.

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#### 2.4.4 - Product Sampling, Inspection, and Analysis

**2.4.4.1** - The methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in-progress, and finished product shall be documented and implemented. The methods applied shall ensure that inspections and analyses are completed at regular intervals as required and to agreed specifications and legal requirements. Sampling and testing shall be representative of the process batch and ensure that process controls are maintained to meet specification and formulation.

**Response:** Compliant

**Evidence:** • The site's procedures and criteria for sampling, inspecting, and analyzing raw materials, work-in-progress, product labels (to comply with applicable food legislation), and finished product have been documented and implemented in the product sampling, inspection, and analysis SOP (Doc #GMP.066, revision 001, last revised 03/10/2022). The corporate director of QA is responsible for the proper implementation of this procedure. Incoming materials are not tested (the site relies on information provided in the COA provided by the supplier and no loads are received without an accompanying COA). Raw materials are inspected for inbound condition and confirmation that the material listed matches the COA. While the site does not produce high risk materials (all product requires further processing after leaving the site), the site does have a finished goods hold and release program (see 2.4.7) and is compliant with customer 1 requirements.

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**2.4.4.2** - Product analyses shall be conducted to nationally recognized methods or company requirements, or alternative methods that are validated as equivalent to the nationally recognized methods. Where internal laboratories are used to conduct input, environmental, or product analyses, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025, including annual proficiency testing for staff conducting analyses. External laboratories shall be accredited to ISO/IEC 17025, or an equivalent international standard, and included on the site's contract service specifications list (refer to 2.3.2.11).

**Response:** Compliant

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**2.4.4.3** - On-site laboratories conducting chemical and microbiological analyses that may pose a risk to product safety shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel. Signage shall be displayed identifying the laboratory area as a restricted area, accessible only by authorized personnel.

**Response:** Compliant

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**2.4.4.4** - Provisions shall be made to isolate and contain all hazardous laboratory waste held on the premises and manage it separately from food waste. Laboratory waste outlets shall at a minimum be downstream of drains that service food processing and handling areas.

**Response:** Compliant

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**2.4.4.5** - Retention samples, if required by customers or regulations, shall be stored according to the typical storage

conditions for the product and maintained for the stated shelf-life of the product.

**Response:** Compliant

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**2.4.4.6** - Records of all inspections and analyses shall be maintained.

**Response:** Compliant

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#### Summary -

**Response:** All products manufactured on-site are sampled and tested on site, for chemical testing and basic nonpathogenic micro testing (APC, Yeast, mold, coliforms, and E. coli) and, per customer requirement, samples are sent to an ISO 17025:2017 accredited laboratory for testing for to test for Salmonella, Listeria species, Staphylococcus aureus, etc. based on customer requirements. The third party lab accreditation was reviewed: Biological testing compliant to ISO 17025:2017 standards. Certification #L24-482. Expires 07/31/2026. A different company, used for water and air testing, is accredited by the Texas Commission on Environmental Quality for standards that included drinking water, non-potable water, and air. Certificate #TX-C24-00413 Expires 03/31/2025. The second sample goes to the on-site laboratory tests the sample for indicators such as coliform, E. coli, Enterobacteriaceae, and Aerobic Plate Count (APC). The site conducts proficiency testing for the one team member that does internal micro (petrifilm) testing. This is done by a third party lab and includes sample tested for Total Aerobic Mesophilic Coliforms, Enterobacteriaceae, and E. coli, and this was last performed on 04/16/2024. The technician results had negative variance acceptance scores as compared to other laboratories (i.e. the results were within proficiency expectations). The site QA manager trains personnel to perform sampling testing following the company test methods. The training is documented on company Training Matrix. The site also includes a matrix of testing types for raw materials, in process materials, and finished product (Form #QA.038, date of origin 01/24/2022, revision 3) that identified what activities and tests are conducted for each area. As examples, the weight of raw commodities is analyzed every two hours by a QC tech; The package leak integrity is inspected and analyzed (with a leak tester) every two hours by a QC technician. Indicator organisms are sampled and analyzed for every lot by the QC laboratory technician. COA results are reviewed against site product specifications to ensure products have met specifications. The product is placed on a positive hold according to the "Hold and Release Procedure" (GMP.003, Revision 005, Revision Date 02/26/2024) until all results are cleared and reviewed to ensure it meets the specification. Retention samples are maintained for the stated shelf-life of the product and stored in a designated area. The on-site microbiological laboratory, whose operation can pose a product safety risk, is located separately from any food handling and processing areas. A sign on the lab door indicates the laboratory is limited to only authorized personnel. The hazardous waste generated is appropriately disposed of by a licensed company. Sample retention is captured in "Retention of Finished Product Samples" (GMP.007, revision 010, Revision date 08/11/2023) outlines that products are to be stored in similar condition to those expected to be endured in the field, Product is to be retained for the length of shelf life. Samples are collected at the beginning, middle, and end of the shift.

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## 2.4.5 - Non-conforming Materials and Product

**2.4.5.1** - The responsibility and methods outlining how to handle non-conforming product, raw material, ingredient, work-in-progress, or packaging, which is detected during receipt, storage, processing, handling, or delivery, shall be documented and implemented. The methods applied shall ensure i. Non-conforming product is quarantined, identified, handled, and/or disposed of in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product; and ii. All relevant personnel are aware of the organization's quarantine and release requirements applicable to product placed under quarantine status.

**Response:** Compliant

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**2.4.5.2** - Quarantine records and records of the handling, corrective action, or disposal of nonconforming materials or product shall be maintained.

**Response:** Compliant

**Evidence:** • Several holds were reviewed from the 2024-2 hold log book: Hold #1554 – Item# 01-01-3059-04 - Manufactured and Held 10/09/2024 – one pallet held for high weight. After review it was determined that the product would not meet specification and so was discarded on 10/16/2024. Hold #1583 - Item #01-01-1040-04 – Manufactured 10/12/2024 Lot #101224 AC – two pallets held due to metal finding. Product was passed through a metal detector. No foreign material was found during the second pass, and product was Released on 10/15/2024. Hold #1527 – Item 01-01-1040-04 – Manufactured 10/03/2024 Lot #100324 - 806 cases. High coliform count on internal test. The product was retested with 3rd party lab and the results were still high, so product was dumped, and the hold was closed 10/08/2024. The site will also capture equipment holds in the hold log.

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#### Summary -

**Response:** The product is placed on a positive hold according to the hold and release procedure (GMP.003, Revision 005, Revision Date 02/26/2024 – last revised to include the new MH-micro hold procedure designation) until all results are cleared and reviewed to ensure it meets the specification. Defined methods to segregate, identify, handle, and dispose of product include Placing on physical and electronic holds to minimize any inadvertent use, and the type of holds in place. There are three Hold Categories: 1: HACCP Hold (physical, chemical, radiological adulteration, or major quality concern). 2: Quality related holds. 3: MH: Micro hold (the site has a standard micro hold and release process where product cannot be released before all results are received, reviewed, and deemed satisfactory. Products on micro hold have a red ribbon around the impacted pallets and the hold tag number is written on the ribbon on two opposing sides of the pallet.). The site has individual release forms for each product on MH and keeps it in a log. The Director of QA/QC and the QA Manager are responsible for maintaining this procedure. Any site employee may place non-conforming products or equipment on hold, and only QA or QC personnel may remove hold tags. The Director of QA/QC or the QA Manager are the only team members authorized to disposition held product. The release procedures include ensuring that all product inspections and analyses have been verified and documented by authorized personnel to show that all food safety controls have been met. The procedure also includes a requirement to confirm product labels comply with all regulatory requirements of the country of manufacture and country of use. The facility utilizes positive release methods, based on pathogen or chemical testing.

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## 2.4.6 - Product Rework

**2.4.6.1** - The responsibility and methods outlining how ingredients, packaging, or products are reworked shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are overseen by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Reworked product is processed in accordance with the site's food safety plan; iv. Each batch of reworked product is inspected or analyzed as required before release; v. Inspections and analyses conform to the requirements outlined in element 2.4.4.1; vi. Release of reworked product conforms to element 2.4.7; and vii. Reworked product does not affect the safety or integrity of the finished product. Records of all reworking operations shall be maintained.

**Response:** N/A

**Evidence:** • N/A: Finished product is not reworked, recouped, or recycled.

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### Summary -

**Response:** Finished product is not reworked, recouped, or recycled. The site has a rework policy (GMP.029, revision number 004, revision date 03/13/2024), which includes a carry-over policy for in process (WIP) and specific statements that included that finished noodles, returned product, rework/repack are not reworked (only dough trim is carried over).

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## 2.4.7 - Product Release (Mandatory)

**2.4.7.1** - The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel, and only after all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met. Records of all product releases shall be maintained.

**Response:** Compliant

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**2.4.7.2** - Product release shall include a procedure to confirm that product labels comply with the food legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1). If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use.

**Response:** Compliant

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**2.4.7.3** - In the event that the site uses positive release based on product pathogen or chemical testing, a procedure shall be in place to ensure that product is not released until acceptable results have been received. In the event that off-site or contract warehouses are used, these requirements shall be effectively communicated and verified as being followed.

**Response:** Compliant

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### Summary -

**Response:** The site hold and release procedure (GMP.003, Revision 005, Revision Date 02/26/2024 – last revised to include the new MH- micro hold procedure) includes the positive release program. The site conducts in house testing and third party lab testing using an accredited lab. The release procedures include ensuring that all product inspections and analyses have been verified and documented by authorized personnel to show that all food safety controls have been met. The procedure also includes a requirement to confirm product labels to comply with all regulatory requirements of the country of manufacture and country of use. There are three Hold Categories: 1: HACCP Hold (physical, chemical, radiological adulteration, or major quality concern). 2: Quality related holds. 3: MH: Micro hold (the site has a standard micro hold and release process where product cannot be released before all results are received, reviewed, and deemed satisfactory. Products on micro hold have a red ribbon around the impacted pallets and the hold tag number is written on the ribbon on two opposing sides of the pallet.). The site has individual release forms for each product on MH and keeps it in a log. The MH hold procedure is the site positive release procedure. The site had a spreadsheet that outlined internal testing conducted, nothing is released until all results are received and are deemed in compliance with specification. Reviewed testing and releases for 01/15/2025 (release made 01/18/2025); 01/23/2025 (released 01/26/2025); 02/05/2025 (released 02/10/2025), and 02/20/2025 (released 02/24/2025). E-mail verification of release are sent to the warehouse to confirm that the product is released and shippable. As an example, product Item# 01-01-3059-04 produced 03/03/2025 and submitted for testing (APC, E. coli, yeast and mold, plus Staphylococcus species and B. cereus). Results were received and reviewed on 03/06/2025 and an email advising product release was sent 03/06/2025.

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## 2.4.8 - Environmental Monitoring

**2.4.8.1** - A risk-based environmental monitoring program shall be in place for all food manufacturing processes and immediate surrounding areas, which impact manufacturing processes. The responsibility and methods for the environmental monitoring program shall be documented and implemented.

**Response:** Compliant

**Evidence:** • Zone 1: Sites that are direct or indirect product contact surfaces. Zone 1 is not sampled except under special circumstances. The site does conduct Preoperational ATP swabbing to confirm that the line is free of organic material (including microbes) before it is released for use. Zone 2: Sites immediately adjacent to product contact surfaces. Zone 2 tests for SPC, Mold, and Yeast indicator organism and Listeria and Salmonella monthly Limits for each of these is 250 cfu/swab limit (petrifilm testing) for the indicator organisms and Negative for Salmonella and Listeria. Zone 3: Sites away from Zone 2 sites but within processing and storage areas. Zone 3 tests for Listeria monthly and Salmonella quarterly. Limits for each of these is negative per swab. Zone 4: Sites outside the processing room that could impact processing areas through the movement of people, equipment, or materials. No testing unless there is an indication of an issue with zones 2 or 3. EMP test sampled and reviewed: (Z2-Z4) 05/30/2024 - 5 points for Zone 2, 10 points for Zone 3, and 2 points for Zone 4 - all tested for Listeria and all were negative. 09/27/2024 - 5 points for Zone 2, 10 points for Zone 3, and 2 points for Zone 4 - all points were tested for Listeria and all were negative. 12/31/2024 - 5 points for Zone 2, 10 points for Zone 3, and 2 points for Zone 4 - all points were tested for Listeria and all were negative. 02/22/2025 - 5 points for Zone 2, 10 points for Zone 3, and 2 points for Zone 4 - all tested for Listeria and Salmonella and all were negative. Zone 1 ATP testing results reviewed. Maximum value allowed is 149 RLU: 05/18/2024 - 16 sites on Line 05 (Customer 1 line) - one site (aging bowl) had elevated values (543 RLU). Recheck for the area came in within tolerances 43 RLU). Checks were also conducted 08/30/2023, 08/09/2023 08/30/2023 with similar results. 05/14/2024 - 12 areas tested on Line 03. All areas were within expected tolerances. IN house Micro Testing: 05/02/2024 Line 5; 16 points tested. SPC Threshold 250 cfu/swab. (max was 200 cfu/swab); Yeast threshold 250 cfu/swab (max was 40 cfu/swab); Mold Threshold 250 cfu/swab. (max was 80 cfu/swab) 09/11/2024 - 11 areas tested on Line 10. Two areas were high (Aging bowl and Metal detector). Both areas were recleaned and retested below threshold. IN house Micro Testing: 9/11/2024 Line Y11; 21 points tested. Coliform Threshold <10 cfu/swab. Two points were TNTC (Mixer 2 and Slitter). Cleaned and retested - Rechecks were both <10 cfu/swab. E.coli (max threshold <10 cfu/g)- All results <10 Yeast threshold 250 cfu/swab (max was 30 cfu/swab); Mold Threshold 250 cfu/swab. (max was 30 cfu/swab). In house Micro Testing: 9/04/2024 Line Y11; 21 points tested. Coliform Threshold <10 cfu/swab. (max was 200 cfu/swab); Yeast threshold 250 cfu/swab (max was 40 cfu/swab); Mold Threshold 250 cfu/swab. (max was 80 cfu/swab) In house Micro Testing: 9/12/2024 Line Y11; 21 points tested. APC Threshold <250 cfu/swab. Three areas were above threshold all areas were recleaned and results were conforming, (max was 10 cfu/swab); EB threshold 100 cfu/swab. Two areas were above threshold (Mixer 1 260 and mixer 2 320) recleaning and rechecks for both were <10 cfu/swab. 09/04/2024 - 11 points tested on Line 4. No areas had elevated values. 12/17/2024 - Line 5 (customer 1 line) 16 sites. One area (Chutes) had elevated values (2,479 RLY). Rechecks for the area came in within tolerances (3 RLU). 12/21/2024 - Line 10 - 11 points tested. No areas had elevated values. 02/26/2025 - Line Y10 (customer 1 line) - 16 points tested. No areas had elevated values. 02/26/2025 - Line Y11 (customer 1 line) - 16 points tested. No areas had elevated values. The program had visual aids to help identify the different zones. Samples are collected during production, at least 3-4 hours after start-up. Pathogen testing is not conducted on food contact surfaces. Preoperational ATP testing is conducted weekly prior to line starting up (lines are alternated so that testing occurs daily but all lines are tested over the course of a week). The Maximum allowable RLU reading is 149 - If results exceed the threshold then the area is re-sanitized and retested. If results are still above the threshold, then additional steps would take place (i.e. investigation of the

area for potential issues or false reading contributors; possible recleaning of the entire area or equipment, etc.).

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**2.4.8.2** - An environmental sampling and testing schedule shall be prepared. It shall at a minimum: i. Detail the applicable pathogens or indicator organisms to test for in that industry; ii. List the number of samples to be taken and the frequency of sampling; iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and iv. Describe the methods to handle elevated or undesirable results.

**Response:** Compliant

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**2.4.8.3** - Environmental testing results shall be monitored, tracked, and trended, and preventative actions (refer to 2.5.3.1) shall be implemented where unsatisfactory results or trends are observed.

**Response:** Compliant

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### Summary -

**Response:** The plant environmental monitoring program (Doc #GMP.016, Revision 021, Revision Date 02/08/2025 – last revised to change potability from quarterly to monthly and require yeast and mold testing for water. In addition, increased the number of water site tested to 10.) includes that the program is the responsibility of SQF Practitioner and the company QA Director. Frequency of testing includes: Listeria is tested monthly (30 days +/- 5 days); Salmonella is tested quarterly. Air plates are conducted quarterly. As of 2/08/2025, water testing is conducted monthly and heavy metal testing is conducted annually. The sampling procedure for each is outlined in the program 2023 Annual Drinking water Report for the city of Humble All primary and secondary attributes were complaint with national standards for drinking water. The site has a hygienic zoning map, broken into yellow areas (GMP area where hair restraints are required – including P1 and P2 room, holding freezer, sugar warehouse, etc.) and green areas (Non-manufacturing area where no PPE is required such as offices, boiler rooms, dumpster area, etc.) (from QA.062 revision date 10/09/2023, revision #001) The site had protocols for testing, results review, trending, and corrective actions. If there is a presumptive positive, then corrective actions include: investigative sampling; conduct site testing and vector swabs (even into adjacent zones, if appropriate), potentially increasing sampling frequency. If a Zone 2 or 3 site is positive, samples must have three consecutive negatives to allow equipment or relevant area to be released back into service. If it is a drain finding and the risk cannot be eliminated, then the line nearest the drain must be stopped and an action plan formulated, The site conducts trend analyses on both Listeria and Salmonella. No findings were documented in the past 12 months, Environmental Risk Assessment has been conducted on Drains, as they are considered to be the highest risk area of the plant. Per the risk assessment of 12/08/2023, Listeria had a medium likelihood and high growth opportunity which led to a decision to test for Listeria monthly, and Salmonella has a Low/medium assessment which led to a decision to conduct swab testing for Salmonella quarterly.

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## 2.5.1 - Validation and Effectiveness (Mandatory)

**2.5.1.1** - The methods, responsibility, and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall validate that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required results; ii. Critical food safety limits are reviewed annually and re-validated or justified by regulatory standards when changes occur; and iii. Changes to the processes or procedures are assessed to ensure the controls are still effective. Records of all validation activities shall be maintained.

**Response:** Compliant

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**Evidence:** • The nonconformity in this element from the previous audit was corrected and the effectiveness of the corrective action was confirmed during this audit.

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### Summary -

**Response:** The site validation and verification program (GMP.057, revision 005, Revision Date 05/20/2024 – new program developed for all sites as part of HACCP team meeting activities) included that the SQF Practitioner (with appropriate training and qualifications to properly verify and validated relevant activities for the site). Indicates that the plant manager is responsible for developing any corrective actions or preventive actions. Programs considered for validation included product testing and analysis, training, calibration, traceability GMPs, CCP and supplier approval and verification. The program includes how validations are verified. As examples: - Trace and recall: Ability to follow the mock recall procedure as a simulation for actual recalls, The criterion for effectiveness of the recall program is to be able to conduct a mock recall with at least a 97% recovery within four hours, excepting when customers require more stringent timing and recovery (as an example customer 1 requires 100% recovery in 2 hours). If there are areas of noncompliance, the recall team must develop a CAPA report and analyze the corrective action in detail, to avoid recurrence and conduct a new mock recall after the failed mock recall. References include: SQF Code (edition 9) module 2.6.2, Codex general principles of food hygiene CXC 1-1969 (2020) -section 5.8 - GMPs: The site uses the internal monthly GMP audit format QA.055 to audit the proper areas and practices. Each element of the inspection is either pass (100%) or no pass (0%). This is combined for an overall score. The overall score must be 90% or above. A score of less than 90% will generate an additional GMP audit 2 weeks later with the expectation that all identified NCs will be adequately completed and closed. QA is responsible for assuring that relevant activities are performed correctly. The methods applied confirm that each element has been deemed effective. Methods to ensure that procedure or process changes are still effective in controlling food safety are in place and documented in Food Safety Plan. Critical food safety limits related to CCPs are re-validated at least annually by the QA Director by positioning various metal test pieces at extreme ranges of possible detection on the finished goods metal detector and passing the detection wands through 20 times each for the leading, middle, and trailing part of the machine (this was conducted 03/19/2024), This was conducted on the oldest unit and one metal detector for a customer specific request. 360 total checks for each machine and all tests passed. Validation Activities for PRPs included: GMP review (annually) : The criteria are completeness of documentation (i.e. reviews are accomplish in a timely fashion, documents are completed fully and accurately. Allergen results review (Annually) – Review of allergen test records for complete results and, if any results are nonconforming, corrective actions are implemented. In addition there was a review of several related document including: Review of QA.053 Warehouse audit to ensure review of allergen storage has been conducted. Review of QC.048 ATP monitoring Site Log and QC.049 Microbiological Plate Count Monitoring Log records confirm that logs are complete and any findings have corrective actions associated with them. Metal detection validation QC.069 – Calibration and records (Annually) – confirm that records are complete and have been reviewed in a timely fashion. Metal Detector Validation Testing is conducted once per year. This is conducted by running the test wands through on the top, middle, and bottom three time for the front, middle, and trailing edge of the product and repeating each of the scenarios 20 times (540 tests in total). Testing was conducted 03/19/2024 (all machines). All tests for all units passed. Each document was reviewed on the day that it was tested and confirmed that the validation was in compliance. All records reviewed were observed to be conducted per written procedures. The site had several studies to support whether food safety steps required a CCP. Examples included: FDA CPG 555.425- "Foods, Adulteration Involving hard or Sharp Foreign Objects"; "Control of Salmonella in Low moisture foods" (GMA Feb 2009); "Control of L. monocytogenes in RTE Foods: Guidance for industry" FDA 01/2017.

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## 2.5.2 - Verification Activities (Mandatory)

**2.5.2.1** - The methods, responsibility, and criteria for verifying monitoring of Good Manufacturing Practices, critical control points, and other food safety controls, and the legality of certified products shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record.

**Response:** Compliant

**Evidence:** • The site validation and verification program (GMP.057, revision 005, Revision Date 05/20/2024 – new program developed for all sites as part of included that the SQF Practitioner is responsible for included that the SQF Practitioner is responsible for assuring that relevant activities are performed correctly) includes the methods, responsibilities, and criteria for verifying monitoring of good manufacturing practices, critical control points, and other food safety controls, and legality of certified products were also contained in this document, as well as an outline of the verification frequency and responsibilities for each verification activity. There is a verification schedule that includes specific expected verification frequencies (examples: GMPs are verified via of site observations and inspections and this is accomplished the QA/QC manager and supervisor on a daily basis. Other items on the schedule include CCPs, product testing and analysis, training of personnel and traceability exercises.

**2.5.2.2** - A verification schedule outlining the verification activities, their frequency of completion, and the person responsible for each activity shall be prepared and implemented. Records of verification of activities shall be maintained.

**Response:** Compliant

### Summary -

**Response:** Verification activities included: - GMP employee inspections, and internal GMP inspection (Monthly) - Sanitation Preoperational inspection and Operational inspection, daily work logs (Monthly) - Microbiological Plate Count, daily work logs (Monthly) - Metal detection log (weekly) - Maintenance equipment repair log and PM log (Quarterly) - Pest Control trend logs (quarterly) - Glass and brittle plastic (quarterly) - Housekeeping Pest room, and lunchroom logs (monthly) Record verification reviewed are included in the relevant sections of the audits. Examples reviewed included: - Preoperational ATP swab testing - 01/20/2025 All records were signed as being reviewed within 24 hours of completion. - Bio-security Truck Inspection Report – 08/08/2024, 08/12/2024, 10/09/2024, 11/07/2024, 12/16/2024, 01/17/2025, 01/20/2025 - Packing Report - 01/23/2025 - Finished Foods transfer form - 01/23/2025 - Daily Packing Report – 01/23/2025 - Transfer of pallets into production – 1/23/2025 - Final Count of Packaged Product - 1/23/2025 - Mixer Sheet – Total Liquid – 01/20/2025 (A & B shift). - Mixer batch sheet – 01/20/2025 (A & B shift). - Product in racks 01/20/2025. - Heating and Cooling Log (Form FD.051, Revision Date 08/26/2024, Revision 004) – 01/20/2025. - Preoperational Inspection Noodle Room – 01/20/2025 - X-Ray Detection log - 01/20/2025 - Sanitation Records – Daily Sanitation Checklist - 01/01-31.2025 - GMP audit reviews conducted for audits - 04/24/2024, 08/01/2024, 01/13/2025. All records were signed as being reviewed within 24 hours of completion.

## 2.5.3 - Corrective and Preventative Action (Mandatory)

**2.5.3.1** - The responsibility and methods outlining how corrective and preventative actions are determined, implemented, and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented. Deviations from food safety requirements may include customer complaints, nonconformances raised at internal or external audits and inspections, non-conforming product and equipment, withdrawals and recalls, as

appropriate.

**Response:** Compliant

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**2.5.3.2** - Records of all investigation, root cause analysis, and resolution of non-conformities, their corrections, and the implementation of preventative actions shall be maintained.

**Response:** Compliant

**Evidence:** • An example of corrective action documentation reviewed: Deviation on the metal detection on 02/24/2025 – Product 01-01-1040-04 Chow Mein 3 lbs. At the 13:17 check none of the test wands were successfully rejected by the metal detector; 8 pallets were placed on hold, because the metal did not pass. The metal detector was repaired and then re-passed through on the same day. No rejected product was found. A corrective and preventive report was written for this issue. Date 02/24/2025 Report #02245. An investigation showed that the sensitivity was not sufficient for the metal detector to detect the test pieces. The site was not able to determine what happened to the sensitivity of the metal detector between the prior good checks (times- 06:21, 09:26, 10:10, 11:27, and 12:16 all had successful tests.) and the failed check at 13:17, but determined that sensitivity settings were adjusted and the metal detector was performing as intended. The site also determined that all food safety protocols were followed (i.e. failed check, supervisor notified, product held to last good check, and rerun through a functioning metal). The CAPA was closed on the same day.

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**Summary -**

**Response:** The site's Corrective and Preventative Action program is written in the "Corrective and Preventive Action" (GMP.056, Revision 004, last revised 03/10/2022) program. The program describes the methods and responsibilities for investigating, resolving, and managing corrective action in determining risk assessment. The QA Director or QC Manager determines deviations and places the product on hold. The shipping and receiving manager maintains products in-house. The production manager isolates the affected product. Inventory Control isolates and maintains products from shipping. The maintenance manager repairs affected machinery and keeps records. There should be at least one corrective and preventive action for each root cause. The identification of root causes and resolutions to deviations of critical control limits are documented.

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## 2.5.4 - Internal Audits and Inspections (Mandatory)

**2.5.4.1** - The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code: Food Manufacturing are audited per the SQF audit checklist or a similar tool; ii. Objective evidence is recorded to verify compliance and/or non-compliance; iii. Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and iv. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative actions.

**Response:** Compliant

**Evidence:** • The last SQF internal audits were reviewed. These were conducted using the SQF checklist and are conducted annually. Module 2 was conducted on 03/12-15/2025. This included the clause reviewed, the guidance/criteria used to audit against, the primary response (i.e. compliant, minor, major, critical deficiency), the evidence/supporting documentation reviewed, and the correction/corrective action. All areas were deemed to be compliant. The audit was conducted by a Corporate Director QA/QC and the corporate QC Technical Manager. For Module 2. The audit included the documents reviewed and relevant observations. - One minor nonconformity was noted for 2.8.1.2 – noting that the site standard is that egg allergen is stored in its own area and wheat allergens are stored in a segregated area. The finding indicated that the new inventory

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of egg arrived and was not placed in the designated area. Additional notations were that the correction was made during the audit. Module 11 auditing was conducted 03/16/2025 – The document did have the evidence and documents reviewed and was patterned after the Module 2 document. Two findings were noted: - 11.1.3.1 – A light fixture in the pasteurization area was burnt out and insufficient light to this area. The site root cause was that the overhead lighting was blocked by the overhead hoods so did not allow for the full amount of lighting for the area. The corrective action was to put lighting along the side walls to illuminate across the room and this was completed as noted on WO# 4133. In addition, the site determined that the ceiling (overhead) light fixtures needed to be removed and this is still in progress. - 11.3.2.3 – A soap dispenser in P2 was left without soap. A sanitation team member was notified and the soap was restocked at the time of the audit. Audit findings are conveyed in the managers weekly meetings. Follow-ups are typically via e-mail or text and the QA manager is responsible for verifying that the corrective actions have been completed.

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**2.5.4.2** - Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical, staff conducting internal audits shall be independent of the function being audited.

**Response:** Compliant

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**2.5.4.3** - Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and facility and equipment maintenance are compliant to the SQF Food Safety Code: Food Manufacturing. The site shall: i. Take corrections or corrective and preventative action; and ii. Maintain records of inspections and any corrective actions taken.

**Response:** Compliant

**Evidence:** • The site monthly GMP Self-Inspections are recorded on the “Monthly Food Facility GMP Self-Inspection Checklist (Form QA-002 revision 003, revision date 05/17/2022, supersedes 05/13/2022). The audit is conducted using a points system (i.e. full compliance on a given section is 10 points, partial compliance is 5 points, and noncompliance is zero point) and is based on 21CFR part 117 - 04/24/2024 – No issues noted. 100% score. - 08/01/2024 – o Dock 2 had water buildup – The pump was not activated so the water had not been pumped, The shipping department was notified to notify maintenance when water is building up. Pictures after water was drained were taken and the area looked drier and was deemed to have been corrected - completed 08/05/2024. o Delivery of sanitizer was taken under a table at the loading dock, sanitation was not notified and so, it was left under the table. A meeting was conducted on 08/05/2024 with the warehouse team to make sure that proper notifications occur whenever a load is received in situations like this. Overall 98.6% score. o 01/13/2025 – Examples: □ - Trash cans were observed without lids and one was upside down. Corrective action: Plant manager conducted retraining on the proper storage and placement of trash cans. Training conducted 01/27/2025 and closed the same day. □ - Sanitation - 3 compartment sink was damaged and missing a drain pipe piece. This was repaired on 01/27/2025 and closed out. - Open door observed in the generator room to the outside. Closed the door and closed on 01/13/2025. 91.7% overall score.

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**2.5.4.4** - Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits shall be recorded as per 2.5.3. Changes implemented from internal audits that have an impact on the site's ability to deliver safe food shall require a review of applicable aspects of the SQF System (refer to 2.3.1.3).

**Response:** Compliant

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#### **Summary -**

**Response:** The internal audit procedure (Doc #GMP.055, Revision 011, Revision Date 11/28/2023 – revised to include that QA manager will not audit their own area of ownership.) is the site’s procedure for scheduling and conducting internal audits to assess the effectiveness of the SQF system has been documented and implemented. The QA/QC Director maintains the internal audit program. All applicable SQF Code

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requirements, using the SQF checklist, are part of the internal audit program. Audit results are communicated to relevant management personal and staff responsible for implementing and verifying corrective and preventive actions by means of the annual management meeting. Personnel conducting audits have been properly trained under the oversight of the QA manager.

## 2.6.1 - Product Identification (Mandatory)

**2.6.1.1** - The methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage shall be documented and implemented to ensure: i. Raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products are clearly identified during all stages of receipt, production, storage, and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements.

**Response:** Compliant

**2.6.1.2** - Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person. Procedures shall be implemented to ensure that label use is reconciled, and any inconsistencies investigated and resolved. Product changeover and label reconciliation records shall be maintained.

**Response:** Compliant

**Evidence:** • The “Finished Goods Label Verification Process” (GMP.082 Revision 000, Created and Last revised 07/12/2021) outlines the process for verifying labels prior to the start of product and during the shift – QC is responsible for verification of labels and works in conjunction with production to verify labels are correct prior to start up The label verification process which included the initial label printing was observed during the site tours., QC reviewed the label to confirm that the product, lot dates, site address, ingredient statement and allergen information is correct. This is put on a “Daily Printing Labels” record along with the date and time, item#, Code, packing date, expiration date printed quantity, received by and returned by, returned quantity, production printer and production supervisor names, ingredient and code date, and the date and time checked, along with a copy of the label itself. The observed process was consistent with the process outlined in GMP.082. No product changeovers occurred during the audit. Preoperation activities were observed and this included bringing labels to the production floor (there were no labels to remove during this time). Labels matched the information on the production sheet. Label confirmation of product being made during the site tours indicted that the product label matched the mixer batch sheet (i.e. The label indicated Won Ton Wrappers C 245 24 A best By APR 30, 2025. Allergen: Wheat and this matched the product identified on the batch sheet). Minor ingredients were in containers and these were all labeled with the lot number of the ingredient. Mixer batch sheets were reviewed during site tours. This included lot numbers and weights for soybean oil (lot 0720400). This matched the lot identification labels on the corresponding raw ingredient containers. Examples of labels reviewed Lo Mein Nests – Pack Date 03/18/2025 AC. Use Before May 18 2025. Ingredient statement: Water, wheat flour, highly refined soybean oil, vital wheat gluten, salt, potassium carbonate, sodium carbonate, riboflavin. Allergen: Wheat. Manufactured on equipment that also processes Eggs. Keep frozen 10F or below. Also review labels for Chow mein, 3 lb. 03/19/2025 AC. Best before 040925. All documents were signed by both production and QC Product Coding procedures were outlined in “Product Coding Procedure’ (GMP.006, Revision Date 04/20/2022, revision 19).

### Summary -

**Response:** The product coding procedure (Doc #GMP.006, Revision 20, Last revision date 05/28/2024 – no

changes – reviewed and updated) has documented a policy defining how products are identified from receipt through production and shipping. The site's identification system ensures that all raw materials, ingredients, packaging materials, work-in-progress, process inputs, and finished goods are identified at all stages of their process. Production personnel is responsible for correctly adhering to the codes to unit packages and cases. The site uses reverse Julian date to track lots of finished goods. For example, : H 355 25 B Production Date 1/11/2025 H=Plant 355=reverse Julian Date (i.e. 365-355+1=11 which is the 11th day of the year) 25=Production year (i.e. 2025) B=production shift (i.e. B shift or second shift). The site identify preserved foods (GMP.054 revision 004, revision date 06/24/2024) outlines the site and company requirements for declaring identify preserved foods. While claims for nonGMO, gluten free, and organic are relevant for the entire company and are covered in the document, the only claim valid at the site audited was kosher. The site Kosher Certificate was valid through 05/31/2025.

## 2.6.2 - Product Trace (Mandatory)

**2.6.2.1** - The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier; ii. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products.); iii. Traceability is maintained where product is reworked (refer to 2.4.6); and iv. The effectiveness of the product trace system is reviewed at least annually, as part of the product recall and withdrawal review (refer to 2.6.3.2). Records of raw and packaging material receipt and use and finished product dispatch and destination shall be maintained.

**Response:** Compliant

**Evidence:** • The site had a procedure covering Mock Recall" (Procedure #: GMP.031, Revision Date 09/05/2023 Revision #013) which outlined the procedure for tracing finished product and raw materials. Success criteria include: accounting for product within 4 hours of the trace initiation (2 hours for customer 1) and capturing 100% +/- 3%. If these criteria are not met, then the mock trace is considered a failure, and the team must meet and ascertain why the failure occurred. A follow up mock recall will occur within 30 days of the failure. Mock recall exercises are to be conducted at least twice a year. The site trace time of two hours or less, conducted twice per year with finished goods, ingredients, and packaging, and tracing 100% of finished product complies with customer 1 requirements. A trace exercise was conducted during the audit: Produced 01/23/2025 – Precooked noodle 16 oz (Customer 1); 01-01-5036-04 – Best by 04/20/2025 Participants in the mock trace included: QA manager, Inventory Control Supervisor. Packaging Material Traced: Film for bag Time Start: 08:35 am Time Finish: 09:36 am 14,604 units – 12,000 cases on shift A and 2,604 cases shift B. Water, Salt, Potassium Carbonate, Sodium Carbonate, Riboflavin, Niacin. Packing Report – 421 cases on A shift, and 84 cases on B shift There are 28 units/case. (Total units packed 14,140 units. Total Cases packed 505). Missing 464 units from production. 390 units/lbs. was waste. Eight units were pulled for samples. 99.54% accounted. Product was all shipped on one order Order# 0422118 – 70 cases shipped 01/29/2025 Order# 0422502 – 70 cases shipped 01/31/2025 Order# 0422503 – 85 cases shipped 01/31/2025 Order# 0422289 – 140 cases shipped 01/31/2025 Order# 0422480 – 70 cases shipped 02/05/2025 Order# 0422479 – 70 cases shipped 02/05/2025 TOTAL CASES SHIPPED 505. This was 100% reconciliation of the cases packed, and 99.54% reconciliation of the original units made.

### Summary -

**Response:** Supporting Documentation for the trace - Production Report for 01/23/2025 that includes the amount made and lot numbers of raw materials used in making the product. - Bio-security Truck Inspection Report – 10/09/2024 and 11/07/2024 - PO for Salt received 10/08/2024 on PO# 86947, and 11/06/2024 on PO#

86948. - BOL for Salt received 10/08/2024 and 11/06/2024 - COA – Salt (10/08/2024 and 11/06/2024); Sodium Carbonate (02/13/2024); Riboflavin (12/14/2024); Niacin 08/10/2024; Hard red noodle flour 01/16/2025, Potassium Carbonate – 02/23/2024. - Shipping Reports using the Bio-security Truck Inspection report 01/29/2025 – temp 34 F; reviewed 01/30/2025; 01/31/2025 reviewed 02/01/2025; 02/05/2025 reviewed 02/06/2025. - Packing Report 01/23/2025 A shift: Product Item: 04-01-5036-04 Packed 421 case. Time start 06:40 time finished 10:18, Temperature packed 40 F. (Manufacturing date was 01/20/2025, packaging date was 01/23/2025); Expiration date was 04/20/2025; FG packaging code 034625AC Best Before 04/20/2025. For coding there was a QC tech signature. - Finished Foods transfer form 01/23/2025. - Includes pallet number, time of transfer, code date, cases, production initial. - Daily Packing Report (PD.060, revision date 10/18/2023, revision 003) Includes the production line, Item #, Product name, Unit weight, total cases (421). This report includes the amount of waste (in lbs.) - Transfer of pallets into production – 01/23/2025 - Final Count of Packaged Product (showed packing on 1/23/2025 – and time for each pallet of product – 70 cases/pallet. - Material Disposal form (QC.085, Revision Date 03/09/2020, revision 004) – No product disposed of. - Mixer Sheet – Total Liquid – 01/20/2025 (A & B shift). Includes amount of each ingredient, batch time, and the formula for the product. - Mixer batch sheet – 01/20/2025 (A & B shift) includes the addition of flour, vital wheat gluten, and total liquid, as well as batch #, and batch time. - Product in racks 01/20/2025 - this is the product that has been mixed and formed into individual quantities, then placed on racks for cooling prior to packaging, - Heating and Colling Log (Form FD.051, revision date 08/26/2024, revision 004) 01/20/2025 – Includes Rack #, Heating cabinet #, Time in, Time Temperature was achieved in the cabinet, time out, temperature on the screen (must be between 202 and 208 F – this was recorded for all six cabinets as 206 F; Main pressure 50 psi; cabinet pressure 50 psi. - Waste for different areas (rollers, tunnel, baskets, IQF, Metal detector) 01/20/2025 – waste was noted at the rollers at the three times checked. - Preoperational Inspection Noodle Room – Line 5 01/20/2025. Includes areas such as floors and walls, doors and curtains, food contact areas, and areas near and over product streams 01/20/2025 – no issues noted. - X-Ray Detection log 01/20/2025 - (6:24 (Preop), 7:25, 8:46, 9:32, 10:34, 11:10, 12:16, 13:10, 14:06, 15:10, 17:14, 18:10 (end of production). Passed for three passes each for 2.5 ferrous, 3.5 stainless steel, 3.5 nonferrous, 3.5 glass, 3.5 mm ceramic. All notes indicated that all tests were successfully rejected. - Sanitation Records – Daily Sanitation Checklist (01/01-31/2025) included 01/20/2025 pricing includes five areas of dry cleaning (mixer, platform, combine and continuous rollers, cutters) and four areas of wet cleaning (basket system, steam chamber, tunnel, and oil tank) This also included if the previous product was an allergen. The sanitation list was completed and signed as reviewed 01/31/2025. Mass balance on Film: - The film came in 08/02/2023 PO 0081614. A COA was included – 790 rolls were received - Remaining rolls in house: 0 - Transfer 192 Rolls to a sister plant 10/13/2023 - Transfer of 96 and 48 Rolls to a sister plant 08/19/2024 (two deliveries) - The lot of film was from 12/19/2023 to 03/04/2025 – 454 rolls used in house during those dates. Reconciliation was 100%

### 2.6.3 - Product Withdrawal and Recall (Mandatory)

**2.6.3.1** - The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing, and investigating a product withdrawal or recall; ii. Describe the management procedures to be implemented, including sources of legal, regulatory, and expert advice, and essential traceability information; iii. Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner appropriate about the nature of the incident; and iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as essential organizations and notified in instances of a food safety incident of a public nature or product recall for any reason.

**Response:** Compliant

**Evidence:** • The site has a recall action plan (Procedure Number GMP.018, revision 24, revision date 10/16/2023 – updated CB recall group contact information), defining the methods and responsibilities for withdrawing and recalling product if necessary. A recall team has been designated and is led by QA Director (the VP of Sales and Marketing is the recall coordinator). The withdrawal policy includes the requirement to investigate a recall and determine the root cause of a recall/withdrawal with a corrective action. It also includes a communication plan to notify customers, consumers, regulatory authorities, and other essential regulatory bodies. This includes SQFI and the Certifying Body, who must be notified within 24 hours in writing of any food safety event requiring public notification. Investigation into the root cause of any product recall, mock recall or product withdrawal, with actions taken, was observed to be documented. The site also had a “Recall plan template” (Form QA.035, Revision 005, Revision Date 10/27/2023) that is to be used during a mock recall or actual recall. The template included a summary balance, detail related to WIP, shipping, reconciliation of raw materials and finished goods, recall team, determination if a recall is necessary, FDA communication templates, contacts for the FDA, checklist for activities to be conducted during a recall, distribution tables, consignee lists, effectiveness checks, and a recall notification. The mock recall SOP (Procedure #: GMP.031, Revision Date 09/19/2024 Revision #016 – member changes) outlines the general Mock recall protocols along with protocols and requirements for key accounts (including customer 1 forward and backward traces and a packaging trace). Mock traces for internal traces require 97 to 100% recovery (this is also applicable to ingredients) within 4 hours (unless customer requirements dictate otherwise). If the mock recall is unsuccessful, the recall team must meet and ascertain why the mock recall failed. Corrective action will be applied and a follow up mock recall will be performed within 2 weeks days to judge if corrections were successful

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**2.6.3.2** - The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability one step forward). Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.

**Response:** Compliant

**Evidence:** • Reviewed the Mock recall conducted 08/05/2024 – After hours recall 06:00 pm finished 07:45 pm. Product was No bake chow mein, 3 lbs. Item # 01-01-1040-04. Manufactured 07/24/2024 Code 072424 AC. Scenario: Finished product was found to have high counts of E. coli – it was determined that the product would need to be recalled if it was not at the facility. Team members were listed including the site QC manager, scheduler, inventory control clerk, warehouse supervisor, and purchasing (site). WIP (Item #02-01-1012-00) - 10,091 units (1,009 cases). Waste was 210 units. Total finished product was 988 cases. Shipped 720 cases to Dallas on PO 54942c44. 240 cases shipped to Oklahoma on PO 87822c02; 5 cases shipped to a local customer on PO845267. The site confirmed that the remaining 23 cases were in house. Total recovery: 100%. Additional information included: - Recall team participants. - A chart that showed the steps to determine if a recall is necessary. - FDA recall notification template – Included lot number, explaining the code, expected shelf life (21 days) - Summary of reasons and actions for mock recall, including an assessment of adjacent lots for E. coli (none was found). - Effectiveness check summary. - Consignee list (of where product was shipped to) - Recall public communication letter including contact information and a template for use in the event of an actual recall, Customer list of all contacts.

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**2.6.3.3** - Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied.

**Response:** Compliant

**Evidence:** • Mock traces for internal traces require 97 to 100% recovery (this is also applicable to ingredients)

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within 4 hours (unless customer requirements dictate otherwise). If the mock recall is unsuccessful, the recall team must meet and ascertain why the mock recall failed. Corrective action will be applied and a follow up mock recall will be performed within 5 days to judge if corrections were successful. The customer 1 requirement of the site conducting a mock recall traceability exercise annually, using customer 1 product was satisfied.

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**2.6.3.4** - SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at [foodsafetycrisis@sqfi.com](mailto:foodsafetycrisis@sqfi.com).

**Response:** Compliant

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#### Summary -

**Response:** Additional traces conducted by the site that were reviewed included: 08/06/2024 – The site conducted a trace of salt used in multiple products – Salt lot Number 0040620600 – The scenario was that the salt manufacturer indicated that there might be an egg contaminant in the salt. – traced of 29,400 lbs. received on 5/31/2024 on PO0084251. - The trace also included each lot of product that the salt was used in. including the amount of salt used in each product. Of the 29,400 lbs., 3,697 lbs. were used in product and the balance remained in house (100% reconciliation). Time start 11:45 am Time finish 3:45 pm. 06/13/2024 – Durum flour trace – Start 3:30 pm finished 4:45 pm – Lot code 02012024. 42,500 lbs. received 02/07/2024. 4,250 lbs. were used in production 02/10/2024. The balance remained in house.

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## 2.6.4 - Crisis Management Planning

**2.6.4.1** - A crisis management plan based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather events, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe food shall be documented by senior management, outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include at a minimum: i. A senior manager responsible for decision making, oversight, and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure any responses do not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.

**Response:** Compliant

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**2.6.4.2** - The crisis management plan shall be reviewed, tested, and verified at least annually with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.

**Response:** Compliant

**Evidence:** • The last test scenario was a power outage conducted on 08/07/2024 (this was an actual event). The information was captured on an incident report form ((FD.004, Date of review 01/31/2021, revision 000). Power went out at 3:40 pm and all of production (in P1) was impacted – four lines were running at the time of the outage. The shift was cancelled and team members were safely removed from the building and roll call was taken to ensure all members were accounted for. After roll call was complete, all team members were dismissed from the site. The building was allowed to be reentered at 4:30 pm, at which time product on site was assessed. Product in the coolers was determined to be acceptable and no product was discarded that had

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been stored in coolers. Product on the line was deemed to have been exposed for too long, so all in process production was discarded. Root cause for the power failure was that a power transformer outside of the plant blew a fuse. The energy company replaced the fuses and brought the site back on line approximately an hour after the event started. This was noted as being completed at 5:00 pm and supporting documentation included the daily sanitation waste report (where the disposed of product was documented), and two lists of team members and management evacuated from the plant. The site also has an emergency evacuation plan (Doc #DS.004, Revision Date 02/24/2022, revision #008) and a pandemic plan (Doc #SD.003, Revision Date 03/19/2021, Revision # 002).

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### Summary -

**Response:** The crisis management and continuity plan dated (Doc #FD.003 version 007, last revised 03/20/2024) was reviewed. The plan has been implemented and addresses serious threats which could cause an extended interruption of the business. Issues considered included Earthquake, Fire, Flood, Hurricane, Tornado, Power Outage, Snow, Recall, Pandemic/Epidemic. Each item has a risk assessment (the category assessments included: people, facility, product, and operations – each graded on a 1 to 4 scale for risk (1=low, 4=high)). Earthquakes, fires, power outage, and pandemic were rated as the highest risks to business continuity. Procedures to manage each of these scenarios were included in the documentation. Food disposition is also included, as well reopening procedures and actions to keep food safe for several hours. The Plant Manager has oversight of the Plan and a Crisis Management team has been identified and trained as evidenced by Senior Management Crisis Training. If the site was down for an extended time, all products made at the site could also be made at a sister site so production would be sent to one of the other sites that make the same products or use the same process.

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## 2.7.1 - Food Defense Plan (Mandatory)

**2.7.1.1** - A food defense threat assessment shall be conducted to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident.

**Response:** Compliant

**Evidence:** • A food defense assessment (USDA Food Defense Plan – Security measures for food defense) was conducted 02/12/2025 by the Director of QA & QC. No areas were identified as having food defense related gaps.

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**2.7.1.2** - A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum: i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident; ii. The name of the senior site management person responsible for food defense; iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points; iv. The methods implemented to protect sensitive processing points from intentional adulteration; v. The measures taken to ensure the secure receipt and storage of raw materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents; vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, and finished products are held under secure storage and transportation conditions; and vii. The methods implemented to record and control access to the premises by site personnel, contractors, and visitors.

**Response:** Compliant

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**2.7.1.3** - Instruction shall be provided to all relevant staff on the effective implementation of the food defense plan (refer to 2.9.2.1).

**Response:** Compliant

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**2.7.1.4** - The food defense threat assessment and prevention plan shall be reviewed and tested at least annually or when the threat level, as defined in the threat assessment, changes. Records of reviews and tests of the food defense plan shall be maintained.

**Response:** Compliant

**Evidence:** • A food defense Plan annual review and challenge was conducted 03/14/2025. The scenario: The site sent an order for donuts with explicit instructions to only deliver the product to the QA manager in the quality control area. At 11:50 am the delivery person arrived and was granted entry to the lobby. The delivery person spoke to the receptionist and said that the delivery person was to personally deliver the donuts to the QA manager. The receptionist indicated that the manager was not present and could receive it on behalf of the QA manager and that, in any event, the delivery person could not be granted entry to the premises. After some further discussion, the delivery person agreed to leave the donuts with the receptionist and, dropped them off and left without incident. The site had a debriefing and noted that all personnel had followed the established procedure, and the challenge was deemed to have demonstrated that the security plan in this area was executed appropriately and successfully. Prior to entry into the site each day of the audit, the auditor was required to sign in and a photo tag was issued to be worn during the time on site. The auditor was always accompanied while on site, including during tours, and was required to sign out each day prior to leaving the facility.

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#### Summary -

**Response:** The site "Food Defense and Plant Security" (Number FD.001, revision number 005, Revision Date 06/04/2024 – annual review and update) based on the threat assessment in which the methods, responsibilities, and criteria for preventing deliberate food adulteration have been documented and implemented was in place. A food defense protocol includes the name of the senior manager responsible for food defense (Safety Manager) methods to allow access to the site only for authorized personnel, designated access points, the secured storage of materials, and hazardous chemicals and the control of access to contractors and visitors. Instructions have been provided to all relevant staff by means of in person training as evidenced by records provided from the HR Manager. The program is managed by the safety Manager/HR manager. There is a committee responsible for program oversight. The site has security cameras throughout and access to these are limited to the plant manager, safety manager and HR Manager. Topics in the program included: Physical security of the plant, laboratory safety, employees, personal items, computer systems, suppliers, operations, plant air security, finished products, and security strategies. The site additionally has a "Buddy system" (operators observing other operators); Glass and brittle plastic audits, a knife program, and Metal Detection in place. The threat assessment and prevention plan are required to be reviewed at least annually. There are also specific procedures for mail handling (Doc #SD.007, Revision # 001, Date of Origin 11/29/2021). The site also tracks all inbound and outbound trucks via the "Biosecurity Truck Inspection Report" (Form #WH.1430, Revision Date: 11/01/2023 – Revision 014). Report information includes: Trucking company name; truck inspection integrity; PO #; truck reefer temp setting number; are receivables and allergens labeled? Is the truck locked or sealed? dated and segregated; start load time; finish load time; and QC tech initials. Shipping Reports using the Bio-security Truck Inspection report 01/29/2025 – temp 34 F; reviewed 01/30/2025; 01/31/2025 reviewed 02/01/2025; 02/05/2025 reviewed 02/06/2025. Reports reviewed included: Receiving: 08/08/2024, 08/12/2024, 09/17/2024, 10/09/2024, 11/07/2024, 12/03/2024, 12/16/2024 05/2024, 01/29/2025, and 01/30/2025. Shipping: 01/29/2025, 01/30/2025, and 02/05/2025 All reports had no food

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security issues identified and all were released for receiving or shipment.

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## 2.7.2 - Food Fraud (Mandatory)

**2.7.2.1** - The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained.

**Response:** Compliant

**Evidence:** • The “Food Fraud Vulnerability Assessment and Mitigation” procedure (Procedure GMP.065, revision number 005, date of revision 01/05/2022) was reviewed. The program includes a scope of all products sold or distributed by the site and is overseen by the Director of QA/QC. Five stages of food fraud assessment were identified: 1) Identify the risks 2) Determine any needed corrective/preventive actions based on the risk assessment 3) Review and verify the program is functioning correctly. Annual Program review. 4) Maintain all records associated with the assessment and review. 5) Training for all team members on food fraud every 2 years.

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**2.7.2.2** - A food fraud mitigation plan shall be developed and implemented that specifies the methods by which the identified food fraud vulnerabilities shall be controlled, including identified food safety vulnerabilities of ingredients and materials.

**Response:** Compliant

**2.7.2.3** - Instruction shall be provided to all relevant staff on the effective implementation of the food fraud mitigation plan (refer to 2.9.2.1).

**Response:** Compliant

**2.7.2.4** - The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually with gaps and corrective actions documented. Records of reviews shall be maintained.

**Response:** Compliant

**Evidence:** • Food fraud assessments have been conducted for all raw materials and include an assessment for consequences and utilize Impact (1 to 5 score: negligible to severe) and likelihood (1 to 5 score: very unlikely to very likely/certain) and, based on the resulting matrix, have identified threat levels (Threat A - very high risk to Threat E - negligible risk). Higher risk items will result in the creation of a prevention, detection, and mitigation of food fraud document. In the processing the diagram chart was reviewed, and it identified the risk levels for each step. Most steps were identified as having negligible risk. Two steps were identified as having some risk: Rice and Rice Noodles (including site manufactured rice noodle 5 mm 30 x 1.4 oz 03-01-2005-00) (assessed and reviewed 11.19.2024) - Threat risk Medium (Ingredients were fairly likely to be affected by food fraud with minor consequences) . Considerations included: historic incidents, emerging concerns, size of market, price and price fluctuations, trading properties, geographic origins, etc. The ingredients were also assessed for risk on 5-point likelihood (1=Very unlikely to 5=very likely/certain) and consequences (1=negligible to 5=severe) - reviewed starch (22 different areas were considered for likelihood (e.g. historic incidents, emerging concerns, etc.). 10 different area were considered for consequences (e.g. country of origin standards for composition, etc.). All other ingredients were deemed to be of low risk.

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### Summary -

**Response:** A full site vulnerability assessment of all process steps at the site was conducted using the risk assessment developed for the site. Examples of process steps - 01/02/2025 - The threat level was 3 (of 5) for

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likelihood and also a 3 (of 5) leading to an overall assessment threat level of C. Prevention included restricting mixer operation cleaning, and maintenance for authorized personnel, The mixing operation is visible, and camera monitored; A buddy system is in place; a glass and brittle plastic program, a knife log, and metal detection are all in place. Other steps reviewed included storage (low risk). There were individual raw material assessments by ingredient type (example – the material group “starch” included corn starch used at the site). The assessment was conducted 11/19/2024. Fraud risk was deemed to be fairly likely, but with only minor consequences and was deemed to have a medium risk (i.e. action is needed, with occasional monitoring to mitigate the risk). Mitigations included: Purchase from suppliers with whom the site has long term relationships. Raw material approval programs include LOG and 3rd party audits. All inbound raw materials require COA. All incoming trucks are sealed. It was observed that the food defense plan contained methods to secure incoming products from sabotage, the food fraud vulnerability assessment identifies threats to incoming product substitution, mislabeling, and dilution, and the food fraud mitigation plan demonstrates these threats are controlled.

### 2.8.1 - Allergen Management (Mandatory)

**2.8.1.1** - The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors; iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known; iv. A list of allergens that is accessible to relevant staff; v. The control of hazards associated with allergens and incorporated into the food safety plan; and vi. Management plans for control of the identified allergens.

**Response:** Compliant

**Evidence:** • The site “Allergen Control Program” (Doc #WH.002, Revision 008, Revision Date 12/23/2024 – annual review and update – no changes) identifies the allergens that are used at each site. Procedures for allergen removal via Sanitation are outlined (including that if a line cannot be cleaned sufficiently to remove the allergen, production will be moved to a different line), as well as Storage and incoming material (including a statement that all materials with allergens must have an allergen control label. A risk analysis was observed for allergens including raw materials, ingredients, and processing aids such as food grade lubricants. Workplace allergens from locations such as lunchrooms, locker rooms and vending machines were found to be part of the allergen program. The operation was found to have a product identification system that includes clear identification and labeling of products to meet regulatory requirements when made on production lines used for allergenic products. Proper procedures for cleaning of food contact surfaces, including periodic validation of cleaning methods by protein-specific testing, were found to be in place. Product changeovers where allergen cross contamination could occur use validated cleaning, scheduling, and approved supplier program eliminate the risk of cross contact. The product trace system ensures the complete trace of allergenic ingredients, containing allergens.

**2.8.1.2** - Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens.

**Response:** Compliant

**2.8.1.3** - Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation

procedures shall be implemented and continually monitored.

**Response:** Compliant

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**2.8.1.4** - Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.

**Response:** Compliant

**Evidence:** • The site segregates wheat from non-wheat ingredients and has a separate section in the warehouse for gluten free items (the site has a small gluten free production. Egg powder is stored in a corner rack at the bottom shelf away from all other non-egg containing materials. The site conducts allergen testing for egg after the egg noodle product has been run. The site has procedures for "Gluten Testing of Product and Surfaces (Procedure TM.024,, Revision 008, Revision date 03/10/2022, that outlines the testing frequency (ingredients are tested at receiving and prior to each lot being used in gluten free production) and in finished product (testing is conducted on every run of gluten free product). The procedure was documented in the program. Testing for gluten free (prior to start up was conducted 01/14/2025) on 11 points on Udon 4 (where the rice noodles are run). All points tested points were without gluten presence. Also reviewed 02/17/2025 (no gluten detected). The site also had a sanitation cleanliness check – Allergen (Egg)" (Procedure #TM.014, Revision 002, Revision date 11/09/2020) – which outlined the procedure for testing the line for egg. Egg testing results reviewed included: - 02/11/2025 for Line Y 10. 15 tested points (post sanitation and prior to start-up). Two results were above threshold (aging bowl and dusting conveyor). Both areas were recleaned and recheck and both passed. All other results were <2.4 ppm (Negative) – and the results were reviewed 02/14/2025. - 02/12/2025 for Line Y 11. 15 tested points (post sanitation and prior to start-up). Two results were above threshold (aging bowl and blue conveyor). Both areas were recleaned and recheck and both passed. All other results were <2.4 ppm (Negative) – and the results were reviewed 02/14/2025. - Egg testing results were also reviewed for testing conducted 05/16/2024 (reviewed by the QC Manager 05/16/2024) – all results negative for 11 tested points. The egg test has five levels of presence (green means it is acceptable. Gray, light gray, dark gray, light purple, and dark purple are all indications of a positive test for the allergen and require recleaning and retesting.

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**2.8.1.5** - Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.

**Response:** Compliant

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**2.8.1.6** - Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

**Response:** Compliant

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**2.8.1.7** - The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured.

**Response:** Compliant

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**2.8.1.8** - The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.

**Response: Compliant**

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**2.8.1.9** - The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures.

**Response: Compliant**

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**2.8.1.10** - Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable.

**Response: Compliant**

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**2.8.1.11** - Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.

**Response: Compliant**

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#### **Summary -**

**Response:** The allergens of concern in this operation were observed to be wheat, which is in all products, and eggs, which are used in one product. The site uses soybean oil but it is highly refined and does not contain the soy allergen. This was confirmed by specification review of the soybean oil) and this was included in the list of products produced at the site. Instructions, in the allergen training program have been provided to all relevant staff involved in handling allergenic product. Team members interviewed were knowledgeable about the allergens that were on site and that their lunches may contain allergens as well, so handwashing after eating is critical. Allergen containing ingredients are stored in the warehouse such that all wheat allergens are stored away from non-allergen (in a separate aisle across from other raw materials. As all finished products at the site contain wheat there is no finished product separation. Egg allergens were stored in a bottom corner rack, away from other ingredients. Labels are verified prior to putting them on the line, including confirmation for allergen accuracy. Product preoperation checks were observed during the site tours and the checks included a review of the labels to ensure that allergens were properly declared. The operation was found to have a product identification system that includes clear identification and labeling of products to meet regulatory requirements when made on production lines used for allergenic products. Packaging film was only put on the line after it had been released after preoperational inspection had occurred. Allergen preventive controls included: warehouse storage of flour in bags in an assigned area; tagged of wheat with allergen tags for ease of identification, visual inspection of tagged pallets daily by QC team members (confirming that the allergen is in the correct area and tagged) as part of daily pre-op,. Each HACCP Plan includes a product log allergen assessment. As an example for the Noodle, Heat treated, HACCP plan, four products were identified: Yakisoba, noodles, ramen noodles, and Udon noodles All four product lines contain wheat and none of the product lines contain soy. The Udon noodle was identified as the only product containing egg (Note: There are no longer any products containing soy at the facility). The site also has a corporate provided international allergen listing (captured on Form QA.033, revision 003, revision date 07/04/2024), which includes 25 different allergens and the country or countries that they are considered allergens in.

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**2.9.1.1** - The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented (refer to 2.1.1.6).

**Response:** Compliant

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**2.9.1.2** - Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.

**Response:** Compliant

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#### Summary -

**Response:** The site had a "Training Description" document (Doc #SD.011, Revision 005, Revision Date 03/10/2020) that indicates what types of training the site performs. This included: Job task/performance training Company Safety and Quality Procedures GMPs HACCP Bio Security and Food Defense Allergen Glass and Brittle Plastics Food Safety and Quality Appropriate training is provided for all plant personnel for all tasks to ensure the effective implementation of the SQF system. Training programs are the assigned responsibility of HR Manager. Some site team members come from an agency and the agency is required to provide food safety training prior to coming to the site. Training was evident by team member interviews and training documents review. Training records were reviewed for several of the team members that were interviewed. Examples included: Trainers were either subject matter experts (i.e. the Director of QA/QC and QA manager have participated in offsite HACCP courses, and PCQI training) or have been trained by subject matter experts. Training documents included: Date, training topic, trainer, duration of training, trainee name and signature. Training was conducted in Spanish and English.

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### 2.9.2 - Training Program (Mandatory)

**2.9.2.1** - A training program shall be documented and implemented that at a minimum outlines the necessary competencies for specific duties and the training methods to be applied to personnel carrying out tasks associated with: i. Implementing HACCP for staff involved in developing and maintaining food safety plans; ii. Monitoring and corrective action procedures for all staff engaged in monitoring critical control points (CCPs); iii. Personal hygiene for all staff involved in the handling of food products and food contact surfaces; iv. Good Manufacturing Practices and work instructions for all staff engaged in food handling, food processing, and equipment; v. Sampling and test methods for all staff involved in sampling and testing of raw materials, packaging, work-in-progress, and finished products; vi. Environmental monitoring for relevant staff; vii. Allergen management, food defense, and food fraud for all relevant staff; and viii. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF code. The training program shall include provisions for identifying and implementing the refresher training needs of the organization.

**Response:** Compliant

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**2.9.2.2** - Training materials, the delivery of training, and procedures on all tasks critical to meeting regulatory compliance and the maintenance of food safety shall be provided in language(s) understood by staff.

**Response:** Compliant

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**2.9.2.3** - Training records shall be maintained and include: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Verification that the trainee is competent to complete the required tasks.

**Response:** Compliant

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### Summary -

**Response:** The site has implemented an employee training program (GMP.010 revision 006 last revised dated 03/16/2023), which covers the necessary competencies for plant personnel. This program requires training to be conducted in implementing HACCP, CCP Monitoring, Personal Hygiene, Non-GMO Procedures, GMPs, Sampling and Test Methods, Basic Microbiological Standards, Environmental Monitoring, Allergen Management, and other tasks identified as critical to meeting the effective implementation of the SQF code. Periodic refresher training is conducted annually, or when needed. From a review of refresher training records covering HACCP, GMP, Allergen, Sanitation Procedures, Food Safety and Defense, Food Quality, SQF, Employee Safety, IIPP, and interviews with Light Employee, Laborer, Lab Technician, and QC Technician it was evident the proper refresher training has been conducted to ensure food safety and the SQF system are maintained. The training language and materials are in English and Spanish (the languages used in the operation and understood by all plant personnel). Training records reviewed included the participant's name, skills description, description of training, date of training, trainer, and training verification. The site has task descriptions that are used for team member training on specific positions and job tasks. Examples reviewed included: - Product weigher (PDC.JD.009 Revisions 01/13/2020, revision 001) - Case movement (PDC.JD.0010 Revisions 01/13/2020 Revision 001) These are also instructions for position activities and these are required to be signed by the team member taking the training, the supervisor conducting the training and the plant manager who confirms the team member understands the training.

## 11.1.1 - Premises Location and Approval

**11.1.1.1** - The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities. The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

**Response:** Compliant

### Summary -

**Response:** Neighbors include an equipment repair company, a police station, individual warehouses, and a residential home. A premises location risk assessment was conducted 04/14/2022. This include a visual inspection of surrounding buildings to confirm that there was no risk. The risk assessment included a site overhead picture (Google earth) of the businesses, sports complexes, etc. in areas removed from those noted as directly surrounding the site. The site premises location also is captured in a premises location document (MD.922, revision 000, Date of origin 02/13/2021) The site has a business license from the Texas Department of State Health Services (License #1026022 Expires 12/15/2025). The state of Texas does not have a requirement for food processor licensing, per the site. Texas Sales and Use Tax Permit #3-20716-6038-8 Effective 02/01/2020 (there is no expiration date) FDA Registry (# xxxxxxx9612). Expires 12/31/2026. During the audit, the site's buildings, property, and surroundings were observed not to pose a food safety risk to products. Measures have been established to maintain a suitable external environment, and the facility performs external inspections as part of its internal audit program. The site business license was current and compliant with customer 1 requirements.

## 11.1.2 - Building Materials

**11.1.2.1** - Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to

allow the effective removal of all overflow or wastewater under normal working conditions. Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

**Response:** Compliant

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**11.1.2.2** - Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

**Response:** Compliant

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**11.1.2.3** - Waste trap system shall be located away from any food handling areas or entrances to the premises.

**Response:** Compliant

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**11.1.2.4** - Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 11.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

**Response:** Compliant

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**11.1.2.5** - Ducting, conduit, and pipes that convey ingredients, products, or services, such as steam or water, shall be designed and constructed to prevent the contamination of food, ingredients, and food contact surfaces and allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.

**Response:** Compliant

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**11.1.2.6** - Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients, and food contact surfaces and shall allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.

**Response:** Compliant

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**11.1.2.7** - Doors, hatches, and windows and their frames in food processing, handling, or storage areas shall be of a material and construction that meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction, and windows shall be made of shatterproof glass or similar material.

**Response:** Compliant

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**11.1.2.8** - Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. Drop ceilings, where present, shall be constructed to enable monitoring for pest activity, facilitate cleaning, and provide access to utilities.

**Response:** Compliant

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**11.1.2.9** - Stairs, catwalks, and platforms in food processing and handling areas shall be designed and constructed so they do not present a product-contamination risk and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.5).

**Response:** Compliant

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#### **Summary -**

**Response:** Floors are constructed of smooth and dense impact-resistant material (epoxy coated concrete) and graded adequately for adequate drainage of overflow or wastewater. Waste trap systems are located outside the facility, away from food-handling areas. Wastewater during the audit was observed to be adequately

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discharged via stainless steel, grated trench drains. Drains were observed to be located and constructed for ease of cleaning and inspection. Walls were of painted galvanized metal, were smooth, washable, and of durable construction. The ceilings in all food processing and handling areas are constructed of corrugated carbon steel, which is easily cleaned and prevents product contamination. Doors have a durable construction with smooth and light-colored surfaces. These areas were observed to be clean during the audit tours. Ducting, piping, and conduit conveying services were appropriately designed and installed to prevent contamination and for ease of cleaning. Overhead cleaning was found to be part of the master cleaning schedule. The overhead wastewater pipe installations did not pose a contamination hazard to food, materials, or contact surfaces. Stairs, catwalks, and platforms were observed during facility tours to be constructed and designed to avoid food contamination and avoid open grates above exposed product surfaces. Construction of platforms was primarily diamond plate steel and solid with toe kicks and no openings to allow materials to drop to exposed product below. Product contact surfaces not in contact with food and storage areas are constructed of suitable materials, including stainless steel, food-grade plastic, and carbon steel. They were observed during the audit to be adequately maintained so that food safety is not compromised.

### 11.1.3 - Lightings and Light Fittings

**11.1.3.1** - Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light-intensity regulations or industry standards.

**Response:** Compliant

**11.1.3.2** - Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling. Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

**Response:** Compliant

**11.1.3.3** - Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination.

**Response:** Compliant

#### Summary -

**Response:** The site had a lighting program (Doc #MD.003, Revision 006, revision date 09/20/2022) which identified allowable materials for lighting, lighting standards (i.e. 10 Fc for walk-in freezers, cooler, and dry store areas; 20 Fc for hand and utensil washing, utensil storage, food prep areas, etc. ). Lighting was appropriate to allow employees to carry out their tasks efficiently. All lighting in the warehouse, processing area, and any area where the product is exposed was covered or shatter shielded.

### 11.1.4 - Inspection/ Quality Control Area

**11.1.4.1** - If online inspection is required, a suitable area close to the processing line shall be provided for the inspection of product (refer to 2.4.4). The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to handwashing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

**Response:** N/A

**Evidence:** • N/A: Production floor Inspection/Quality Control areas are not required in this operation.

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**Summary -**

**Response:** The site did not have inspection areas on the production floor. Any needed product review, organoleptic inspection or basic product testing occurs in the QC lab which is separate from processing. The lab was clean and well organized, well-lit and had sinks and access to restrooms.

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### 11.1.5 - Dust, Insect, and Pest Proofing

**11.1.5.1** - All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed, and proofed against dust, vermin, and other pests. External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against entry of dust, vermin, and other pests.

**Response:** Compliant

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**11.1.5.2** - External doors, including overhead dock doors in food handling areas used for product, pedestrian, or truck access, shall be designed and maintained to prevent pest ingress by at least one or a combination of the following methods: i. A self-closing device; ii. An effective air curtain; iii. A pest-proof screen; iv. A pest-proof annex; and v. Adequate sealing around trucks in docking areas.

**Response:** Compliant

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**11.1.5.3** - Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or exposed.

**Response:** Compliant

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**Summary -**

**Response:** External windows, doors, and other openings were observed during facility tours to be adequately sealed to prevent any pest infestation or dust coming into the facility. External personnel doors were self-closing and sealed to prevent dust and pest ingress. All external doors and dock doors were sealed to prevent infestation. Electric insect devices and interior and exterior rodent stations are located, so the product is not at risk for contamination. Rodenticide bait is only used on the outside of the facility. Oven vents were sealed with exits to the roof.

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### 11.1.6 - Ventilation

**11.1.6.1** - Adequate ventilation shall be provided in enclosed processing and food handling areas. Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination.

**Response:** Compliant

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**11.1.6.2** - All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.5 to prevent unsanitary conditions.

**Response:** Compliant

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**11.1.6.3** - Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or

a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s).

**Response:** Compliant

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**11.1.6.4** - Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and shall be kept clean.

**Response:** Compliant

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#### Summary -

**Response:** The ventilation program was captured in proofing and ventilation (MD.024, revision date 07/02/2024, revision #005). Adequate ventilation was available, where needed, in enclosed processing and food areas. Ventilation equipment was seen to be adequately cleaned, insect-proofed, and located not to pose a risk of contamination. Ventilation and heat extraction above cookers and other heat-generating operations were adequate, and no condensation was observed.

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### 11.1.7 - Equipment and Utensils

**11.1.7.1** - Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented.

**Response:** Compliant

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**11.1.7.2** - Equipment and utensils shall be designed, constructed, installed, operated, and maintained to meet any applicable regulatory requirements and to not pose a contamination threat to products.

**Response:** Compliant

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**11.1.7.3** - Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. Where possible, food contact equipment shall be segregated from non-food contact equipment.

**Response:** Compliant

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**11.1.7.4** - Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging storage, and cold storage areas shall be constructed of materials that will not contribute to a food safety risk.

**Response:** Compliant

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**11.1.7.5** - Benches, tables, conveyors, mixers, mincers, graders, and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious, and free from cracks or crevices.

**Response:** Compliant

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**11.1.7.6** - Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned as per 11.2.5.1. Bins used for inedible material shall be clearly identified.

**Response:** Compliant

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**11.1.7.7** - All equipment and utensils shall be cleaned after use (refer to 11.2.5.1) or at a set and validated frequency to control contamination and be stored in a clean and serviceable condition to prevent microbiological or

cross-contact allergen contamination.

**Response:** Compliant

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**11.1.7.8** - Vehicles used in food contact, handling, or processing zones or cold storage rooms shall be designed and operated so as not to present a food safety hazard.

**Response:** Compliant

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**11.1.7.9** - Non-conforming equipment shall be identified, tagged, and/or segregated for repair or disposed of in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product. Records of the handling, corrective action, and/or disposal of non-conforming equipment shall be maintained.

**Response:** Compliant

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#### Summary -

**Response:** Specifications for the site's equipment, utensils, and purchase procedures for equipment are documented in the GMP program and were appropriately implemented. Equipment and utensils including tables, mixers, extruders, cookers, coolers, packers, conveyors, tubs, bins, and containers are designed, constructed, and installed to meet regulatory requirements and prevent contamination risks. These items were clean and stored properly after use to prevent cross-contamination. Product contact surfaces, storage areas, and surfaces not in contact with food are constructed of suitable materials, including stainless steel, food-grade plastic, and carbon steel. Almost all processing equipment including conveyor belts, was constructed of stainless steel and was maintained in clean condition. Equipment was observed during the audit to be adequately maintained so that food safety is not compromised. Equipment surfaces were smooth, impervious, and free from cracks and crevices. Containers and bins are made of non-toxic materials were labeled or color-coded for appropriate use with either edible (white or stainless) or non-edible (all other colors – Orange is for Q use. Other colors are used to designate areas for sanitation utensils) materials. Wastewater from tanks, tubs, and other equipment is discharged to the floor drainage system and meets requirements. Equipment and utensils are cleaned according to the Master Sanitation Schedule and validated by visual inspection and under the scope of the environmental program method to prevent microbiological or cross allergen contamination. Vehicles used for food contact, handling, processing area, and cold storage are maintained clean and free from peeling paint. Although there is no non-conforming equipment, there are documented provisions to identify, tag, segregate, or dispose of non-conforming equipment.

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### 11.1.8 - Grounds and Roadways

**11.1.8.1** - A suitable external environment shall be established, and the effectiveness of the measures shall be monitored and periodically reviewed. The premises, its surrounding areas, storage facilities, machinery, and equipment shall be kept free of waste or accumulated debris, and vegetation shall be controlled so as not to attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

**Response:** Compliant

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**11.1.8.2** - Paths, roadways, and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operations of the premises. They shall be adequately drained to prevent the pooling of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

**Response:** Compliant

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**11.1.8.3** - Paths from amenities leading to site entrances shall be effectively sealed.

**Response:** Compliant

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## Summary -

**Response:** The grounds and surrounding areas were observed to minimize dust and be free of waste, so pests are not attracted. Paths, roadways, and dock areas were seen to be adequately and adequately drained and well maintained, so they do not present a hazard. No water pooling was observed. No debris was observed in external areas during the site tours. Walkways from the parking lot and other employee amenities were paved or effectively sealed.

## 11.2.1 - Repairs and Maintenance

**11.2.1.1** - The methods and responsibility for the maintenance and repair of plant, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination.

**Response:** Compliant

**11.2.1.2** - Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety.

**Response:** Compliant

**Evidence:** • The PM Program has transitioned to a PM system and maintenance tracking program. The system includes: PM frequencies (monthly, quarterly, semi-annually, annually), equipment name, who performed the PM, what was done (i.e. lubrication, replacement, etc.), date PM was performed and date of verification. This is managed by the maintenance coordinator.] Work orders (for unplanned maintenance) reviewed included: WO #2435 - 03/27/2024 - air dehumidifier to the silo was not working - The issue was determine to be that the blow wheel motor was not functioning. A new unit was ordered 03/28/2024 (expected completion date 04/17/2024 - Medium priority). Once the new motor came in it was replaced on 04/22/2024 and was closed the same day. Form items included: "Did you follow GMPs?, Did you follow safety and LOTO procedures? Did all tools and parts used were returned? WO #2870- 05/20/2024 - Cutter damaged - The cutter blade was repaired and this was completed and closed on the same day (05/20/2024) and was reviewed on 05/20/2024 as well. WO #4009- 10/30/2024 - Proximity sensor n pusher section was broken. The issue was determined to be a broken transfer cable, which was ordered and replaced on 11/14/2024. This was completed and closed on the same day (11/14/2024) and was reviewed on 11/14/2024 as well. WO #4085- 11/07/2024 - Leaking valve on pasteurizer 4. The valve was tightened and a new valve was ordered and replaced the leaking valve on 11/22/2024. This was completed and closed on the same day (11/14/2024) and was reviewed on 11/14/2024 as well. Preventive Maintenance The computerized maintenance management system (CMMS) includes provisions for printing a master schedule of activities. Daily, a schedule is created and posted on the wall outside of the maintenance office that defines what the activities are for each team member for that day. As an example, the PM scheduled for 03/13/2025 was reviewed and included the maintenance team member name, an hour by hour list of daily and programmed (i.e. weekly, monthly, quarterly, etc.) PM activities by each hour of the work day. Using 1 team member as an example, activities scheduled included: - 05:00-06:00 oil tumbler check - 06:00-10:00 - Oil stand for Oil station - 10:00-13:00 - Tape machine hooks - 13:00-15:00 Udon 3 hook - 15:00-16:00 - clean shop and close work orders Preventive Maintenance examples reviewed included: WO #3853 - PM on thermos-former packing line (includes all sections) 11/04/2024 - designated as a medium priority. Includes - Cutting and forming sections: Verify all safety inter-locks are working (repair as necessary). Inspect all electrical connections, sensors, limit switches, and solenoids for damage or temporary repairs (repair as necessary). Cutting section: inspect all blades and cutters for wear or damage (replace as

necessary); Forming Section: inspect and clean vacuum system, actuators, valves, fillers, hoses, and connections (repair or replace as necessary). General questions at the end included: "Did you follow GMPs?, Did you follow safety and LOTO procedures? Did all tools and parts used were retrieved and returned? Electronically signed as completed 11/04/2024. There is also a part of the system that required review "signature" before allowing close-out. Also, WO 2464 – Main conveyor Monthly Priority medium assigned 04/14/2024. signed as completed 04/23/2024.

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**11.2.1.3** - Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule.

**Response:** Compliant

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**11.2.1.4** - Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling, or storage areas.

**Response:** Compliant

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**11.2.1.5** - The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance activities pose a potential threat to product safety (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside operating times.

**Response:** Compliant

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**11.2.1.6** - Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions.

**Response:** Compliant

**Evidence:** • The "Temporary Repair Program" (Doc #MD.001, version 008, last revised 06/27/2024) was in place. Temporary repairs are rare for the site and the protocol outlines what materials are allowed to be used for temporary repair, what type of documentation is allowed (i.e. a temporary repair tag must be placed on the equipment and affected personnel must be notified). Temporary repairs must be completion within 15 days and a temporary repair report must be filed. The site indicated no temporary repairs were needed in the past 12 months and no temporary repairs were observed during audit. Temporary repairs are allowed, but should be the exception. They are captured in the electronic maintenance program and associated expected dates of full repair are included. Overdue notices are triggered when past due dates occur, and these are captured and managed by the inventory control specialist

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**11.2.1.7** - Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product.

**Response:** Compliant

**Evidence:** • The site "Food Grade Lubricants Program" (Doc #MD.004, revision 005, Revision Date 09/29/2022) indicates that the site is limited to one type of lubricant per specific application. Machinery, conveyors, and other equipment over or near food or food contact surfaces are lubricated with food-grade materials. The food-grade lubricants were appropriately labeled and stored separately in a food-grade cabinet. Paint is not used on food contact surfaces, and any paint in processing areas was noted to be in good condition with no observed flaking.

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**11.2.1.8** - Paint used in a food handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces.

**Response:** Compliant

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## Summary -

**Response:** The site had several programs related to maintenance performance including the "Work Order Program (Procedure MD.009, Revision Number 004, Revision Date 10/03/2021) and the "Preventive Maintenance Program" (Doc #MD.019, Revision 004, Revision Date 10/03/2022) which defines the responsibilities for the maintenance and repair of all plant equipment and buildings. There is a planned Preventive Maintenance schedule, and PM tasks are documented in this program and "MD.009 work order program." Maintenance personnel are trained in good manufacturing practices and food safety. Maintenance and repairs to be undertaken in any processing, food handling, or storage area are communicated to site supervisors, including potential hazards such as loose wire, damaged lighting, and loose overhead objects that threaten product safety. The site also had a "Hygienic Design Program" (Doc #MD.002, Revision 002, Revision date 06/27/2024) and "Construction Program" (Doc #MD.006, Revision 005, Revision Date 09/20/2022) that outlined the procedures and requirements when acquiring new equipment and building materials as well as identifying the maintenance manager as responsible for selecting equipment that complies with the standards set forth in the program. A cross functional team is in place to approve new equipment purchases.

## 11.2.2 - Maintenance Staff and Contractors

**11.2.2.1** - Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3).

**Response:** Compliant

**11.2.2.2** - All maintenance and other engineering contractors required to work on-site shall be trained in the site's food safety and hygiene procedures or shall be escorted at all times until their work is completed.

**Response:** Compliant

**11.2.2.3** - Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed, and inform the area supervisor and maintenance supervisor, so appropriate hygiene and sanitation can be conducted and a pre-operational inspection completed prior to the restarting of site operations.

**Response:** Compliant

## Summary -

**Response:** Maintenance and engineering contractors are trained in the site's food safety and hygiene procedures using the GMP Policy displayed in the front office prior to being allowed access to the site production and warehousing areas. Periodic inspections of ongoing work are completed to ensure loose parts and other materials are not potential contaminants. When repairs and maintenance are complete, maintenance personnel remove all tools and debris and notify a supervisor. Appropriate cleaning and pre-operational inspections are carried out before resumption of operations, documented in the work order, and cleaned and inspected in the sanitation tag. This was reviewed during the audit. No areas were undergoing maintenance troubleshooting during the audit and no maintenance contractors were observed on site during the audit.

## 11.2.3 - Calibration

**11.2.3.1** - The methods and responsibility for calibration and re-calibration of measuring, testing, and inspection equipment used for monitoring activities outlined in prerequisite programs, food safety plans, and other process controls, or to demonstrate compliance with customer specifications, shall be documented and implemented.

Software used for such activities shall be validated as appropriate.

**Response:** Compliant

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**11.2.3.2** - Equipment shall be calibrated against national or international reference standards and methods or to an accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.

**Response:** Compliant

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**11.2.3.3** - Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule.

**Response:** Compliant

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**11.2.3.4** - Procedures shall be documented and implemented to address the resolution of potentially affected products when measuring, testing, or inspection equipment is found to be out of calibration.

**Response:** Compliant

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**11.2.3.5** - Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use.

**Response:** Compliant

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**11.2.3.6** - A directory of measuring, testing, and inspection equipment that require calibration and records of the calibration tests shall be maintained.

**Response:** Compliant

**Evidence:** • Examples of food safety/regulatory equipment calibrations reviewed included: Metal Detection: Six units have been calibrated (One used as back-up). The calibration company uses the site pieces for their calibrations. The site had Certificates of compliance to NIST standard 681/280800-11 for each test piece (i.e. Ferrous (Chrome steel) 2.5 mm Cert #82835 dated 01/31/2015; Non-ferrous (Brass) 3.5 mm Cert #117753 certified 01/01/2020; 316 Stainless Steel 3.5 mm Cert #105657 date 01/01/2020). Metal detector Calibrations occurred 02/18/2025 – Information included: Machine serial Number, Model, Line used on, aperture size, sensitivity, phase, frequency, reject delay 1000 ms, reject duration 2000 ms, belt speed. Notes for each unit tested indicated that the 5 time pass for each test piece was successful and no notations were made about unit adjustments. Final results were “in tolerance” for all five metal detectors. X-Ray checks – dated 02/18/2025 – Included contaminant detection parameters (small, medium, large, other, and wire), machine serial number, belt speed, Model #, Rejection delay (0.50s) Rejection duration (0.45 sec) Tested with Ferrous, nonferrous, stainless steel but not for glass or ceramic, even though the site has these test cards. Scales: 40 scales were calibrated by a third-party calibration company 02/10/2025 Information on the calibration documents included manufacturer/model, serial number of the scale, capacity, test weight used, as found condition, as left condition, and whether a corner test was conducted (and results of the four corner test). All scales passed and none needed adjustment. The Weight Set: used was identified as NIST traceable - HES-K1 test number: 3518576, test date of weights: 03/08/2023. Documentation included that the company used NIST handbook 44m and the state registration number for the field representative conducting the scale test pH meter – 01/08/2025 – Included traceability number Received in tolerance and no adjustment needed. Thermometers for pasteurizer – 05/16/2024 – Included calibration procedure and compliance to ANSI/NCSL Z540-1, IS9001 2015m, etc. standards. All tests were compliant.

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**Summary** -

**Response:** A policy defines the methods and responsibilities for calibrating measuring, testing, and inspection

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equipment and has been implemented. The facility has developed a calibration schedule for all devices listed. This documentation is located in the calibration program (Doc #MD.005 Revision 007, Revision Date 06/27/2024 – added mention of certificates of calibration). The frequency of calibrations is based on the manufacturer’s recommendations or customer requirements. The program includes the procedures to address the disposition of any affected product should inspection equipment be found to be out of calibration, as written in the program. Inspection and testing equipment is protected from damage or unauthorized use by maintaining the equipment in a secure location when not in use. Equipment is calibrated against national or international standards.

#### 11.2.4 - Pest Prevention

**11.2.4.1** - A documented pest prevention program shall be effectively implemented. It shall: i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods and the appropriate documentation for each inspection; v. Outline the frequency with which pest status is to be checked; vi. Include the identification, location, number, and type of applied pest control/monitoring devices on a site map; vii. List the chemicals used. The chemicals are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available; viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests and to identify trends.

**Response:** Compliant

**Evidence:** • The site conducts monthly follow up pest control device assessment that include whether the device is in place, working, accessible and tagged. Checks were reviewed for 08/31/2024 (one interior trap was missing), 10/11/2024 (one trap was not working properly), and 01/25/2025 (everything was working). The pest control company comes on a weekly basis. Reports were reviewed for several dates. Examples included: 08/21/2024 – two traps were blocked by cardboard . Light traps had activity in 6 of 7 locations (light activity: occasional invaders and small flies) No mechanical rodent traps (of 93 inspected), pheromone traps (of 3 inspected), or rodent bit stations had activity. 12/16/2024 – receiving storage area had fixed the finding of space less than 18” from the wall noted in prior visit. Note of vegetation near the building and some pallets preventing access to exterior bait stations. Note of application of cockroach pesticide to the exterior (to prevent entry) and some interior treatment for cockroaches, as well as adding bait to some exterior stations. Light traps had activity in 3 of 7 locations (very light activity: occasional invaders and one large fly). No mechanical rodent traps (58 reviewed), activity in 2 of 3 pheromone traps (a total of 3 IMM), and no rodent bait stations had activity (of 40 reviewed) – one bait station noted as broken and was replaced during the service. 04/16/2024 – No site conditions were noted. Light traps had activity in 2 of 6 locations (light activity: occasional invaders and IMM). 2 of 3 pheromone traps. No mechanical rodent traps, pheromone traps, or rodent bit stations had activity. The pest control company provides a trend grid that covers a three-month period and identifies the level of activity in various site areas (production, loading dock, dry storage freezer, trash room, maintenance, and offices/break room) for 11 different types of pests (e.g. Indian Meal Moth, rats, mice, roaches, etc.) The matrix indicated that activity for all areas and pest types was “low” for the fourth quarter of 2024. There was also a risk assessment for both key interior and exterior areas (0-10 is low risk) all areas were identified as a “1” (low risk). Management representative after visits and were reviewed and found to be completed as scheduled. Any observations or issues noted by the Pest Contractor are addressed and documented by the site.

**11.2.4.2** - Pest contractors and/or internal pest controllers shall: i. Be licensed and approved by the local relevant authority; ii. Use only trained and qualified operators, who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.2.8), which includes a site map, indicating the location of bait stations traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; vi. Provide regular inspections for pest activity with appropriate action taken if pests are present, and vii. Provide a written report of their findings and the inspections and treatments applied.

**Response:** Compliant

**Evidence:** • Pest control provider certifications and time sensitive documentation included: Certificate of Insurance – Expires 07/22/2025; Business license #0673838 Expires 02/28/2026; Commercial Certified Applicator License #0673838 Expires 02/28/2026; Certified applicator licenses (Texas Department of Agriculture) - #0818455 expires 02/28/2026 Alternate Certified applicator licenses (Texas Department of Agriculture) - #0921122 expires 02/28/2026 SDS for insecticides and chemicals used by the pest control company were on file (no pesticides are kept on site and none were observed on site during the tours) The pest control company regional manager conducts an annual site assessment. This was last documented 03/17/2025. No issues were identified.

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**11.2.4.3** - Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be conducted on a regular basis by trained site personnel and the appropriate action taken if pests are present. Identified pest activity shall not present a risk of contamination to food products, raw materials, or packaging. Records of all pest control inspections and applications shall be maintained.

**Response:** Compliant

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**11.2.4.4** - Food products, raw materials, or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation shall be investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.

**Response:** Compliant

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**11.2.4.5** - Pesticides shall be clearly labeled and stored per 11.6.4 if kept on-site.

**Response:** N/A

**Evidence:** • N/A - Pesticides are not stored on-site.

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**11.2.4.6** - No animals shall be permitted on-site in food handling and storage areas.

**Response:** Compliant

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#### Summary -

**Response:** The “Pest prevention Policy” (GMP.024, revision number 11, revision date 12/23/2024 – annual review and no changes) defines the site’s program for pest prevention and the appropriate follow-up to pest prevention issues that may occur. The program was observed during the audit to be effectively implemented. The premises were free of waste and debris, as observed during the interior and exterior tours. No pest activity was identified or noted during tours that presented a risk for product contamination, and corrective action and record-keeping procedures are in place should this occur. A Pest Contractor has been contracted for pest prevention. An updated scope of service dated 03/26/2024 defines pest prevention methods, the frequency of interior and exterior inspections, and targeted pests. A current site map, dated 03/17/2025, is accurate, showing the location of 47 external bait stations, three pheromone traps, seven ILTs, and 95 internal devices. The map was spot checked against the physical device locations and devices were where indicated. A

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pesticide application log gives details and dates of all chemical usage.

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### 11.2.5 - Cleaning and Sanitation

**11.2.5.1** - The methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Validation of the cleaning procedures for food contact surfaces (including CIP); vi. Methods used to confirm the correct concentrations of detergents and sanitizers; and vii. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

**Response:** Compliant

**Evidence:** • The site has cleaning procedures that describe the methods and responsibilities of cleaning processing equipment, the environment, storage areas, bathrooms, and break rooms. Sanitation Standard Operating Procedures are written and include what is cleaned, chemical usage, concentrations, cleaning methods, and who is responsible. This is captured on the "Master Sanitation Cleaning Procedures" (SSOP.002 CA revision 003, revision date 11/01/2023) and included step by step procedures and frequencies for each area (e.g. mixer aging bowl, aging conveyor, etc.) A master sanitation plan includes all facility areas with frequencies and responsibilities for deep cleaning. All areas on a daily schedule were identified on MSS-01 CP Revision 003, revision date 01/23/2024. The weekly, monthly, quarterly, and semi-annual sanitation activities. Each daily checklist is broken down by room or equipment being cleaned. Reviewed daily sanitation completion documentation for 04/01-30/2024 (reviewed 04/30/2024), 10/01-31/2024 (signed 11/01/2024), and 01/01-31/2025 (Weeks 1-5) for all areas. Also weekly for April 2024, and January 2025, and monthly December 2024 through February 2025 which included areas such as ceiling vents, chain covers and scrapers, flour ducts, etc. (each month a new sheet adding the monthly activities on and re-signing the document occurs). Quarterly activities were reviewed for April, July, and October 2024, and January 2025 and quarterly sanitation activities included, lunchroom, ceiling vents, and drop ceilings. Semi-annual (February 2025) and annual (hopper seals cleans 04/12/2024) were also reviewed. All assignments were initialed as completed and were reviewed by the Sanitation Manager within 2 business days of the end of the week. Sanitation assignments are made during daily 5 minute meetings prior to the start of the sanitation shift. Relevant SSOPs reviewed included: "Blood Cleanup Cleaning Procedures" (SSOP.020 CA, Revision Date 11/01/2023, revision 003) outlines the process for performing and bodily fluid clean up needed, including PPE required to perform the tasks. "Safe Handling and Use of Chemicals Training" (SSOP.033 CA, revision 003, revision date 11/01/2023). "New Chemicals" (SSOP.610 CA, revision 003, revision date 11/01/2023). Includes the procedure, which requires that all guarantee, product labels, technical data sheet or specification sheets, and SDS.

**11.2.5.2** - Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use; ii. An inventory of all purchased and used chemicals is maintained; iii. Detergents and sanitizers are stored as outlined in element 11.6.4; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v. Only trained staff handle sanitizers and detergents.

**Response:** Compliant

**Evidence:** • SDS were reviewed for several chemicals, These are in English and Spanish, including: - Foaming chlorinated cleaner – SDS dated 10/04/2018. Harmful if swallowed. Causes severe skin burns and eye damage. Toxic to aquatic life. May be corrosive to metals. - Metal Activator (used in conjunction with disinfectant cleaners to allow use on soft metals such as aluminum) – SDS 10/16/2019. Causes severe skin burns and eye

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damage. - Acidic Detergent – SDS dated 01/27/2023. May intensify fire – oxidizer; May be corrosive to metals; harmful if swallowed; causes severe skin burns and eye damage; causes serious eye damage; harmful if inhaled.

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**11.2.5.3** - Detergents and sanitizers that have been mixed for use shall be correctly mixed according to the manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.

**Response:** Compliant

**Evidence:** • The sanitation chemical company provides auto-dilution equipment for sanitation chemicals and checks concentrations on a monthly basis. In addition, the site conducts daily checks of chemical strength prior to dispensing the chemicals for the day. The binder where the dilution test results are contained also includes a sheet with the product, description, compatibility with metal cleaning, the method of application, and the dilution. Only the sanitation lead can dilute the chemicals to the final strength. Examples reviewed included: - Food Surface Chlorine Sanitizer testing from 02/01/2025 to 02/28/2025 indicated that all tests were within the specified tolerances of 50 to 200 ppm. - Quaternary ammonia sanitizer testing from 02/01/2025 to 02/28/2025 indicated that all tests were within the specified tolerances of 150 to 400 ppm (results ranged from 200-400 ppm). - Liquid Chlorinated Alkaline Foam Cleaner testing from 02/01/2025 to 02/28/2025 indicated that dilution is determined by the drop method and all dilutions documented required 6 to 7 drops. All strengths were (trained by the chemical provider) and reviewed by the Sanitation manager. Test kit chemicals were reviewed for code date expiration, and all were still within expiration date. Examples reviewed included: - Peracetic Acid strength test kit – expiration 09/2026 - Chlorine Strips – expiration 12/01/2025 Quaternary ammonia test strips – expiration 01/31/2026.

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**11.2.5.4** - Cleaning-in-place (CIP) systems, where used, shall not pose a chemical contamination risk to raw materials, ingredients, or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored, and recorded (e.g., chemical and concentration used, contact time, and temperature). CIP equipment, including spray balls, shall be maintained, and any modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.

**Response:** N/A

**Evidence:** • N/A – Internal Clean-In-Place procedures are not carried out at the site.

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**11.2.5.5** - Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of processing areas, product handling equipment, and storage areas as well as the tools themselves.

**Response:** Compliant

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**11.2.5.6** - Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these cleaning operations shall be controlled so they do not interfere with manufacturing operations, equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required.

**Response:** Compliant

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**11.2.5.7** - Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start of production. Pre-operational inspections shall be conducted by qualified personnel.

**Response: Compliant**

**Evidence:** • Sanitation tasks and pre-operational inspections by qualified personnel are documented. The pre-operational inspection of Preop 03/19/2025 was observed – QC technician reviewed areas of each line for visible cleanliness (ATP swabs are taken once per week and were not observed during this preop). Several areas were determined to need additional cleaning, and these were documented. There was a corrective action section that indicated the actions taken to address the nonconforming observations (i.e. recleaning the area). After the recleaning, the area was again reviewed and all three areas were deemed to be satisfactory. New packaging was brought to the line and verified against a control set of packing by the QA technician. The line was released to production at 6:15 am. During the inspection the QA technician used a flashlight to ensure visibility and was escorted by a group of sanitation members who corrected the non-conformances immediately after they were identified. Other preoperational inspection and ATP testing dates reviewed included: 07/24/2024 – 16 areas tested on Yakisoba 5 (Customer 1 line). Two areas had elevated values. Rechecks for both areas came in within tolerances. 08/06/2024 – 12 sites on Yakisoba 10 – one check had an elevated value. The area was recleaned and sanitized and the recheck came in within tolerances. 01/20/2025 – 18 sites for Yakisoba 11. Two areas had elevated values. Rechecks for both areas came in within tolerances.

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**11.2.5.8** - Staff amenities, sanitary facilities, and other essential areas shall be inspected by qualified personnel at a defined frequency to ensure the areas are clean.

**Response: Compliant**

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**11.2.5.9** - The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared. A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

**Response: Compliant**

**Evidence:** • Sanitation is verified via ATP swab testing and test results must be satisfactory before the line is released to production. Procedures for this are contained in The “Plant Environmental Monitoring Program” (Doc #GMP.016, Revision 020, Revision Date 04/16/2024) and the “Master Sanitation Cleaning Procedures” (SSOP.002 CA revision 003, revision date 11/01/2023). This is compliant with customer 1 requirements.

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**Summary -**

**Response:** Cleaning materials are stored securely in a locked room off of the production area, and had chemicals stored appropriately (including bulk chemicals in containment systems) and were adequately labeled, with SDS information available to all employees. In order to maintain sanitation equipment segregation a color coding system has been implemented for sanitation utensils: Blue: Production Red: Restrooms Grey: Lunchroom/office Black: External area/parking lot Site tours demonstrated that the site was maintained clean. Interviews with sanitation team members showed a demonstrated understanding of the cleaning processes, handwashing techniques, where SDS binders were located and what to do if an unknown chemical was found (i.e. notify the sanitation manager – do not use until instructed in proper use).

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**11.3.1 - Personnel Welfare**

**11.3.1.1** - Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed. Medical Amendment added: Code Amendment #1A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

**Response: Compliant**

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**11.3.1.2** - The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury that causes the spillage of bodily fluid, a properly trained staff member shall ensure that all affected areas, including handling and processing areas, have been adequately cleaned, and that all materials and products have been quarantined and/or disposed of.

**Response:** Compliant

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**11.3.1.3** - Personnel with exposed cuts, sores, or lesions shall not engage in handling or processing exposed products or handling primary (food contact) packaging or touching food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored, metal-detectable bandage or an alternative suitable waterproof and colored dressing.

**Response:** Compliant

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#### Summary -

**Response:** A Good Manufacturing Practice policy for all employees has been documented and implemented. Employees are prohibited from working in food handling or open food storage areas who are suffering from, or who are or were carriers of, an infectious disease that may be passed through food. The site has documented measures to prevent contact of product materials with bodily fluids and respond appropriately to any bodily fluid spillage. The policy includes prohibiting any food handling activity for persons with exposed cuts, sores, or lesions. It requires that minor cuts or abrasions be covered with a waterproof, metal detectable, colored bandage or dressing. No team members were observed to have obvious signs of illness or exposed wounds during the site tours. Team members interviewed indicated that they should not come into work when ill and to use metal detectable blue bandages if a minor cut occurs.

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### 11.3.2 - Handwashing

**11.3.2.1** - All personnel shall have clean hands, and hands shall be washed by all staff, contractors, and visitors: i. On entering food handling or processing areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating, or drinking; and v. After handling wash down hoses, cleaning materials, dropped product, or contaminated material.

**Response:** Compliant

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**11.3.2.2** - Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

**Response:** Compliant

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**11.3.2.3** - Handwashing stations shall be constructed of stainless steel or similar non-corrosive material and at a minimum supplied with: i. A potable water supply at an appropriate temperature; ii. Liquid soap contained within a fixed dispenser; iii. Paper towels in a hands-free cleanable dispenser; and iv. A means of containing used paper towels.

**Response:** Compliant

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**11.3.2.4** - The following additional facilities shall be provided in high-risk areas: i. Hands-free operated taps; and ii. Hand sanitizers.

**Response:** Compliant

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**11.3.2.5** - Signage in appropriate languages instructing people to wash their hands before entering the food



processing areas shall be provided in a prominent position in break rooms, at break room exits, toilet rooms, and in outside eating areas, as applicable.

**Response:** Compliant

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**11.3.2.6** - When gloves are used, personnel shall maintain the handwashing practices outlined above.

**Response:** Compliant

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#### Summary -

**Response:** A policy covering hand washing requirements has been documented and implemented. Hand washbasins are located at appropriate employee access points to processing areas. Handwash sinks are made of non-corrosive materials and supplied with tempered potable water. Liquid soap, paper towels, and waste containers are available. Hands-free operated taps and hand sanitizers are available in the high-risk areas of the facility. Signs are posted reminding employees to wash their hands before returning to work in restrooms, at handwash stations prior to entering process areas, and in the break room. Employees are required to wash their hands when wearing gloves. Team members interviewed were able to identify when hand washing was needed and to demonstrate proper handwashing technique. Team members handling product were observed to be wearing gloves that were intact during these activities. Observed hand washing and glove use, and sink locations, were compliant with customer 1 requirements.

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### 11.3.3 - Clothing and Personal Effects

**11.3.3.1** - The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food, and food contact surfaces from unintentional microbiological or physical contamination.

**Response:** Compliant

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**11.3.3.2** - Clothing worn by staff engaged in handling food shall be maintained, stored, laundered, and worn so it does not present a contamination risk to products.

**Response:** Compliant

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**11.3.3.3** - Clothing, including shoes, shall be clean at the start of each shift and maintained in a serviceable condition.

**Response:** Compliant

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**11.3.3.4** - Excessively soiled uniforms shall be changed or replaced when they present a product contamination risk.

**Response:** Compliant

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**11.3.3.5** - Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area, and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or in designated sealed containers in personnel lockers. They should not be placed or stored on packaging, ingredients, product, or equipment.

**Response:** Compliant

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**11.3.3.6** - Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned. All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

**Response:** Compliant

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**11.3.3.7** - Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities.

**Response:** Compliant

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**11.3.3.8** - Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or into any area where food is exposed. Wearing plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted, provided these items are properly covered and do not pose a food safety risk. All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.

**Response:** Compliant

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#### Summary -

**Response:** The site's clothing requirements have been implemented based on a documented risk assessment found in the personal attire policy. Protective clothing meets documented specifications, is easily cleaned, and is made of material that will not contaminate food. Employees store clothing on racks adjacent to access points when going on breaks. Clothing, including shoes, was observed clean at the commencement of the shift and during production. . Employees interviewed indicated an understanding of the need to change clothes when they were soiled, torn or contaminated and to take off smocks and PPE prior to entering restrooms or break rooms. Employees were observed to comply with the clothing requirements of the facility. Jewelry and other loose objects are prohibited in food processing and handling areas. Employees were observed to comply with the jewelry policy during the audit tours. Plain bands are allowed by the facility's policy. When approved by management, prescription Medical Alert bracelets or jewelry for religious or cultural reasons can be allowed by policy.

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### 11.3.4 - Visitors

**11.3.4.1** - All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing and handling areas or shall be escorted at all times in food processing, handling, and storage areas.

**Response:** Compliant

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**11.3.4.2** - All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 11.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area.

**Response:** Compliant

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**11.3.4.3** - Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled and processed.

**Response:** Compliant

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**11.3.4.4** - Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all handwashing and personnel practice requirements.

**Response:** Compliant

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#### Summary -

**Response:** The site visitor policy has documented and implemented a policy defining visitor and contractor requirements. The policy requires that visitors be trained in hygiene and food safety requirements before entering food processing or handling areas or be continually escorted while in those locations. Visitors in

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those areas include the proper use of access points, hand wash requirements, suitable protective clothing and footwear, removal of jewelry or other loose objects, and an absence of visible signs of illness. Prior to entry into the site each day of the audit, the auditor was required to review site GMP policies, site illness policies and sign indicating an acknowledgement and understanding of these policies. A photo tag was issued to be worn during the time on site.

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### 11.3.5 - Staff Amenities (change rooms, toilet, break rooms)

**11.3.5.1** - Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product.

**Response:** Compliant

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**11.3.5.2** - Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean.

**Response:** N/A

**Evidence:** • N/A - Change rooms are not required at this facility.

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**11.3.5.3** - High-risk change areas shall be provided for staff engaged in the processing of high-risk foods or processing operations in which clothing can be soiled.

**Response:** N/A

**Evidence:** • N/A - There are no high-risk areas on-site.

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**11.3.5.4** - Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, food contact zones, food, and packaging storage areas.

**Response:** Compliant

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**11.3.5.5** - Where required, a sufficient number of showers shall be provided for use by staff.

**Response:** Compliant

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**11.3.5.6** - Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and vi. Kept clean and tidy. Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas.

**Response:** Compliant

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**11.3.5.7** - Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations.

**Response:** Compliant

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**11.3.5.8** - Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.3.

**Response:** Compliant

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**11.3.5.9** - Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at

one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.

**Response:** Compliant

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**11.3.5.10** - Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for the introduction of contamination, including pests to the site.

**Response:** N/A

**Evidence:** • N/A - Outside eating areas are not present at this site.

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#### Summary -

**Response:** Employee bathrooms and break rooms were observed to be appropriately lit, cleaned, ventilated, and available for all personnel at the facility. Restrooms and washrooms were observed to be separate from food processing and handling areas and accessed via a separate room or air lock. An area has been provided to store outer garments and other items while using the facilities. Sanitary facilities were sufficient for all employees and were cleaned and maintained regularly. Site drawings and on-site observations provided satisfactory evidence that sanitary drainage is separated from plant drainage and disposed of following regulations. The sanitary facilities have handwash sinks that comply with the requirements of the SQF Code. The lunchroom was adequately separated from production, well-lit, adequately ventilated, and appropriately sized for facility employees. Lunchrooms include hot and cold potable water, food storage areas, and refrigerators with hand and utensil washing capabilities. Signs reminding employees to wash their hands before returning to work were observed at the exit to lunchrooms. Lunchrooms were observed to be clean and well-maintained during the audit.

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### 11.4.1 - Staff Engaged in Food Handling and Processing Operations

**11.4.1.1** - All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging, product, and ingredients shall be kept in appropriate containers as required and off the floor; v. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor.

**Response:** Compliant

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**11.4.1.2** - Personnel working in or visiting food handling or processing operations shall ensure that: i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 11.4.1.4; ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food; iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed. iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging,

tools, or equipment storage.

**Response:** Compliant

**Evidence:** • All team members in the processing and storage areas were observed to be wearing hair nets, and (as appropriate) beard nets. This is compliant with customer 1 requirements.

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**11.4.1.3** - The flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized.

**Response:** Compliant

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**11.4.1.4** - In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone, the site shall implement controls and procedures to ensure: i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel only; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; and v. Equipment used for sensory evaluations is sanitized, maintained, and stored separately from processing equipment.

**Response:** N/A

**Evidence:** • N/A - Sensory evaluations are not conducted in food handling/processing areas.

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#### Summary -

**Response:** Food handling procedures for all employees are documented and implemented. Personnel must access the processing areas through personnel doors only, and doors were observed closed when not in use. Team members enter the facility through one entry point and have a single path to travel to the wash sinks at the entry of the processing room. Waste was contained and disposed of per-site policy and cleaning practices. False fingernails or fingernail polish, long nails, and false or extended eyelashes are prohibited, and no violations were noted. Hair restraints and beard nets were worn appropriately where the product was exposed and throughout the production and warehouse areas. Packaging Materials, Products, and ingredients were in appropriate, labeled containers, and kept off the floor. The GMP policy prohibits smoking, eating, drinking, or spitting in the facility. Smoking is permitted only in designated areas. The process was logical, with a continuous flow designed to prevent cross-contamination. It was observed during audit tours that the flow of employees is such that any cross-contamination is minimal. Wash-down hoses were stored adequately on racks when not in use.

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### 11.5.1 - Water Supply

**11.5.1.1** - Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility.

**Response:** Compliant

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**11.5.1.2** - Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use.

**Response:** Compliant

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**11.5.1.3** - Supplies of hot and cold water shall be provided, as required, to enable the effective cleaning of the premises and equipment.

**Response:** Compliant

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**11.5.1.4** - The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained.

**Response:** N/A

**Evidence:** • N/A - Non-potable water is not used at this site.

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**11.5.1.5** - The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent backflow or back-siphonage.

**Response:** Compliant

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**11.5.1.6** - Where water is stored on-site, storage facilities shall be adequately designed, constructed, and routinely cleaned to prevent contamination.

**Response:** N/A

**Evidence:** • N/A - Water is not stored on-site.

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#### Summary -

**Response:** Potable water is sourced for use in the facility for processing and cleaning the premises and equipment. Potable water is supplied from the municipality of Humble, TX. The city water report for 2023 was available. All parameters tested for were within Federal standard tolerance limits. The crisis management plan outlines that the plant should cease operations if the water is deemed contaminated. It was determined that there was adequate hot and cold water for cleaning and processing. Hose stations, taps, and other water sources prevent backflow or back-siphonage.

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### 11.5.2 - Water Treatment

**11.5.2.1** - Water treatment methods, equipment, and materials, if required, shall be designed, installed, and operated to ensure water receives effective treatment. Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

**Response:** N/A

**Evidence:** • N/A - Water is not treated at the facility.

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**11.5.2.2** - Water used as an ingredient in processing or for cleaning and sanitizing equipment shall be tested and, if required, treated to maintain potability (refer to 11.5.2.1).

**Response:** N/A

**Evidence:** • N/A - Water is not treated at the facility.

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**11.5.2.3** - Treated water shall be regularly monitored to ensure it meets the specified indicators. Water treatment chemicals usage shall be monitored to ensure chemical residues are within acceptable limits. Records of testing results shall be kept.

**Response:** Compliant

**Evidence:** • N/A - Water is not treated at the facility.

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#### Summary -

**Response:** Potable water is supplied from the municipality of Humble, TX. Water is not treated at the facility.

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### 11.5.3 - Water Quality

**11.5.3.1** - Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for: i. Washing, thawing, and treating food; ii. Handwashing; iii. Conveying food; iv. An ingredient or food processing aid; v. Cleaning food contact surfaces and equipment; vi. The manufacture of ice; or vii. The manufacture of steam that will come into contact with food or be used to heat water that will come into contact with food.

**Response:** Compliant

**11.5.3.2** - Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.

**Response:** Compliant

**11.5.3.3** - Water and ice shall be analyzed using reference standards and methods.

**Response:** Compliant

#### Summary -

**Response:** Water used in processing, thawing, treating, conveying food, cleaning, or handwashing is monitored periodically for potability by the site. The site's testing frequency is set at a minimum annual frequency based on risk. All products manufactured on-site are sampled, and one sample is sent to an ISO 17025:2017 accredited laboratory (Certificate #TX-C24-00413 Expires 03/31/2025). Water was last tested on 03/01/2025 with samples taken from seven locations: - Total liquid Tank - HPC <1 cfu/ml; Coliform Total - Absent /100 ml; E. coli - Absent /100 ml - Handwash station #1 (Production) - HPC <1 cfu/ml; Coliform Total - Absent /100 ml; E. coli - Absent /100 ml - Handwash Station #2 (Production) - HPC 1,400 cfu/ml; Coliform Total - Absent /100 ml; E. coli - Absent /100 ml - Women Bathroom Sink (production) - HPC 440 cfu/ml; Coliform Total - Absent /100 ml; E. coli - Absent /100 ml - Men' bathroom sink, (production - HPC 69 cfu/ml; Coliform Total - Absent /100 ml; E. coli - Absent /100 ml - Handwash Station #3 - HPC 370 cfu/ml; Coliform Total - Absent /100 ml; E. coli - Absent /100 ml - Handwash Station #4 - HPC 1,300 cfu/ml; Coliform Total - Absent /100 ml; E. coli - Absent /100 ml Limits are 500 cfu/ml for HPC; and absent for 100 ml for coliforms and E. coli. Actions were taken for the elevated HPC findings at handwashing station #2 and #4. The site determined that new water filters were needed and these were installed 03/17/2025. Resampling of the two high points will occur 03/20/2025. Heavy Metal results 12/13/2024 - General screen and arsenic, cadmium, mercury, and lead - All tests had compliant values. Backflow prevention device testing was last conducted 02/20/2025 - three units tested by a certified tester and included make, model, serial number, and calibration date. 1 - 1st check held at 9.9 psi, closed tight, relief valve opened at 2.5 psi 2 - Assembly was slightly different so: 1st check held at 3.2 psi and closed tight. 2nd check held at 1.3 psi and closed tight. 3 - 1st check held at 8.1 psi, closed tight, relief valve opened at 3.5 psi All parameters were within expected tolerances and the device was deemed to have passed. This was conducted by a licensed contractor approved for performing this testing on behalf of the city of Humble. The use and testing of potable water and backflow prevention devices was compliant with customer 1 requirements.

### 11.5.4 - Ice Supply

**11.5.4.1** - Ice provided for use during processing operations, as a processing aid, or an ingredient shall comply with 11.5.3.1.

**Response:** N/A

**Evidence:** • N/A - Ice is not used at the facility.

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**11.5.4.2** - Ice that is purchased shall be from an approved supplier and included in the site's food safety risk assessment. Ice shall be supplied in containers that are appropriate for use, cleanable if reused, and tested as appropriate.

**Response:** N/A

**Evidence:** • N/A - Ice is not used at the facility.

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**11.5.4.3** - Ice rooms and receptacles shall be constructed of materials as outlined in element 11.1.2 and designed to minimize contamination of the ice during storage, retrieval, and distribution.

**Response:** Compliant

**Evidence:** • N/A - Ice is not used at the facility.

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**Summary -**

**Response:** N/A - Ice is not used at the facility.

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### 11.5.5 - Air and Other Gasses

**11.5.5.1** - Compressed air or other gases (e.g., nitrogen or carbon dioxide) that contact food or food contact surfaces shall be clean and present no risk to food safety.

**Response:** Compliant

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**11.5.5.2** - Compressed air systems and systems used to store or dispense other gases that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually.

**Response:** Compliant

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**Summary -**

**Response:** The site uses nitrogen for freezing (via tunnel) – The site had a letter on file from the nitrogen supplier, dated 02/02/2021, indicating the safe use and application of nitrogen for food production purposes. The site also provided COAs for the nitrogen that included the statement of purity (Spec= >99.999000% Nitrogen) and the actual level of purity for the nitrogen. Examples reviewed included: Nitrogen – 04/23/2024 – Lot #6688-042224-17 - O2 (Limits <5 ppm) Actual 0.94 ppm - CO (Limits <10 ppm) Actual 0.20 ppm - Nitrogen (Limits >99.99000 %) Actual 99.999820 % Ambient Air testing is conducted in house. The last ambient air test (exposure time 15 minutes) was conducted on 03/28/2024 – at 15 points. The limits are <40 yeast or mold per exposure. Maximum yeast value was 8 cfu/exposure; Mold Max results for air tested was 7 cfu/exposure Compressed air is used in the bag packing system. The compressed is used to move piston parts, and there is no direct compressed air contact with product. Compressed Air testing was last conducted 12/21/2024 at four points of the air usage (plus a control) . All results were 1 cfu/plate for yeast and mold. The site had an “Air Quality Program” (Doc #MD.008, Revision 006, Revision Date 06/27/2024) which included the frequency of maintenance (for both internal team and external contractors), and internal PM checks (for leaks, filter in good condition, etc.).

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### 11.6.1 - Receipt, Storage and Handling of Goods



**11.6.1.1** - The site shall document and implement an effective storage plan that allows for the safe, hygienic receipt and storage of raw materials (i.e., frozen, chilled, and ambient), ingredients, packaging, equipment, and chemicals.

**Response:** Compliant

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**11.6.1.2** - Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-contamination risks. Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk.

**Response:** Compliant

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**11.6.1.3** - The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented.

**Response:** Compliant

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**11.6.1.4** - Procedures shall be in place to ensure that all ingredients, materials, work- in-progress, rework, and finished product are utilized within their designated shelf-life.

**Response:** Compliant

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**11.6.1.5** - Where raw materials, ingredients, packaging, equipment, and chemicals are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there are no risks to the integrity of those goods, no potential for contamination or adverse effect on food safety.

**Response:** Compliant

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**11.6.1.6** - Records shall be available to verify the effectiveness of alternate or temporary control measures for the storage of raw materials, ingredients, packaging, equipment, chemicals, or finished products.

**Response:** Compliant

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#### **Summary -**

**Response:** The site has implemented an effective program for receiving, storing, and transporting raw materials, ingredients, packaging, equipment, and chemicals. The first in, first out policy (WH.001, revision date 02/10/2023, revision 003) and the incoming goods program (WH.003 revision date 03/10/2023, revision 002) were reviewed during the audit. Procedures for how to complete the shipping and receiving reports are captured in the shipping and receiving bio-security truck inspection report (WH.012, date of origin 11/01/2023, Revision 006). Dry ingredients and packaging were stored separately from unprocessed raw materials and frozen and refrigerated items. The site has implemented stock rotation based on FIFO to ensure that all materials, including rework, are used within their designated shelf-life. All temporary or overflow storage conditions not designed explicitly for that purpose are subject to an effective risk analysis to ensure no risk to integrity, food safety, or potential contamination. No overflow conditions were observed during the site tours and the site indicated that there was no need for temporary or overflow storage in the past 12 months. Receiving records were reviewed. Examples included: Sodium Carbonate – 08/12/2024 PO86425 and 08/08/2024 PO86427, including a transfer notification from the site warehouse in California. Documentation was captured on the “Shipping/Raw Material Inspection (#QC.055). Questions on the record included: - LOG on file? - Kosher cert of file? - Organic Certificate on file? - Integrity of Materials: - Is the material: Clean? Sealed? Marked? Does the material include: name of item? lot or code? Manufacturer? - Integrity of truck/trailer: Clean? Sealed? Locked? Other reports reviewed included: - Riboflavin received 12/16/2024 - Potassium sorbate received 09/17/2024 - Silo flour (Hard red noodle flour) received 01/20/2025 - Bagged flour received 01/17/2025 - Potassium carbonate received 03/14/2024 - Soybean oil, 12/03/2024 All records reviewed

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appeared to be complete and indicated product condition was acceptable for receipt.

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### 11.6.2 - Cold Storage, Freezing and Chilling of Foods

**11.6.2.1** - The site shall provide confirmation of the effective operational performance of freezing, chilling, and cold storage facilities. Chillers, blast freezers, and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of food and be easily accessible for inspection and cleaning.

**Response:** Compliant

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**11.6.2.2** - Sufficient refrigeration capacity shall be available to chill, freeze, store chilled, or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.

**Response:** Compliant

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**11.6.2.3** - The site shall have a written procedure for monitoring temperatures, including the frequency of checks, and corrective actions, if the temperature is out of specification. Freezing, chilling, and cold storage rooms shall be fitted with temperature monitoring equipment that is located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible. Records shall be kept of frozen, cold, and chilled storage room temperatures.

**Response:** Compliant

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**11.6.2.4** - Discharge from defrost and condensate lines shall be controlled and discharged into the drainage system.

**Response:** Compliant

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#### Summary -

**Response:** Chillers, freezers, and cold storage areas are designed and constructed for hygienic and efficient refrigeration. There appeared to be sufficient capacity for the facilities' requirements and sufficient space for periodic cleaning. The condensate lines were connected directly to the plant drainage system. Temperature monitoring devices are located at the warmest part of the refrigerators/freezers, and temperatures are periodically (at least once per day) monitored and recorded. Refrigeration equipment is maintained on the plant's preventive maintenance schedule. An outside contractor conducts any needed servicing of the refrigeration equipment. Temperatures observed during the audit were compliant with program requirements (i.e. the freezer reading was 5.9 F, and the cooler was 38.2 F as observed during the audit). Products are not ready to eat, so cooler and freezer storage is for maintaining shelf life as the product must go through subsequent cooking. The freezer and cooler logs were reviewed. Examples reviewed included: FREEZER - temperatures above 20 F require maintenance notification and temperature checks. Temperatures above 32 F require additional action. - 08/15/2024 - Temps ranged from 19.5 F to 22.5 F - four of the five checks were above 20 and there was a notation included that the supervisor was contacted were indicated for each hour the temperature was over tolerance limits. It was noted that the ambient temperature was above 105 F which created significant difficulty in keeping temperatures within tolerances. - 12/24/2024 - temperatures were taken eight times during the day and all temperatures were below 15 F. COOLER - temperatures above 42 F are alarmed, require maintenance notification, and product temperature checks. Temperatures above 42 F require additional action. - 08/15/2024 - temperatures were taken 7 times during the day. Results ranged from 42.5 to 44.2 F. A supervisor was notified from the third check on. It was noted that the ambient temperature was above 105 F which created significant difficulty in keeping temperatures within tolerances. 12/24/2024 - temperatures were taken 8 times during the day and all temperatures were below 40 F except for one check at 9:02 am which was 43 F - it was noted that the warehouse team was frequently entering and exiting the

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warehouse at that time, so temperatures were elevated due to the length of time the doors were open in aggregate.

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### 11.6.3 - Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

**11.6.3.1** - Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration and prevent packaging from becoming a harborage for pests or vermin.

**Response:** Compliant

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**11.6.3.2** - Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and behind the racks. Storage areas shall be cleaned at a pre-determined frequency.

**Response:** Compliant

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#### Summary -

**Response:** Storage areas for raw materials, packaging, and finished goods were located away from any wet areas, clean and well maintained. The product is protected from contamination, deterioration, and pest harborage. Racking is designed and constructed from impervious materials and located so storage areas can be cleaned and inspected. Forklifts and other vehicles in processing and storage areas were maintained in good operating condition and did not present a food hazard. Lot numbers of several products in dry storage were reviewed to ensure that none were expired. Examples: - Premium hard wheat flour – Manufactured 02/13/2025. Use By 02/13/2026. Sodium Carbonate – 03-01-5008-00 – Lot E4157350, expires 06/03/2025.

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### 11.6.4 - Storage of Hazardous Chemicals and Toxic Substances

**11.6.4.1** - Hazardous chemicals and toxic substances with the potential for food contamination shall be: i. Clearly labeled, identifying and matching the contents of their containers; ii. Included in a current register of all hazardous chemicals and toxic substances that are stored on-site; and iii. Supplemented with current Safety Data Sheets (SDS) made available to all staff.

**Response:** Compliant

**Evidence:** • The procedure “Storage of Hazardous Chemicals and Toxic Substances” Program (Doc #MD.007, Revision Date 09/20/2022, revision 003) indicates that every manager of each department is responsible for keeping a hazardous chemical and toxic substances inventory All hazardous chemicals were observed to be appropriately stored and labeled and did not appear to present a hazard to personnel or food products. No processing utensils or packaging were stored next to chemicals. Pesticides are not stored on-site. Chemical storage areas were locked during site tours and had instructions on handling hazardous chemicals, an up-to-date inventory of all chemicals, and available first aid and spill containment equipment. Daily supplies of chemicals were stored correctly. All stored chemicals reviewed had SDS information on file at the facility, accessible to all team members.

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**11.6.4.2** - Storage of hazardous chemicals and toxic substances shall be: i. Located in an area with appropriate signage indicating that the area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii. Adequately ventilated;iv. Stored where intended and not comingled (e.g., food versus non-food grade);v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and vi. Stored in a manner that prevents a hazard to finished

product or product contact surfaces. Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

**Response:** Minor

**Evidence:** • Minor NC: The site had a silicon sealant stored in the food grade cabinet that was not labeled as NSF H-1 (or equivalent) compliant and did not have an independent verification that they were compliant with use for incidental food contact.

**Root Cause:** Maintenance clerk, who lacks experience in presenting documentation during an audit, could not explain properly and in detail why this product is considered adequate to be placed in the food grade cabinet. With a lot of documentation on hand, she got overwhelmed and was not able to clearly explain where the evidence was. With her dedication to food safety, she influenced the decision to invest in purchasing this silicone that was four times more expensive than a regular silicone, because this sealant had a certification from NSF that states "Sealant for Food Zone 1". (Evidence 3.1)

**Corrective Action:** With information and technical document evidences provided by the manufacturer and information gathered by the three maintenance managers, we confirmed that the silicone was certified under the same certification board NSF. This product complies with standard NSF/ ANSI 51 food equipment material for food zone 1 which is equivalent to NSF H-1. NSF H-1 applies to Lubricants only and does not apply for sealants. NSF/ ANSI 51 meets the following FDA regulations: 21 CFR 174-178: Covers indirect food additives, including polymers, adjuvants, and sanitizers used in food contact materials. 21 CFR 177: Specifically addresses polymers used in food contact applications, such as plastics. 21 CFR 178: Focuses on adjuvants and production aids, ensuring they are safe for incidental food contact. Based on the NSF/ ANSI 51 certification and evidence attached, we conclude that this sealant for food zone 1 is adequate to store in the food grade cabinet.

**Verification Of Closeout:** The auditor reviewed the following documents: •(Evidence 3.1) Listing NSF-ANSI 51  
•(Evidence 3.2) NSF Form •(Evidence 3.3) Technical document

**Completion Date:** April 15, 2025

**Closeout Date:** April 15, 2025

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**11.6.4.3** - Hazardous chemicals and toxic substances shall be correctly labeled and: i. Used only according to manufacturers' instructions; ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-in-progress, finished product, or product contact surfaces; iii. Returned to the appropriate storage areas after use; and iv. Be compliant with national and local legislation.

**Response:** Compliant

**Evidence:** • Sanitation and Maintenance chemical SDS sampled (and, as appropriate allergen letters) and reviewed included:

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**11.6.4.4** - Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of food processing equipment and surfaces in food contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel.

**Response:** N/A

**Evidence:** • N/A: Pesticides are not stored on-site.

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**11.6.4.5** - Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals; i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use; ii. Be provided first aid equipment and personnel protective equipment (PPE); and iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements.

**Response:** Compliant

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**Evidence:** • Employees handling chemicals have been trained to handle, use, store, and adequately disposal of the chemicals. Examples included: Sanitation Team member training: Food Safety Chemical Training 08/09/2022; Chemical Safety and Smart Sanitation Training 02/28/2023; Use of Bump Caps 02/07/2023; Gluten Free Manufacturing 03/19/2024; Dangerous Microorganisms, 03/19/2024.

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**11.6.4.6** - The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are: i. Not reused; ii. Segregated and securely stored prior to collection; and iii. Disposed through an approved vendor.

**Response:** Compliant

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**11.6.4.7** - In the event of a hazardous spill, the site shall: i. Have spillage clean-up instructions to ensure that the spill is properly contained; and ii. Be equipped with PPE, spillage kits, and cleaning equipment.

**Response:** Compliant

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#### Summary -

**Response:** Storage protocols are outlined in the storage of hazardous chemicals, and toxic substance program" (Doc #MD.007, Revision 002, Revision Date 10/01/2021) which outlines that the maintenance manager is responsible for managing the hazardous chemical program. The storage of hazardous chemicals and toxic substances program (Doc #MD.007, Revision Date 10/01/2021, revision 002) indicates that every manager of each department is responsible for keeping a hazardous chemical and toxic substances inventory. All hazardous chemicals were observed to be appropriately stored and labeled and did not appear to present a hazard to personnel or food products. No processing utensils or packaging were stored next to chemicals. Pesticides are not stored on-site. Chemical storage areas were locked during site tours and had instructions on handling hazardous chemicals, an up-to-date inventory of all chemicals, and available first aid and spill containment equipment. Daily supplies of chemicals were stored correctly. All stored chemicals reviewed had SDS information on file at the facility, accessible to all team members.

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### 11.6.5 - Loading, Transport, and Unloading Practices

**11.6.5.1** - The practices applied during loading, transport, and unloading of food shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination.

**Response:** Compliant

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**11.6.5.2** - Vehicles (e.g., trucks/vans/containers) used for transporting food within the site and from the site shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the product.

**Response:** Compliant

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**11.6.5.3** - Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems.

**Response:** Compliant

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**11.6.5.4** - Loading and unloading docks shall be designed to protect the product during loading and unloading. Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity during loading and transport.

**Response:** Compliant

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**Evidence:** • Examples of shipping documents reviewed included: Shipping Reports using the Bio-security Truck Inspection report 01/29/2025 – temp 34 F; reviewed 01/30/2025; 01/31/2025 reviewed 02/01/2025; 02/05/2025 reviewed 02/06/2025. 01/29/2025: Truck inspection – all parameters were okay. Truck Temp (34 F), product temp (31 F). Date, time of inspection and name of inspector were included. 01/31/2025: Truck inspection – all parameters were okay. Truck Temp (-9 F) product Temp (-2.4 F). Date, time of inspection and name of inspector were included. Other shipping records reviewed included those dated 04/26/2024 and 02/06/2025. There was no loading or unloading of trucks observed during the audit. Warehouse team members were interviewed and were knowledgeable about the site loading and unloading procedures, food safety checks relevant to the warehouse, allergens present at the site, food defense protocols, GMPs for warehouse (i.e. no eating food in the warehouse, wear hairnets when entering production areas, etc.), etc.) The site’s policy requires that all trailers be inspected for cleanliness, infestation, odors, and damage before loading and that vehicles be secured from tampering using a seal.

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**11.6.5.5** - Refrigerated units shall maintain the product at the required temperature. The unit’s temperature settings shall be set, checked, and recorded before loading, and the product temperature shall be recorded at regular intervals during loading, as applicable.

**Response:** Compliant

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**11.6.5.6** - The refrigeration unit shall be operational at all times and checks completed of the unit’s operation, the door seals, and the storage temperature at regular intervals during transit.

**Response:** Compliant

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**11.6.5.7** - On arrival, prior to opening the doors, the food transport vehicle’s refrigeration unit’s storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently, and product temperatures shall be recorded at the start of unloading and regular intervals during unloading.

**Response:** N/A

**Evidence:** • N/A - The site does not receive refrigerated or frozen items.

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**11.6.5.8** - Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity.

**Response:** N/A

**Evidence:** • N/A - The site does not receive refrigerated or frozen items.

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#### Summary -

**Response:** A policy defining the practices for loading, unloading, and storing food products has been documented and implemented in the site also tracks all inbound and outbound trucks via the “Biosecurity Truck Inspection Report” (Form #WH.1430, Revision Date: 11/01/2023 – Revision 014). The report information includes: Trucking company name; truck inspection; PO #; truck refrigeration temperature setting number; are receivables and allergens labeled, dated and segregated; start load time; finish load time; and QC tech initials.

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### 11.7.1 - High-Risk Processes

**11.7.1.1** - The processing of high-risk food shall be conducted under controlled conditions, such that sensitive areas, in which the high-risk food has undergone a “kill” step, a “food safety intervention” or is subject to post-process handling, are protected/segregated from other processes, raw materials, or staff who handle raw

materials, to ensure cross-contamination is minimized.

**Response:** N/A

**Evidence:** • N/A - The site does not produce any high-risk products.

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**11.7.1.2** - Ambient air in high-risk areas shall be tested at least annually to confirm that it does not pose a risk to food safety.

**Response:** N/A

**Evidence:** • N/A - The site does not produce any high-risk products.

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**11.7.1.3** - Areas in which high-risk processes are conducted shall only be serviced by staff dedicated to that function.

**Response:** N/A

**Evidence:** • N/A - The site does not produce any high-risk products.

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**11.7.1.4** - Staff engaged in high-risk areas shall change into clean clothing and footwear or temporary protective outerwear when entering high-risk areas. Staff access points shall be located, designed, and equipped to enable staff to change into the distinctive protective clothing and practice a high standard of personal hygiene to prevent product contamination.

**Response:** N/A

**Evidence:** • N/A - The site does not produce any high-risk products.

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**11.7.1.5** - Product transfer points shall be located and designed, so they do not compromise high-risk segregation and minimize the risk of cross-contamination.

**Response:** N/A

**Evidence:** • N/A - The site does not produce any high-risk products.

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#### **Summary -**

**Response:** The site does not produce products that are deemed high risk (all products require further processing at the customer site or further downstream), but does have an environmental monitoring program. This complies with customer 1 requirements.

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### **11.7.2 - Thawing of Food**

**11.7.2.1** - Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose. Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature do not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor or shall be appropriately plumbed.

**Response:** N/A

**Evidence:** • N/A - The facility does thaw any product.

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**11.7.2.2** - Air thawing facilities shall be designed to thaw food under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.

**Response:** N/A

**Evidence:** • N/A - The facility does thaw any product.

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**11.7.2.3** - Provision is to be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.

**Response:** N/A

**Evidence:** • N/A - The facility does thaw any product.

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**Summary -**

**Response:** N/A - The facility does thaw any product.

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### 11.7.3 - Control of Foreign Matter Contamination

**11.7.3.1** - The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff. Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

**Response:** Compliant

**Evidence:** • NOTE: The site has a glass and brittle plastic policy, and a register which includes pictures and locations of items containing glass and brittle plastic. The site is developing an overall map as a supplement to the glass and brittle plastic program to comply with requirements for customer 1.

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**11.7.3.2** - Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation). Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition.

**Response:** Compliant

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**11.7.3.3** - Regular inspections of food handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory.

**Response:** Compliant

**Evidence:** • Glass and Brittle Plastic audits are conducted by production clerks. The audits are broken out by areas and then date. Records of Glass and Brittle Plastic inspection reviewed. Examples reviewed included: - P1 Entrance: 01/07/2025, 02/03/2025, 03/03/2025. Five points identified. No issues noted on any of the dates. - P1-Y11 Continuous Roller Power Switches. 01/07/2025, 02/03/2025, 03/03/2025. Twelve points identified. No issues noted on any of the dates. - Blast Freezer Control: 01/07/2025, 02/03/2025, 03/03/2025. Five points identified. No issues noted on any of the dates. - Mixer P1 Control Panel: 01/07/2025, 02/03/2025, 03/03/2025. Five points identified. No issues noted on any of the dates. An example of a finding in the glass and brittle plastic program for the audit conducted 03/09/2025. An overhead at P2 without a light cover (near an entrance and with very low food safety risk). This was repaired on the on 03/19/2025 . This was captured on Work Order 2312, that included before and after pictures of the light without and with the cover. There were questions on the WO including: Did you follow the GMPs, Did you follow the Safety and LOTO procedure and did all tools and parts used get retrieved and returned? In all cases the initial of the auditor was in place. At the end of the binder containing the GBP materials, there was the signature of the auditor and the review of the documentation by the QA Manager or QA Supervisor. All records were reviewed within 3 days of audit completion.

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**11.7.3.4** - Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

**Response:** Compliant

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**11.7.3.5** - In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, thoroughly inspected (including cleaning equipment and footwear), and cleared by a suitably responsible person prior to the start of operations.

**Response:** Compliant

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**11.7.3.6** - Wooden pallets and other wooden utensils used in food processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

**Response:** Compliant

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**11.7.3.7** - Loose metal objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard.

**Response:** Compliant

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**11.7.3.8** - Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

**Response:** Compliant

**Evidence:** • Knives were not observed in the processing area during the audit. The site had a hand tool In/out log" (PD.004, Date of Origin 08/31/2015, Revision 002) Information on the log Includes: Date, name of hand tool , hand tool #, Time out, Employee name (checking out), Department, Return time, Hand tool condition (Good or damaged), employee name (checking in), supervisor initials. Reviewed forms for: - 12/29/2024-01/03/2025 All documents appeared to be completely filled out and no issues were identified regarding hand tool quality on the dates reviewed. - 02/11-13/2025 All documents appeared to be completely filled out and no issues were identified regarding hand tool quality on the dates reviewed. - 03/06-10/2025 All documents appeared to be completely filled out and no issues were identified regarding hand tool quality on the dates reviewed.

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**11.7.3.9** - Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3).

**Response:** Compliant

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#### **Summary -**

**Response:** The site glass and brittle plastic policy (SOP.016) and foreign material control SOP define the methods and responsibilities to prevent foreign material contamination. The policy's implementation was demonstrated by pre-operational inspections and regularly scheduled maintenance inspections conducted and documented for equipment condition and any potential contaminants. A glass and brittle plastic register has been documented with glass, brittle plastic, and ceramic sources included in all plant areas. A Cross check of glass and brittle plastic items in the plant against the register showed general correlation of the items. Wood pallets were clean and in good condition, and the facility has a policy prohibiting or controlling wooden utensils in processing and food-handling areas. Periodic maintenance inspections include looking for loose objects and potential contaminants from overheads. Gaskets are removed, cleaned, and inspected during pre-operational inspections. Multiple points in production were identified and cross referenced with the glass and brittle plastic register during the audit, including: Yakisoba 10 tower switches and emergency stop button;

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an exit sign and security light above the P1 exit to hallway; and the guards over the four continuous rollers wonton line 11. All areas physically observed and cross checked were found on the register.

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#### 11.7.4 - Detection of Foreign Objects

**11.7.4.1** - The responsibility, methods, and frequency for monitoring, maintaining, calibrating, and using screens, sieves, filters, or other technologies to remove or detect foreign matter shall be documented and implemented.

**Response:** Compliant

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**11.7.4.2** - Where detection and/or removal systems are used, the site shall establish limits for detection, based on a risk assessment of the product and its packaging, and identify the location(s) of the detector(s) in the process.

**Response:** Compliant

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**11.7.4.3** - Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated, and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

**Response:** Compliant

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**11.7.4.4** - Records shall be maintained of the inspection of foreign object detection devices, of any products rejected or removed by them, and of corrective and preventative actions resulting from the inspections.

**Response:** Compliant

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**Evidence:** • The metal detector log was reviewed for: - 04/20/2024 – Time start: 09:50 pm, 10:05 pm; 04/22/2024 Time start 06:24 am, 07:29 am, 09:50 am. Other dates reviewed included: 07/24/2024, 10/12/2024, 01/20/2025, and 03/18/2025 and were found to be complete, legible, and initialed by the staff undertaking the monitoring activity. No issues were noted. X-Ray testing is at start up, every hour (+/- 30 minutes) and at end of production. Checks were reviewed for: - 4/27/2024 – 6:30 (first check), 8:30, 11:58, 2:00 pm, 3:58 pm, 5:30 pm, 7:30 pm, 8:15 pm (last check) tested for 2.5 mm Fe, 3.5 mm nonFe, 3.5 mm Stainless Steel, 2.0 mm Ceramic, and 2.0 mm Quartz Glass.. All checks were satisfactory. Other dates reviewed included 04/29/2024 and 01/20/2025. The operation of the metal detector was observed during the site tours, and the unit in operation appeared to be functioning as intended. Interviews with the QC technician responsible for verifying metal detector functionality demonstrated knowledge of the metal detection and X-Ray test process and what to do if the metal detector and X-Ray deviated from the process during testing or malfunctioned during use (the X-Ray was not in use during the audit). The test methodology is to run the test piece through two times, catching it before it drops, then run it through once more, waiting until the piece is rejected and drops through the retraction system. The site use of X-Ray is complaint with customer 1 requirements. NOTE: customer 1 discontinued purchasing the product designated for them in March 2025 so the X-Ray unit has been removed from service until this business resumes and so X-Ray checks were not able to be demonstrated during this audit. The site also had certificates of conformance for the materials used for testing the metal detection and X-ray functionality (examples: 3.5 mm alumina ceramic tested 02/22/2022 and 3.5 mm fused quartz glass 04/16/2024).

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**11.7.4.5** - In all cases of foreign matter contamination, the affected batch or item shall be isolated, inspected, reworked, or disposed of. Records shall be maintained of the disposition.

**Response:** Compliant

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#### Summary -

**Response:** An example of a deviation on the metal detector occurred 02/24/2025 and was reviewed. Product:

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01-01-1040-04 Chow Mein 3 lbs. - At the 13:17 check none of the test wands were successfully rejected by the metal detector; 8 pallets were placed on hold, because the metal did not pass. The metal detector was repaired and then repassed through on the same day. No rejected product was found. A corrective and preventive report was written for this issue, date 02/24/2025 Report #02245. An investigation showed that the sensitivity was not sufficient for the metal detector to detect the test pieces. The site was not able to determine what happened to the sensitivity of the metal detector between the prior good checks (times- 06:21, 09:26, 10:10, 11:27, and 12:16 all had successful tests.) and the failed check at 13:17 but determined that sensitivity settings were adjusted, and the metal detector was performing as intended. The site also determined that all food safety protocols were followed (i.e. failed check, supervisor notified, product held to last good check and rerun through a functioning metal detector). The CAPA was closed on the same day. A policy defining the methods and responsibilities for foreign material detection and removal devices has been documented and implemented. "Metal Detection/X-Ray Procedure" (Doc #TM.008 Revision Date 08/15/2024, revision 015 – added statement to ensure power cord is connected to a dedicated power source and documented). The site has five metal detectors with four in use at the site (the other one is a back-up). Critical Limits: 2.5 mm Ferrous, 3.5 mm Nonferrous, and 3.5 mm Stainless steel (metal detector is on and functioning). For X-Ray, the same Ferrous, Nonferrous, and Stainless Steel limits applied, plus 3.5 mm Ceramic, and 3.5 mm Quartz Glass. Monitoring Procedures, Frequency, and Responsibility – the metal detector and/or X-Ray unit is tested before production starts, every hour (+/- 30 minutes), and after production ends. The site passes each test sample through three times, and this is recorded on Metal detection log QC.013. Corrective Action: If the test sample is not detected or there is a deviation from the Critical Limit, the QA Manager or designee is responsible for determining the root cause of the deviation and corrective actions to eliminate the deviation. Product is held to the last good check, then product will be tested once control of the MD has been reestablished. The site's policy requires that any product affected by foreign material contamination be isolated, inspected, reworked, or disposed of. Product rejected must be passed through three times again without rejection. If it is rejected the product must be investigated for metal inclusions, If a contaminant is found then the sample must be saved and included in the investigation form. Investigated product must not be placed back on the line.

### 11.8.1 - Waste Disposal

**11.8.1.1** - The responsibility and methods used to collect and handle dry, wet, and liquid waste and how to store it prior to removal from the premises shall be documented and implemented.

**Response:** Compliant

**11.8.1.2** - Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.

**Response:** Compliant

**11.8.1.3** - Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements.

**Response:** Compliant

**11.8.1.4** - Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin.

**Response:** Compliant

**11.8.1.5** - Adequate provision shall be made for the disposal of all solid processing waste, including trimmings,

inedible material, and used packaging.

**Response:** Compliant

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**11.8.1.6** - Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

**Response:** N/A

**Evidence:** • N/A - The site does not have trademarked materials.

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**11.8.1.7** - Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health.

**Response:** N/A

**Evidence:** • N/A - The site does not supply materials for animal feed.

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**11.8.1.8** - Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards.

**Response:** Compliant

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**11.8.1.9** - Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards.

**Response:** Compliant

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**11.8.1.10** - Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports.

**Response:** Compliant

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#### **Summary -**

**Response:** A policy defining the methods and responsibilities for handling dry, wet, and liquid waste has been documented and implemented is found in the waste management program (SOP.015, revision 004, revision date 09/27/2021). Waste was observed to be removed on a scheduled basis and is documented on pre-operational inspections and internal audits conducted by the plant. Waste containers, hoppers, bins, and storage areas on the facility's interior and exterior were well-maintained and clean. No insect activity was noted in or around waste containers. Solid waste from processing was observed to be appropriately disposed of. Wastewater is discharged to plant drains and collected for disposal to the municipality's wastewater system.

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