Audit Report Global Standard Food Safety Issue 8

1. Audit Summary			
Company name	Fortress Nutrition LLC	Site Code	9166900
Site name	Fortress Nutrition LLC		
Scope of audit	Custom blending and packaging of nutritional and functional food and dietary supplement powder products including teas, cocoa, and grain products, and proteins, co-packed for further processors and customers serving retail markets in multi-walled bags, (MWB), pre-formed foil pouches, and canisters.		
Exclusions from scope	Christopher Morgan DC and canned beverage line.		
Justification for exclusion	Christopher Morgan Distribution Centre is in the same building but segregated from the production and storage of Fortress Nutrition. Canned beverage line is in a separate room with no similarity or cross over to in-scope products.		
Audit Start Date	2022-08-16	Audit Finish Date	2022-08-18
Re-audit due date	2023-08-28	Head Office	No

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

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit Programme	Announced
Previous audit grade	AA		Previous audit date	2021-08-10	
Certificate issue date	2022-09-28		Certificate expiry date	2023-10-09	
Number of non-conformities			Fundamental	0	
			Critical	0	

2. Audit Results

	Major	0
	Minor	2

3. Company Details

Address	16595 West Stratton Drive, Suite 1, New Berlin, WI 53151		
Country	USA	Site Telephone Number	2627807292
Commercial representative Name	Christopher Rebholz	Email	crebholz@fortressllc.com
Technical representative Name	Jon Rykwalder	Email	jrykwalder@fortressllc.com

4. Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3

Shift Pattern	Single Production Shift: 06:00 - 14:30 Mon- Fri
Subcontracted processes	No
Other certificates held	Kosher, Organic, GFCO.
Regions exported to	None
Company registration number	XXXXXXX3798
Major changes since last BRCGS audit	New QA Manager joined July 2022.

4. Company Profile

Fortress Nutrition LLC is a privately held company established in 1989 and located in an industrial park in New Berlin, WI. The facility is in the same building as the sister company, Christopher Morgan, which is a distribution and fulfilment centre and media company. All functions of the operations are segregated, and entrances into respective areas are by key card access. This is the only location and Head Office for Fortress Nutrition LLC. The company does custom blending and packaging of nutritional and functional food and dietary supplement powder products including teas, cocoa, and grain products, and proteins, co-packed for further processors and customers serving retail markets in multi-walled bags, (MWB), pre-formed foil pouches, and canisters. The company spans over 27,000 square feet (2508 square meters), with 10 separate rooms. There are two blending rooms, and four packing lines; 2 pre-weighing rooms; chemical/sanitation room and clean parts room. There are approximately 63 employees, who operate on a single production shift from 6:00 am -2:30 pm, 5 days a week. Volume is confidential.

5. Product Characteristics

Product categories	15 - Dried food and ingredients				
Finished product safety rationale	Water activity (Aw) for ingredient blends is <0.60. Finished goods are held under dry ambient conditions.				
High care	No	High risk	No	Ambient high care	No
Justification for area	The raw materials handled and packed are not a known source of contamination for vegetative pathogens due to low water activity.				
Allergens handled on site	Egg Soya Milk				
Product claims made e.g. IP, organic	Organic, Kosher, Gluten Free				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Pre-biotic Powder 375g				

6. Audit Duration Details

Total audit duration	20 man hours	Duration of production facility inspection	10 man hours

6. Audit Duration Details	
Reasons for deviation from typical or expected audit duration	New QA Manager started 3 weeks prior to the audit. High level of documentation detail for the auditor to review.
Next audit type selected	Announced

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1	2022-08-16	08:00	16:00
2	2022-08-17	08:00	16:00
3	2022-08-18	08:15	12:30

Audit Team	Auditor number	Name	Role
Lead Auditor	21860	Aaron Campbell	Lead Auditor
Second Auditor	Click or tap here to enter text.		Please select

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)				
Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Christopher Rebholz / President	X			X
Jonathan Rykwalder / QA Director	X	X	X	X
Bobbie Jo Sharon / QA Manager	X	X	X	X
Jason Weil / Maintenance Manager	X	X	X	X
Ben McGuire / Director of Operations	X			X
Lynn Schwartz / Planning & Inventory Management	X		X	X

Jerry Belante / Operations Manager	X			X
Victor Jaramillo / Production Supervisor	X	X		X

GFSI Post Farm Gate Audit History		
Date	Scheme/Standard	Announced/Unannounced
2020-08-06	BRCGS Food Safety	Announced
2021-08-10	BRCGS Food Safety	Announced
2022- 08-16	BRCGS Food Safety	Announced

Document control			
CB Report number	F0006/08/2022		
Template Name	F834 Food Safety Audit Report Template v11 BRCGSF613_Audit Report Food 17/02/2022 v21		
Standard Issue	8	*Template issue date*	2022-02-15
Directory allocation	Food	*Version*	1.0

Non-Conformity Summary Sheet

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

Critical			
No.	Clause	Detail	Re-audit date

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

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	3.11.2	The most recent mock recall exercise, conducted on July 6th 2022, included the start and finish times but did not include the timings of the other key activities.	Updated Recall & Mock Recall Procedure QP-27 to include recording start and finish times for key activities. Training completed for personnel on updated procedure. Updated the following forms to include requirement for times to be recorded: QF-27.3 Recall Finished Product Accountability Form QF-27.4 Recall Distribution Tracking Form	Updated Recall & Mock Recall Procedure QP-27 to include recording start and finish times for key activities. Training completed for personnel on updated procedure. Updated the following forms to include requirement for times to be recorded: QF-27.3 Recall Finished Product Accountability Form QF-27.4 Recall Distribution Tracking Form	Dates of activities were being recorded. Unaware of the requirement that times be recorded.	2022-09-15	A. Campbell
2	4.7.5	There was a grease gun containing food grade grease in the maintenance workshop, that was not labelled or identified on the exterior pertaining to the contents within.	Unlabeled grease gun was removed from the food grade cabinet and disposed of in accordance with QP-52 step 7.5.3.	Added training for all Maintenance personnel for Chemical Control Procedure QP-52.	Chemical Control Procedure QP-52 training was not required for all Maintenance personnel.	2022-09-15	A. Campbell

Comments on non-conformities
Click or tap here to enter text.

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit date

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

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

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There is a Quality Statement in place, in English and Spanish, signed on May 6th 2022 by the CEO which states the site's commitment to manufacture safe, high quality, legal, wholesome authentic products with the highest integrity, and meeting or exceeding food safety and quality standards. It further provides for continuous improvement in all operations to exceed customer requirements, provide full integrity, innovate the industry, and ensure growth. Staff underwent refresher training on its contents between 27th July - 10th Aug 2022 by the QA Director and Quality Administrator. The Quality Statement along with organizational chart are posted in the main employee entrance.

Food Safety & Quality Culture and Continuous Improvement Program dated 2021-01-20 describes how the site will develop, implement, and continuously improve food safety and quality culture to exceed obligation to produce safe, legal, and high-quality authentic product. Professional development is encouraged and sponsored. Continuous Improvement Policy describes how the culture is measured and how it is improving, based on tabulated results. The culture is maintained through provisions of resources, evaluation of performance indicators and setting of food safety and quality goals and objectives that need to be supported by senior leadership, through consistency in setting examples for the employees.

There are monthly meetings with departmental managers and hourly employees to provide opportunities for cross functional communications and provide an opportunity for employees to communicate potential food safety and quality issues and contribute in planning of related improvements. Employee suggestions are reviewed during the monthly management meeting and an action plan is drawn with time scales for completion. The actions are reviewed during the management meeting. Departmental managers provide the status of completion of the action plan and effectiveness of the action taken.

The food safety, and quality KPI's for 2022 included:

- Customer complaints zero is target
- Food safety system failures zero is target
- CAPA's from audits internal and external 2nd and 3rd party
- Food safety system failures <1 per month.

These goals are reviewed on a quarterly basis in the management meetings which also doubles as the HACCP Food Safety Team Meetings. The goals are given color based on the traffic light system and were on target for 2022. The site had a soft copy of the BRCGS Food Safety v8 Standard.

Food safety culture questionnaires, 9/9/20 had 9 questions with 1-7 scale e.g. I can freely speak up if I see something that may neg affect food safety or quality. The scores are trended for review vs previous years.

The monthly management meeting minutes were observed for 24th May, 21st June and 28th July 2022.

The financial and human resources were more than sufficient for task and a new QA Manager was employed recently, and the Operations team has been expanded. Also higher quality cameras have been installed, both internally and externally. The President and Director of Operations are the most senior positions at the site; both attended opening and closing meetings of the audit.

BRCGS logo not used on marketing material as site were aware of the scope exclusion policy.

1.2 Organisational structure, responsibilities and management authority

The reporting structure is captured in the Organization Chart (updated 8th Aug. 2022), generated by the HR Manager. The President / CEO and Director of Operations are the most senior positions at the site. Direct reports include Managers, Supervisors and Lead-hands.

The Director of QA is responsible for Food Safety, and reports to the CEO and is separate function from production. There is one QA Manager that reports directly to the Director of QA and also deputises for him.

Alternates, roles, and responsibilities to the BRCGS program are defined in Food Safety Job Descriptions, dated 2020-06-17. Director of Operations ensures all resource requirement are met, establish food safety and quality objectives, member of HACCP and Oversee production scheduling. The alternate is the Director of QA. The Director of QA ensures compliance to GFSI and regulatory requirements, food safety plan development, maintenance of all controlled documents and records, and overseeing internal audit programs. The induction training program and contents were verified with the QA Manager who is a recent hire.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
1.1.13	BRCGS logo not used.

2 The Food Safety Plan – HACCP

The company has a documented Food Safety Plan reviewed 2021-08-10, signed by CEO, and the scope of the plan is based on the Codex Alimentarius principles and complies to FDA 21 CFR 117.

The Food Safety team is established and includes Director of QA, QA Manager, Director of Operations, Production Supervisor, Maintenance Manager, Account / Project Manager and Operations Manager. Director of QA is the Food Safety Team Leader / Coordinator. Director of QA is HACCP certified (2019-08-25) and PCQI (2018- 08-29). The QA Manager is deputy Co-ordinator and is PCQI certified (2019-12-04).

The site has documented the following pre-requisite programs: Sanitation, Pest Control, Maintenance, Personal Hygiene and GMPs, Training, Purchasing and Supplier Approval, Chemical Control, Storage and Transport, Traceability, Control of Non-Conforming Product, Corrective Actions, Security, Labelling/Pack Control, Product Authenticity, and Allergen Controls. The control measures and monitoring procedures are documented as part of the quality systems and are incorporated in the Internal Audit Program. There is an

Environmental Monitoring program in place to monitor Salmonella and Listeria. 3M Swab technology is utilized to monitor environmental pathogens. 3M swab test records were reviewed and were current.

There is one HACCP Plan that has been developed based on 21 CFR 117 and Codex and is based on historical data, FDA alerts and FSMA. The facility receives ingredients from their customers- protein based blended powders, natural coloured plated lactose powder and single ingredient dietary supplements. Products are ready to eat, and bulk products are for customer repack/industrial use. Retail packed bags are also produced. Product description and intended uses are kept by each customer contract in the "Product Background" information e.g., protein powder blends for chocolate truffle, vanilla bean, and nutritional yeast flakes. The list of ingredients and relevant process flows are defined and includes the list of products. Misuse could be improper storage or unsealing of pouches. Intended consumers is the general public. Sensitive populations are addressed under labelling instructions for allergens present.

Allergens include milk, soy, egg, products. All customers are domestic.

Shelf life of products range from 1 - 5 years depending on product type. All products stored at ambient.

There are several product flows are available, and each product description references the relevant flows i.e. semi-automated pouches, hand packing, automated canisters, mix and package. Products received pass through ambient storage, screening, packing, coding, storing before shipping. Rework processes can be applied at various steps such as steps for sealing. Magnets and liquid additions are only for the Mix & Package flow. Products may be manually weighed or via automated processes. All packaged products go through a metal detector or x-ray machine. Process inputs include compressed air. The process flows are verified by the Food Safety team by walk through annually and signed by the Food Safety Team.

A Hazard Analysis worksheet is constructed for each line. It includes raw material hazards and all steps of the process. The likelihood and severity of each hazard is documented for each step. Justification for each step is documented, including acceptable hazard levels or control via a prerequisite program.

Physical hazards identified in risk assessment include metal, plastic, and wood. Biological hazards identified in the risk assessment include the pathogens- salmonella and listeria. Chemical and radiological hazards identified in the risk assessment include allergens, pesticide, and antibiotic residuals.

The site identified two CCPs for each process flow, namely metal and X- ray detection. The critical limits for metal detector and x-ray depend on the line and size of the product and have the following ranges: 1.5 to 2.0 mm Fe, 1.5 to 2.5 mm Non- Fe, 1.5 to 2.5 mm SS. The metal detector/X- Ray machine must detect and reject each type of metal.

The metal detector/X- Ray check procedures for monitoring the CCP are documented in the Metal Detector/X- Ray Check Policy Work Instruction. Monitoring is performed prior to start up, every half hour per shift, and at the end of shift and at the time of changeover by production employees and every hour by QA employees. Records of monitoring include time, result, operator/QA, line, and product. Corrective actions include holding product back to the last good check and re-running affected product through a functioning metal detector prior to release. All rejected product is investigated for the presence of metal. In addition, the QA Supervisor conducts a daily verification. During the audit, the metal detectors were successfully challenged and the interview of QA staff performing the tests showed competence in performing these tests.

There are also three preventive controls identified under allergen control. Records of monitoring include time, result, operator/QA, line, and product. Corrective actions include holding product back to the last good check and re-running affected product through a functioning metal detector prior to release. All rejected product is investigated for the presence of metal. In addition, the QA Manager conducts a daily verification.

Reviewed random CCP reports for metal detector/X- ray machines from Jan – Jul 2022 and no deviations were observed for the records sampled.

The metal detectors and X- Ray machines are calibrated annually by 3rd party contractors. The Label validation is carried out on internal audits, customer complaints and quarterly audits by the Director of QA.

The HACCP program procedure and pre-requisite programs is required to be reviewed annually or when there is a change in the program. Last annual review was conducted on 2022-08-16.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
	None

3. Food safety and quality management system

3.1 Food safety and quality manual

All contents of the food safety and quality management system are maintained electronically in INTELLECT – a inhouse quality management software, password protected and backed up nightly. Document Control and Document Control Change Order Process describes the protocol for request / change order. Document name and number is assigned after creation and placed on the master list. The current revision and release dates are in INTELLECT. If the document migrated from the previous QMS software, the revision history can be accessed in that legacy form. The reason for revision is described in the Change Order. There is a record of all changes, who approved the change, and the date of revision, approval, and release. All documents are accessible for read-only viewing to all employees. Only management members can request edits and document owners review them minimum every 2 years.

3.2 Document Control

There is a Document Control SOP in place, June 2nd 2019 rev.1, which states the records are maintained for up to 7 years. Hard copies available for use when required; all contents of the manuals are on INTELLECT software are readily accessible to key staff in English. The manual is password controlled. It can be initiated by any departmental manager but only approved by Director of QA.

3.3 Record completion and maintenance

There is a documented Record Retention Procedure (2019-12-06). All records must be retained for at least 6 years, electronically and manual records are physically archived in QA office. The stated best by date is up to 5 years from packaging. Requested records were available as needed during the audit. Reviewed records were retrievable and complete. Hard copy records were legible; any corrections observed were done according to company policy (single line-out with correction and initials).

3.4 Internal audits

There is a risk based Internal Auditing Program (2021-08-10) implemented. The Operations Manager and the QA Director are the Internal Auditors, certified by SCS Global on July 11-12th 2022. Each auditor is independent to the BRCGS Section they audit. The site performs internal audits every quarter, covering all seven sections of the Standard and the schedule was reviewed for 2022. The internal audit inspections include the scope of GMPs, the raw materials warehouse, plant structure, equipment, external grounds, maintenance, and sanitation. There is an internal audit matrix for 2022. Section 1, 2, 3 were completed between March 11th – May 19th 2022; section 4 & 5 were completed on May 19th 2022. Completed audits on record have dated corrective actions.

GMP/Building fabrication Inspections are done monthly and documented on the Food Safety Inspection Report. The checklist includes the location, area inspected, and details/non-conformities. Majority were related to GMP practices, document controls, and general hygiene practices. No major food safety risks have been identified.

Any NC are added to CAPA with 30 days to rectify and close out.

Inspections – GMP covers exterior and glass and brittle plastics conducted monthly by QA and Production or Maintenance – findings are prioritised and discussed in monthly meetings. Auditor reviewed records from June 9th 2022, July 13th and Aug 11th 2022.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Supplier Approval Program (2020-03-05) is in place and includes risk assessment for adulteration, substitution, or fraud. All ingredients are purchased by the customers from approved suppliers. Suppliers must provide information for ingredient, complete a questionnaire and GFSI certificates. Customers may provide their questionnaires, and document hazards identified. QA must obtain completed forms back from the supplier and will review forms for any hazards. All ingredients are classified based on risks of allergens, foreign bodies, microbiological and chemical contamination. Procedure Risk Assessment describes the process for testing and acceptance procedures for each risk level of ingredients.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

There is an established receiving program on record updated 2021-03-12. All raw materials are required to have a COA to accompany the load. Items that are considered critical to quality will have the COA/COC crosschecked to the company's internal specification. A visual inspection is completed upon receipt and records of receiving are reviewed, including the Bill of Lading and Receiving Report. The Receiving report contains information for each item including inspection, condition of trailer, seals, lot numbers, and screen inspection.

3.5.2.3: N/A- The site does not receive any live animals

3.5.3 Management of suppliers of services

There is a documented supplier of services procedures dated 2020-03-18. Suppliers of services include pest control, laundry, laboratories, maintenance contractors, and waste management. Every year, each supplier must complete the supplier compliance manual. The manual covers GMP and food safety requirements for the facility. The manual contains a formal agreement that is signed by each provider annually. All service contracts on file were current during the audit. In addition, all visitors and contractors must report to the reception area and sign in electronically including a visitor GMP and Safety declaration.

3.5.4 Management of Out sourced processing

3.5.4: N/A -No outsourced processing occurs at this facility.

3.6 Specifications

The policy states specifications must be on file for raw materials, packaging, and finished products. Specifications were reviewed during the vertical audit for Xylitol Powder – last revised 17th May 2021 and the primary packaging pouch. Also reviewed finished product specification on file for Xylitol which included handling instructions, shelf life, and packaging instructions.
The QA Document Technician compares the Bill of Materials and packing slips. This review includes all information including label. Any non- conformances are addressed using root cause analysis, via QA and then to customer for final disposition. All non-conformances are reviewed weekly by the Food Safety team members.
Specifications are reviewed minimum every 3 years or when any change to product or ingredient.

3.7 Corrective and preventive actions

A Corrective Action Procedure is outlined, last revised on 2020-06-29. The scope covers audit findings, internal, or external complaints, food safety system failure, managements review, non-conformance, and causes to food safety risk, and trend analysis. All deviations documented on an NCR report and followed with RCA (5 Why's or Fishbone) and CAPA form. A Process Deviation Form is initiated if process controls are not met. The root cause, corrective action, and verification of corrective actions are conducted by QA. QA will oversee all close-out CAPA's. Examples of CAPA's were sampled for internal audits, control of non-conforming products, and customer complaints. Reviewed completed reports for 2022 and they were completed within the required timeframe.

3.8 Control of non-conforming product

There is a documented risk based non-conforming product procedure on record (2020-06-29). Program identifies what, when, who, how a non-conforming product is to be handled. The 3PL management software system is utilized to manage and control the hold and release program. QA lab techs are responsible for placing the items on QA Quarantine (RED Tag) and segregating in the storage room. Records are current and up to date. No product was observed on hold during the audit.

3.9 Traceability

There is a documented Traceability Procedure which was last updated 05th May 2022.

The program requires minimum 2 traceability tests performed annually which must include ingredient, food contact packaging and finished product. The Lot Tracking Procedure also requires to be completed within 2 hours with 100% recovery.

The most recent exercise was conducted July 6th 2022 for a finished product cheese additive with product code 295FG0004 and Dec 29th 2021 for a potato starch ingredient. The recovery was 99.9 - 100% and were completed in 21 minutes and 1 hour and 55 minutes respectively.

During the audit, a traceability exercise was conducted on 2.5 lb Xylitol, product code 283FG-6986, produced between 20th – 27th April 2022 with lot code 3246203. Total 20,784 x 2.5 lbs = 51,960 lbs produced. All product was shipped to 1 customer's DC on two shipments – 9264 units on 3rd May 2022 and 11520 units on 4th May 2022. A mass balance was conducted on the Xylitol raw material which was received on 4 loads – 1 x Jan 31st 2022 and 3 x Mar 10th 2022 and used between Feb 24th – May 11th 2022. Recovery was 100% in 1 hour with start time of 09:30 and end time of 10:30 on day 1 of the audit. Documents utilized for the trace included, receiving records, production usage summary, production summary, transaction history report, item activity report, pick tickets, shipping inspection and BOL transportation documents, pallet tickets, COA's, return inventory list, distribution records, and production lot recall report. A mass balance trace concept was utilized and included all raw materials, packaging, rework, and finished goods, were identified for the trace exercise.

Rework traceability is maintained via the hold log and the rework log.

3.10 Complaint-handling

There is documented customer complaint program (2021-04-23) describing all complaints will be answered in a timely and professional manner. All complaints are received by account managers and then directed to the Director of QA. Auditor reviewed customer complaints for 2021-22 of which there were 8. All complaints received are investigated on how actions to be taken and are based on the seriousness of the complaint. There are documented trend analysis on record to date 2022. The departmental Managers review all complaints monthly with the employees. Product quality complaints and specification compliance were identified in the trend analysis. Of the 8 complaints in 2022, the majority were process related. Improved quality program and improved root cause analysis techniques have contributed to the complaints trending down. Complaints are tracking on average less than 1/month.

3.11 Management of incidents, product withdrawal and product recall

There is a Crisis Management Program on record dated 2020-01-15. The procedure addresses disruptions to normal flow of production, product storage, or shipping. The program also includes a section for supply chain interruption, facility compromise and internal key contacts.
There is a Recall & Mock Recall Procedure dated 2021-09-27 and includes an established recall team, with plant and Senior Management accountability. The policy references the FDA class I, II, III recalls and key responsibilities for communication are identified by area. The plan states the procedures for recording timing of key activities and plan for RCA and implementing improvements to prevent recurrence.

There is an updated list of key contacts. The Director of QA is the Recall Co-ordinator and CEO is the spokesperson. Documented contacts lists are on file for the FDA, Certifying Body (Eurofins USA), Emergency Services, and legal department. Recall co-ordinator would be responsible for contacting external regulatory agencies and determining the need for additional resources.

The policy requires a mock recall to be conducted on finished product, raw material, and product contact packaging annually. Reviewed the mock recall performed on July 6th 2022 for a finished product cheese additive with product code 295FG0004. The recovery was 99.9% and was completed in 21 minutes. Timings of key activities were recorded, together with all the relevant pertaining documents.

It is stated in Recall Policy that the Certification Body will be notified within 3 days of the decision to recall product.

Minor Non-Conformance:
3.11.2 - The most recent mock recall exercise, conducted on July 6th 2022, included the start and finish times but did not include the timings of the other key activities.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.2.3	N/A- The site does not receive any live animals.

4. Site standards

4.1 External standards

The site owns an entire building within an industrial park where other food and non-food companies are located. The location of the site does not pose a threat to finished product integrity. Observed adequate drainage during the perimeter walk.

The external grounds are clean and traffic areas are paved in good repair. The exterior of the building is brick and tilt-up concrete panels, which are in good repair and do not pose potential for pest entry or ingress of other contaminants.

4.2 Site security and food defence

There is documented Site security and Food Defence Program (updated 2020-02-14).A Site Security Risk Assessment based on FDA guidelines was last conducted on 2021-08-10. Production areas are restricted to authorized personnel and a security badge key card is required for entry to the plant and to exterior doors.

Surveillance cameras are utilized (interior/exterior), monitored 24/7. Visitors are required to sign in at the front desk and are identified with visitor specific clothing and visitor badge. All staff are trained on food defence annually – last conducted July 27th – Aug. 10th 2022.

The Food Defence Team meets annually and reviews the program – last conducted Aug 9th 2022 updated emergency contact list includes, Wisconsin Department of Homeland Security, County Health Department, State of Department of Health, Wisconsin Department of Agriculture, Trade, & Consumer Protection, FBI for Milwaukee, and FDA Wisconsin District Office. No deviations were found, and the plan was deemed effective.

The site is registered with the FDA.

4.3 Layout, product flow and segregation

The site plan is documented (2019-08-19) and identifies enclosed product areas (coloured blue); non-product areas (coloured yellow) and Open Product area (coloured orange). The facility produces low risk items. There are no high-care or high-risk items produced.

The site plan includes access points for personnel and travel routes, location of staff facilities and routes to the facilities from places of work, the general production process flow, routes for rework and trash removal (updated 2019-08-19). The movement of WIP, waste and rework does not compromise safety of products. There is a designated walkway for access from production floor entry to the break room.

Contractors and visitors are made aware of special requirements when they report to the front desk and sign the visitor GMP form. Contractors are under the supervision of a designated person.

The process flow and procedures minimize the risk of contamination.

The premises allow for enough working and storage space for operations to be carried out hygienically.

4.3.5: N/A- There were no temporary structures observed during the audit

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

The single storey building, and floors are constructed of concrete and found to be in good repair. Floors in production areas were concrete and epoxy sealed. The ceiling was sheet metal. Depending on the production activity, the wall material was found suitable for operational requirements. Some walls were painted white and were of dry-wall panels for dry packing rooms, and the blending room was panelled with PVC panels to allow for the ease of cleaning. Some retail pack rooms, and the sanitation room walls were

covered in white, vinyl like coverings that were found to be in good repair. Walkways and mezzanine were made solid metal plates. Areas where there was potential product contamination on mezzanines and walkways have been sealed. Kick plates have been installed to prevent foot traffic debris on stairs and walkways. The voids in suspended ceilings are inspected weekly by PCO. Windows were found to be in good repair and did not pose any immediate risk to open areas. Doors were sealed to prevent pest entry. Ventilation was found to be adequate, and aspirators to remove debris have been installed on blending equipment. Additional suspended lighting has been installed in inspection areas such as hand sorters. Both storage and processing areas were observed to be well lit.

4.4.7: N/A- No windows are designed to open for ventilation

4.5 Utilities – water, ice, air and other gases

Monitoring of potable water, environmental air, and compressed air is done through the Environmental Program Procedure date revised on 2022-06-17. Water is sourced from the City of New Berlin, WI. The 2021 Water Report from City of New Berlin is tested for Coliforms, E.coli, HPC, and Pseudomonas Aeruginosa and heavy metals.

There is a water schematic on file and show points of water distribution. Water is used for sanitation purposes and hand washing. Water is not used in processing the food. Water is tested quarterly for HPC, coliforms and E.coli and there have been no retests required since the previous BRCGS audit.

Compressed air is a process input and used for cleaning purposes. Compressed Air Testing for non-viable particle assessment, dew point temperature analysis, oil mist saturation, and microbiological testing is done by 3rd party contractor. The filters are checked monthly as part of PM. The size of filters is 0.01 micron.

Environmental air is tested annually for yeast and mould – tested on July 28th 2021, and currently awaiting 2022 results.

4.6 Equipment

The majority of the is equipment is constructed of stainless steel and containers of readily cleanable, food grade plastics. Paint was not observed on any equipment. The Design Standards Program 28th July 2020 was in place and stated its purpose as ensuring the production equipment is safe and effective for manufacturing of all products.

Equipment is inspected during pre-operational inspections. Records of inspections were sampled during the traceability exercise and found to be complete.

4.7 Maintenance

The Maintenance SOP (2020-08-27) was reviewed and effectively documents the requirements for planning and scheduling preventive maintenance activities. There are defined methods for Emergency Maintenance and Preventive Maintenance. There are defined methods for performing condition assessments and ensuring routine maintenance is performed.

Preventive maintenance is overseen by the Maintenance Manager who is also responsible for managing repairs. Repairs and PMs are to be documented on the Work Order form. The details of the work and

location are documented on the work order. Work completed near or on the line will require a QA inspection and equipment release signature. Tools and parts are to be cleaned before use and accounted for after work is performed. A process to implement new equipment is also included in the procedure. Before install, the Food Safety Team will review the sanitary design. No temporary repairs are performed at the facility and no temporary repairs were observed during the audit.

The program and tasks to be performed are documented on the Preventive Maintenance Log report. Auditor chose 3 rooms at random and checked completed work orders on doc. MF-7.1 for room 2 Capper on 28th Jan 2022, room 3 replacing towel dispenser on 3rd Feb 2022 and room 4 chipping paint on walls repaired on 15th Aug 2022. All work is verified and signed by the Maintenance Manager.

Reviewed SDS and storage cabinet for food grade lubricants- GF Silicone Spray H1 NSF # 017393 and CRC FG Synthetic Grease H1 NSF # 144237, which both had allergen certificates and a letter of NSF approval on file.

Minor Non-Conformance:
4.7.5 - There was a grease gun containing food grade grease in the maintenance workshop, that was not labelled or identified on the exterior pertaining to the contents within.

4.8 Staff facilities

The facility has designated break room areas that are separated from processing and storage areas. There are sufficient storage areas for outdoor clothing and for storing employee items.

There are sufficient hands-free hand wash stations located in production rooms. The stations observed were effectively maintained with warm water, soap, paper towels and signage. The restrooms do not enter directly into production or storage areas. The restrooms observed were well maintained. The hand wash stations were hands free, stocked effectively and signs are present. Hand washing is required before leaving the break room and entering production.

There is a designated smoking area outside of the facility that was observed to be effectively maintained. Waste disposal was appropriately controlled. There are fridges in place as designated locations for storage of food brought from home. The areas were observed to be neat and orderly.

The site does not utilize catering services. Microwaves are available. The vending machines are managed effectively by the site management. No food or drink is allowed in production or storage areas.

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

4.9.1 Chemical control

There is a documented Chemical Control Policy (2020-03-16). All chemicals used in the plant must be approved. There is a documented list of all approved chemicals and any chemical introduced into the plant must be approved by QA Management. The approval program and chemical control is reviewed annually or when new chemical is introduced. Reviewed SDS for Sani King 451 sanitiser, Foam Brite 377 degreaser, Immense cleaner, Floor Quat 318 powder for footwear and Grease X 367 degreaser. The policy covers the use of strongly scented products is prohibited. Observed chemical storage area locked during the walkthrough. Employees working in sanitation receive annual sanitation chemical control training upon hire, delivered by the chemical supplier. The sanitation staff must check the concentration of

the chemicals by titration at beginning of the sanitation and the results are recorded. The results are reviewed and verified by the QA Technician (reviewed reports from Jul - Aug 2022.

4.9.2 Metal control

Knife Control Procedure (2020-03-20) have been documented and implemented through multiple programs. A knife inventory is maintained using the Knife Check In- Check Out Sheet Date, last revised on 2021-04-02. The condition of the knife is inspected daily, and the operators must verify knife ring is in a locked cabinet. Operators sign the knives in and out daily.
Records were sampled from Jan – Jul 2022 . New knives issued are verified by Production Supervisor and QA. Employees are instructed to report any broken or missing knives.
The use of snap off blades is not permitted. The GMP program stipulates that paper clips and staples are not permitted in production zones. Corrective action protocol is documented in the procedure. The procedure details isolation of affected product and the re-inspection of all products back to the last good check.

4.9.3 Glass, brittle plastic, ceramics and similar materials

The Glass and Brittle Plastic Control/Breakage Procedure (2020-04-02) details the actions taken in the case of breakage, including quarantine of the area; cleaning' inspection of the area; changing of work wear and inspection of footwear; and recording the incident.

There is a list of glass and brittle plastic on the site. Glass audit is conducted by QA Team Leader annually. Auditor reviewed records for 2022 where it is listed in the monthly GMP audits.

There is a glass breakage procedure, describing the area is segregated in case of glass breakage. Special utensils are used to clean up the area, inspected and approved by QA before production can start. There is a glass breakage log report. No glass incident was reported in 2022.

Annual training is given to all staff on glass breakage procedures during GMP refresher.

4.9.4 Products packed into glass or other brittle containers

4.9.4: N/A- Product is not packaged into glass at this facility

4.9.5 Wood

Wood pallets are inspected as per inbound procedures and pre-operational checks. Wooden pallets used are inspected prior to use. Wooden pallets that are found broken or severely splintered are removed from areas. No wooden tools or broken pallets were observed inside the facility during the site inspection.

4.9.6 Other physical contaminants

There is a documented Other Physical Contaminant procedure. In-line magnets and screens have been installed. Hazard analysis has been completed for each type of equipment as part of the hazard analysis. Screen are used before packing of powder of size 10 mesh. Magnets are checked every shift.

4.10 Foreign-body detection and removal equipment

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

Screens are located at primarily blending and mixing steps. In-line magnets are located prior to packing. X-ray and metal detectors have also been installed to remove foreign material on packing lines.

Sensitivities, monitoring, and are detailed in subsequent sections of the report. Findings and rejects are investigated as per CAPA procedure. Unusual findings are turned into management and investigated by QA on the Metal Findings Log report.

4.10.2 Filters and sieves

Sifters and screens are utilized throughout the process. The location of the screen and mesh sizes are as follows:

- Size 10 mesh screens at the blenders (rotary system).
- Screen on hopper on packing canisters are ¼" and 1/8".
- Screen at packing hoppers is size ¼" and 1/8".

Screens are located on flow diagrams, and checks are done daily during pre-operational checks, and after each run. The findings are collected, inspected and atypical findings are logged on the Metal Findings Log report.

Screens are checked after each batch by the line operators and verified by the supervisor. Reviewed batch records on file for 2021-22.

4.10.3 Metal detectors and X-ray equipment

Metal detectors and X-ray machines are located prior to packing and is a CCP. Monitoring, corrective action, and records sampled. Rejects from X-ray machines and metal detectors are inspected. A Metal Findings Log report, is maintained, and any typical finding will warrant an investigation.

The critical limits depend on the line and size of the product and have the following ranges 1.5 mm to 2.0 mm Fe, 1.5 mm to 2.5 mm Non-Fe and 1.5 mm to 2.5 mm SS. The metal detector must detect and reject each type of metal. The reject mechanism on the metal detector is designed to reject the product if a metal is detected with an audible alarm. The rejected product is collected in a locked box, accessible only to QA Staff.

The Metal Detector Check Procedure identifies CCP Monitoring being performed at the start-up, end of shift, changeovers, and every half hour during production. CCP records reviewed and include a section for corrective actions, which includes notifying QA, holding product to last good check, determining the cause of malfunction and repair of the unit, running product through functioning metal detector. All rejected product is investigated for the presence of metal. Metal detectors are calibrated annually by 3rd party accredited company.

The records reviewed for months of March - July 2022 were effectively documented and verified by QA Dept. Interviewed QA and Production Supervisor performing the tests and they were well versed with the process and could perform the test.

4.10.4 Magnets

There is a Magnet Pull Strength SOP, describing the monitoring of magnet strength. A Rare earth magnet is in Room # 4 (Blending room), immediately after rotary screens. The pull strength is 7 lbs. and must demonstrate at minimum 80% of pull strength capacity. The Magnet Pull Strength Test procedure (2019-10-28) describes that the magnets will be tested annually by maintenance.

4.10.5 Optical sorting equipment

4.10.5.1: N/A- The site does not have optical sorting equipment

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

4.10.6: N/A- Glass is not packaged into glass at this facility

4.11 Housekeeping and hygiene

There is a Sanitation Program (2020-04-29), which outlines the responsibilities and frequencies of sanitation tasks. Tasks may be designated as daily, weekly, monthly, quarterly, semi-annual, or annual. Worksheets are printed out weekly that include the steps to complete the task, the chemicals and concentrations, and equipment and materials to be used. The sanitation staff must check the concentration of the chemicals by titration at beginning of the sanitation and the results are recorded. The results are verified by the QA Technician (reviewed reports from Jan – Jun 2022).

ATP swabs are conducted on the various food contact areas in the blending rooms each week during the pre-op. The acceptable levels are per the swab manufacturer's instructions (20 RLU max is pass rate). Results are trended and reviewed. All other equipment is visually inspected. Reviewed swab results months from January to July 2022. SSOPs cover the dismantling of equipment Visual inspections are documented by QA and Production Supervisor during the pre-op inspection after each clean-up. The results are trended by area and reviewed weekly. All sanitation chemicals are locked and segregated.

Allergen clean verification swabs are carried out annually on the 3 allergens using 3M allergen swabs- eggs; soy; milk. The allergen validation test is performed by 3rd party lab.

4.11.7 Cleaning in place (CIP)

4.11.7: N/A- There is no CIP system at this facility

4.11.8 Environmental monitoring

There is a risk based Environmental Program Procedure in place, last revised on 2020-04-01. A hazard analysis was completed on the processing and raw materials introduced. Swabbing frequencies are determined based on the risk assessment. The EMP testing is performed monthly, air plate testing performed quarterly, water testing is performed quarterly, and compressed air tested annually. Zones are defined as 1-4, with 1 being product contact and 4 being areas away from product contact.
Swabbing is done monthly and tested for Salmonella and Listeria in zones 2,3,4. Coliforms will be tested semi-annually due to sufficient history of testing. An aseptic sampling procedure is included in the procedure. Limits are defined on results log where Listeria and Salmonella must be negative. Coliforms must be <10 cfu/sponge. Positive results will require a corrective action using the Vector Analysis Form. Swabbing is done as per the Environmental Sampling Site Schedule. Approximate total of 25 swabs are taken once per month from Zones 2, 3, 4 from across the site for Listeria and Salmonella. Every room and warehouse are included in the schedule and is covered minimum every quarter. Areas to be swabbed include control panels, drains in all rooms, screen covers, load doors, parts cart, and equipment frames. Results were sampled from Jan – Jul 2022 for Salmonella, Listeria and Coliforms, with no positive or out of spec. results detected. All results are trended and reviewed during the management meetings.

4.12 Waste

There is a well implanted Trash Disposal (2020-11-22) and Material Disposal Procedure (2020-03-13) in place which describes process for disposal waste production material. Waste is picked up through a contract service provider. All solid waste is stored in designated containers, and waste containers were

observed properly emptied. A waste compacter and extracted dust container located in the external yard area were observed to be well managed, and free of overflow. Customer branded products are to be discarded as per customer requirements if requested.

4.13 Management of surplus food and products for animal feed

4.13: N/A- There are no products intended for animal feed.

4.14 Pest management

There is a documented Integrated Pest Management Policy (2020-02-14) describing the requirements for the site to develop and maintain pest management practices.
The company has a contracted third-party supplier for Integrated Pest Management (contract signed on 2022-03-08). The following scope of service is documented and followed by the contractor: exterior rodent control – approximately 9 bait stations that are secured and tamper resistant with bar code labels inside, serviced every other week.
Approximately 22 interior traps that are positioned along the perimeter walls and on both sides of doorways, serviced weekly.
There are 8 ILTs and 13 pheromones traps that are serviced weekly.
There are preventive measures in place to prevent birds form entering buildings or roosting above loading or unloading bays.
The PCO has provided current Business license(2022-12-31), Certificates of insurance expires 2023-01-01, Applicators licenses, SDS for Approved chemicals and a map (2022-03-07) of the facility with the stations noted on the diagram.
The Service Technician performs the services at the designated frequency and documents the actions performed, any structural or sanitary issues of concern and the activity (if any) by location. There is an electronic Service Report that is provided to the site management and reviewed prior to the Service Technician departing the site.
The records reviewed from randomly selected dates in 15th Aug, 8th Aug, 25th Jul, 18th Jul and 5th July 2022 were maintained per the plan requirements.
Reviewed SDS for the approved pesticides used in the site- Advion Ant Gel Bait, Demand CS and Invade BioFoam.
The Pest Control manager performs a quarterly in depth inspection and review which includes conducting a trend analysis and is used to assess the effectiveness of service and the procedures in place. There was a current annual assessment of the program available. There were no issues of concern identified and no evidence of pest activity.
The site documents any corrective actions to structural or sanitary issues identified during the regularly scheduled services.
The company personnel are informed during new orientation and annual refresher training for pest awareness of the types of pests that should be reported if observed. There is a pest sighting log for documenting any activity between Service Technician regularly scheduled visits.

4.14.3: N/A-The site personnel do not perform rodent control pest activities.

4.15 Storage facilities

There is documented Material Storage and Warehouse management SOP (2021-09-03), procedure for storing and handling materials, finished products, WIP and packaging components and procedure to protect from cross contamination. Storage requirements have been defined, and all products are stored at ambient. All storage is in one warehouse which is adjacent from production rooms. Storage of product and packaging is done in a protected manner. Additional metal racking has been installed inside the storage

areas. Packaging is stored covered by methods including Saran wrap. All products and packaging were found stored away from the internal perimeter, and warehouses were found clean. FIFO and FEFO systems have been implemented based on customer instructions.

4.15.3: N/A- The site does not have controlled atmosphere storage.
4.15.4: N/A- The site does not have controlled atmosphere storage.
4.15.5: N/A- The site does not store items outside

4.16 Dispatch and transport

Incoming inspection programs have been documented and implemented. Trailers are received by Christopher Morgan, but training is provided by Fortress. Records of trailer inspections are recorded on the Trailer-Receiving Inspection Form (reviewed during trace exercise and site tour). Trailers are inspected by receiving staff to ensure trailers are free of damages, seals or padlocks are applied, and lot codes match the picking list are documented. Shipping personnel was observed and demonstrated the trailer inspection. No deviations were observed, and the procedures were followed as documented. All shipping is done by the DC except for one customer.
All forklifts and hand jacks are cleaned weekly and included in the sanitation SOP. The forklifts and hand jacks observed were clean during the audit.
The site has documented procedures that include the restrictions on mixed loads, locking or sealing of trailers and instructions in the event of vehicle breakdown.
The agreements are on file, and were reviewed, for select for third party carriers.

4.16.4: N/A- Temperature control not required for the shipping the finished product.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
4.3.5	There were no temporary structures observed during the audit.
4.4.7	No windows are designed to open for ventilation.
4.9.4	Product is not packaged into glass at this facility.
4.10.5.1	The site does not have optical sorting equipment.
4.10.6	Glass is not packaged into glass at this facility.
4.11.7	There is no CIP system at this facility.
4.13	There are no products intended for animal feed.
4.15.3	The site does not have controlled atmosphere storage.

4.15.4	The site does not have controlled atmosphere storage.
4.15.6	The site does not store items outside.
4.16.4	Temperature control not required for the shipping the finished product.

5. Product control

5.1 Product design/development

The Product Design and Development Procedure (2020-03-13), describes the procedure for manufacturing of new products and changes to existing products. The facility does not develop new products, but a new product introduction to the site is outlined in the procedure. Onboarding of new customers or processes will be managed by the Account Manager who will also set up contracts. Approvals are granted prior to products are introduced. QA will review in-process specifications, finished product specifications, Packaging Component, and raw material specifications. All new products and ingredients must be approved by the Food Safety Team, before introduced into the facility. If new elements are introduced, and the impact to scheduling and sanitation processes will be determined by QA. Director of QA reviews label review, supplier approval documents, and formulations. Shelf life and validation is determined by clients. Director of QA will implement new specification in the MMR sheets. There have been no new products introduced since the previous audit in Aug 2021. Production trials will be conducted on, as needed.
Records for review and approval were readily available. A new product that has gone through all the stages of NPD, including formula approval, was reviewed for Dextrose (2 lbs.) dated 28th June 2022.

5.2 Product labelling

Product labels are developed by the customers, reviewed, and approved by Director of QA. Introduction of new labels will follow the Product Design and Development Procedure dated 2020-03-03. The Director of QA is responsible compliance. The site ensures labelling requirements are met and controlled while handling raw materials through the authenticity program. Allergen declarations are validated against the formulation and approved as per the customer specification review process. Inspection of all labels against customer specifications is on done through a positive release system and verified for accuracy upon receipt by QA. Records of inspection are in relevant sections of the report.

5.2.3: N/A- No claims made on the labels.
5.2.5: N/A- No cooking instructions on the labels

5.3 Management of allergens

A documented process hazard analysis which considered physical, chemical, biological and allergenic hazards was reviewed for packets, pouches, mix and package, packaging – semi automated dated 8/18/22, and reviewed annually. Each product has a separate product background sheet – reviewed as part of the vertical audit for Xylitol 2.5 lb which contained no allergens.
The Raw Ingredient List Summary documents the presence and type of allergen. The facility lists the following allergens: egg, milk, and soy. A list of allergens containing raw materials and finished product is documented.
The Risk Assessment identifies the potential routes of contamination and procedures for handling Allergens.
A documented Allergen Control Procedure reviewed on 2019-12-06, details process steps on how to control allergen cross contamination.
The control policy emphasizes GMPs, physical or time separation, scheduling and allergen matrix, packaging accuracy, dedicated utensils for cleaning, allergen cleaning procedures, and pre-op inspection.
Employees' personal food is stored in the employee break room.
All allergens are labelled upon receipt and documented on daily operational paperwork.
There is a documented rework policy on record. Rework can only be used in the same product code.
Allergen validation is conducted annually on all lines using 3M swabs. Swab kits were checked for expiry dates, and all were BB 2023. Allergens are tested 1 per year depending upon production volume. The most recent test was for milk which was 6.4 ppm from a pre-clean swab on 16th May 2022 and from the post clean swab was <2.5 ppm.

The production schedules are designed where possible so non allergen products are produced in beginning of the week. Reviewed allergen changes over records for May and June 2021. There are documented checklists on file for each item.
Annual GMP training covers allergens. Employee training records on file for 2022. As part of GMP training, employees, visitors, and contractors are restricted from bringing any food in production area.
Quality Assurance verifies and documents on the pre- operational checklist documentation that appropriate clean up occurred and documentation, including labels are accurate prior to production.
Employees interviewed demonstrated understanding of allergens, and mitigation methods. Ingredients in the warehouse are bore allergen stickers. All allergen utensils are color coded and color charts for allergens was observed in each of the blending room. Controls for batching and mixing were sampled during the on-site traceability exercise.

5.4 Product authenticity, claims and chain of custody

Sources of information on historical and developing threats are identified as email subscriptions and various websites including FDA alerts and horizon scan, through Director of QA.
A documented QL10.2 Vulnerability assessment was in place as last reviewed on 2022-08-14 for all raw materials and the packaging have been included in the relevant hazard analysis date of each customer product. The methods to validate the customer claim is done by the Food Safety Team. Claims are made by customer labels, however, company ensures process controls and handling comply with customer label requirements.
A documented vulnerability assessment for all raw materials and the packaging types (liners and bags).
There is a color-coded likelihood of occurrence and likelihood of detection chart to determine the potential risk categories for raw materials. The assessment must be reviewed annually or every time a new ingredient is introduced or there is a change to vendor.
Claims are verified on pallet tags and MMR sheets where the claims for each product running that day are communicated to relevant staff. In addition, the company conducts 3rd party audits to ensure internal process controls have been implemented.
Customer claims are as follows and are validated through 3rd party certification audits:
Organic – OTCO certificate expires: 2023-01-25.

Kosher – Kosher CRC Certificate expires: 2022-12-31
Gluten Free – GFCO (product specific but claim not currently used)

5.5 Product packaging

There is a documented Approval of Raw Materials/Packaging and Supplier program.
Majority of packaging is sourced by the customer. All packaging is inspected and must be accompanied with a COC using the inspection form Document PCSPEC-006. A record was sampled for pouches, and confirms that there is a COC, letter of guarantee, all artwork and allergens are visually inspected for claims, and approved by QA on 2021-03-15. A Trailer Receiving Inspection Form for metalized pouch received was completed on 2021-06-12, a COC from supplier states materials conform to agreed standards is dated 2021-6-19.
Packaging specifications from the customer are also provided to Fortress. A Customer supplied specification polypropylene pouch. Attributes include visual inspection for dimensions, appearance, and material is FDA Poly Propylene approved on 2020-12-16.
Reviewed records from several packaging suppliers and verified CFR guidelines for direct food contact / food grade.
Letters of Guarantee are on file that all packaging material is food grade and fit for its use (shelf stable dry product).
All obsolete packaging material is labelled and segregated. There is a procedure for disposal of obsolete material (2020-03-13). During the audit, there was no obsolete material on site. A compacter is on site which is a sealed secure unit.

5.5.2: N/A- No product liners or bags used in the site

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Methods for sampling and testing product have been implemented from receiving, blending, packing, and prior shipping. At receiving, sampling, and COA are reviewed. During blending, formulation and MMR sheets are reviewed and approved by QA. Records of both were sampled during the on-site traceability. After packing, finished product is tested based on customer specifications. The typical tests include microbial testing for Salmonella and Listeria through accredited 3rd party Lab. Records of finished product testing were sampled during the traceability exercise.

At shipping, a procedure is in place to verify lot code information matches pick ticket. The customers conduct validation studies on their products. The QA performs a verification of the shelf life on retained samples.

5.6.2 Laboratory testing

A QA laboratory is located in a separate room from all production areas. The lab only conducts sieve size testing, retention sample collection, ATP swabs and allergen verification testing. The lab does not generate any lab waste. There are two QA tech who conducts line checks. The lab is restricted to designated personnel. All other chemical and microbiological testing is done by a 3rd Party accredited ISO/IEC 17025 Lab. The certificate was provided at the time of the audit and observed current. The results are reviewed and trended by Director of QA or QA Manager.

5.7 Product release
Positive release programs have been implemented for all incoming materials and finished product, and is outlined in Hold & Release Procedure, last revised on 2021-03-31. All incoming ingredients are accompanied by COA's, and the ingredients are automatically held in the company's electronic inventory management system pending any further quality testing and guidance from the customer. All products on QA hold, have an Orange Hold placard. Red placards are used for food safety risk quarantines and green is for approved. Quality have the authority to release product and approve all holds. All finished goods are stickered with HOLD placards and automatically held in the company's electronic inventory management system and only released upon customer approval to prevent the release of unsafe products. Positive release records and COA were verified during the traceability.
5.8 Pet Food
5.8: N/A- No pet food is produced at this facility

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.3	No claims made on the labels.
5.2.5	No cooking instructions on the labels.
5.5.2	No product liners or bags used in the site.
5.8	No pet food is produced at this facility.

6. Process control

6.1 Control of operations

Manufacturing Process Control Procedure dated 2022-06-28 is used to ensure operational variations are controlled. QA provides MMR sheets specific to the product being produced based on the formulation sheet. Formula Sheet was sampled and lists the quantity, component, count, and scoop, and pre-printed carton to be used. There are documented procedures and work instructions on record. All items produced require a formula sheet with process steps laid out verifying ingredients, weights, and labelling instructions. Only the trained operators are authorized to make changes to mixing procedures or labelling change. All changes need to be verified by QA and Supervisor.

Claims for the product were Organic and Kosher. During pre-weighing, the quantity and component for each are documented. Work instructions are included, and blend times and mix rates are provided. Labelling and verification of lot code legibility is done alongside weight checks. X-ray and metal detectors are validated daily by passing three test pieces through and using the smallest detectable size to conduct verifications each day. Details of the monitoring are noted in section 2 as part of the CCP monitoring procedures.
There are documented procedures for holding non-conforming product. Pre-op inspection checklist sheet is completed prior to production to verify clean-up from last product run.
Auditor observed pre-weighing, blending operations, and verifications of x-ray and metal detectors. Operators demonstrated labelling and weight verifications checks, and reviewed work instructions provided.

6.1.4: N/A- There are no in-line monitoring devices.

6.2 Labelling and pack control

There is a Packaging and Label Verification Procedure to ensure labels and correct packaging is used have been implemented. Packaging and label verifications are conducted prior to packing and recorded on the Packaging and Batch Record and the Master Manufacturing Records. During pre-operational checks, and after changeovers the production team verifies that the appropriate labels and packaging is used. Label checks are done at the start of packing, every 30 minutes of production, and after changeovers. Labels are also reconciled on the MMR sheets. Unused labels are returned, and records are verified by QA. A picture of the label is also provided to production as a point of cross reference.
Records were verified during the traceability exercise and observed for the hand packing operations during the audit. No changeovers were occurred during the audit. During the audit interviewed the operators and QA who were well verse with the process and capable of performing the procedure.

6.2.4: N/A- There is no online verification equipment

6.3 Quantity, weight, volume and number control

Only weight declarations are made on packaging materials. Methods to verify the weight is accurate is done during packing and recorded on the Master Manufacturing Packaging and Batch Record form. The product name, weight checks, and verification signoffs are done by QA. Weights are taken at the beginning, middle and end of bulk lots, or every 30 minutes for non-bulk items. Records were verified during the traceability exercise and observed during the audit.

NA 6.3.2 All product is sold by weight. .

6.3.3 The site does not have any checkweighers.

6.4 Calibration and control of measuring and monitoring devices

There is a documented Equipment Calibration Program dated 2020-04-02. There is updated documented list of all the equipment to be calibrated (2022-05-09), which includes scales, metal detectors, X- Ray machines, certified weights.
All scales are verified daily using NIST certified weights. All scales are calibrated quarterly or when required by accredited 3rd party contractor (latest-2022-08-12).
Metal Detectors x 5 last conducted on 2022-06-30, and X- Ray machines x 2 last conducted 2022-06-22 are calibrated annually by 3rd party accredited contractor.
A documented equipment list is on record. The list includes the location and identification number for each item. There is a documented calibration program on record. The frequency of calibration is established by the HACCP risk assessment. NIST standards are used for measuring equipment.

Corrective Action parameters are in place and documented in the procedure for failures. Product is placed on hold from the last good check and quality assurance investigates.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
6.1.4	There are no in-line monitoring devices.
6.2.4	There is no online verification equipment.
6.3.2	All product is sold by weight.
6.3.3	The site does not have any checkweighers.

7. Personnel

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

There is a documented Training Program (2022-03-11), describes that all staff will be annually trained to have proper skills to maintain food safe work environment. All employees are trained at hire and annually thereafter in the following topics using INTELLECT software. Training includes GMPs, Sanitation, Food Safety, Food Security, Regulatory Compliance, Allergen awareness, Pest sighting awareness, Food Defense/Food Fraud, Operations Practices, Glass & Plastic control, Confidential Reporting, Food Safety Culture and Label verification. All training is in English and Spanish. The training program also includes relevant contractors such as Pest Control. There is an employee training matrix for 2022, built in the INTELLECT program.
All visitors and contractors receive GMP awareness training at the front desk prior to entry into the plant. Contractors receive GMP and Safety training when they complete the Contractor Agreement.

Training Session Log Sheet includes duration of training, as well as employee signature, date, and trainer. Reviewed training records for:

- EE – Line Lead Operator – GMP refresher 29th July 2022 and 18th Oct 2021 for job specific
- CS – Quality Technician – GMP refresher 27th July 2022 and 14th Dec 2021 for job specific
- VJ – Production Supervisor - GMP refresher 29th July 2022 and 22nd Oct 2021 for job specific

Employees receive quizzes following training; effectiveness of training is also monitored via internal audits and observations. Refresher training is provided as required.

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

Personnel GMP Program (2021-04-09), describe the requirements for maintaining an appropriate level of hygiene. The site restricts jewelry, earrings, watches, rings, and necklaces. Plain wedding bands may be worn if no stones.
The policy restricts fingernail polish and false fingernails, excessive perfume, and aftershave. Personal medications are required to be stored in personal lockers and not taken into production or storage areas. All employees must wash their hands before entering production areas. There are signs at the wash stations and in the rest rooms. The procedure states that all employees must wash their hands after visiting restroom, breakroom, or any time their hands are soiled or contaminated.
Eating and drinking is not allowed in the production and storage area. Smoking is only allowed outside the building in a designated area.
Visitors and Contractors report to the main office entrance and are instructed in the site's GMPs prior to entering the production or storage areas. There is a Visitor Personnel Practices Policy describing requirements. All visitors and contractors are escorted in the site by authorized staff.
The facility issues blue metal detectable bandages to the personnel, as necessary. There is a log for all bandages issued along with the date of issue. There were records of the testing on site using the metal detection devices, the latest are dated 2021-08-02; lot # 225L19.

7.3 Medical screening

Disease Control Procedure 6th Dec 2019 and Health Status Reporting Program (2020-06-23) on record identifies the procedures in place to ensure that personnel are not a source of transmission of food borne diseases. Illnesses are to be reported to the employee's supervisor. Any employee has any symptoms of sickness or high fever will be sent to HR department for final decision. Reportable health conditions are contagious diseases, boils, sores, other bacterial infections.

The visitor sign in log and GMP review form mandates reporting requirements for persons knowingly infected or potentially infected with a transmittable disease.

7.4 Protective clothing: employees or visitors to production areas

Outer Garment Policy (2021-04-09) describes that staff must have appropriate attire before they start their shift. The facility is primarily an enclosed process and employees are provided uniforms with snaps and no pockets above the waist. All employees are provided clean uniform or smocks, protective head cover and beard snoods, and ear plugs, if required.
There is a contracted laundry service provider for the uniforms. Letter dated 2019-03-14 from contracted laundry describes the commercial laundering process in terms of chemicals used pH changes, duration, and temperatures. The company is 3rd party audited which states it is in compliance with GFSI certifications, until 31st Dec 2023. The laundry agreement states they will provide clean clothes with no physical or chemical residues or off-odors, rinsed to remove chemicals; they will keep clean and dirty uniforms segregated during delivery process, and will adhere to site's GMP and security requirements.

Personnel observe / inspect the uniforms upon return from the laundry for cleanliness. Soiled laundry is separated from the clean uniforms and collected in soiled cabinets.
Visitors are required to sign agreement to the GMP policy; they are instructed on the hygiene requirements by the management prior to entering the facility. Contractors that visit the site with any regular frequency is provided a Contractor GMP confidential Agreement for review and sign the agreement.
The policy outlines disposable blue gloves are issued by the company and meet company requirements.

N/A 7.4.6 - There are no items of personal protective clothing that are not suitable for laundering provided to employees

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
7.4.6	There are no items of personal protective clothing that are not suitable for laundering provided to employees.

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

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

8.1-8.7	N/A – No high-risk, high care, or ambient high care areas

9 - Traded Products
9.1 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.2 Specifications
Not applicable
9.3 Product inspection and laboratory testing
Not applicable
9.4 Product legality
Not applicable
9.5 Traceability
Not applicable

Module 11: Meat supply chain assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	
11.3 Raw material receipt and inspection	
Click or tap here to enter text.	

11.4 Management of cross-contamination between species
Click or tap here to enter text.
11.5 Product testing
Click or tap here to enter text.
11.6 Training
Click or tap here to enter text.

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018			
Clause	Module item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice		

	(GMP) requirements of 21 CFR 117.		
13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
13.1.7	All identified known or reasonably foreseeable		

	hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		
13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert,		

	repurpose) of recalled product		
13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRCGS section 2.10.		
13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRCGS sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).		
13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13.1.13	The PCQI (or authorized designee)		

	reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		

13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
13.1.16	Devices used to verify preventive controls must be calibrated.		
13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
13.1.18	All records required by 21 CFR § 117 must include:		

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

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

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

	mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum): • Scale and severity of threat if a contaminant is		

	added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.		
13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.		
13.3.5	Written monitoring procedures shall be		

	established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.		
13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		
13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies.		

	Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities		
13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility		

	becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		
13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		
13.3.11	All documents and records relating to the food defense plan (i.e., all records required by		

	21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary		

	Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
13.4.4	Contracts with loaders shall specify that the		

	loader is responsible for following sanitary specifications provided by shipper.		
13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most		

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

13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job		
13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
13.5.3	One or more supervisors or individuals responsible		

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

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

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

	Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.		
13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.		
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.		

13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: • Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are		

	samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).		
13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive		

	surfaces and the surrounding area to determine the extent of contamination • Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate • Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		

14.1 Additional Specifier requirements
14.1 Traceability
Click or tap here to enter text.
14.2 Environmental Monitoring

Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.