Audit Report

Global Standard Food Safety Issue 8

1. Audit Summary			
Company name	Armada Nutrition LLC	Site Code	1874819
Site name	Armada Nutrition LLC		
Scope of audit	Blending powdered or granulated nutrients (protein, vitamins), packing into plastic containers or pouches. Outsourced processing for blending and packing is utilized.		
Exclusions from scope	None		
Justification for exclusion	None		
Audit Start Date	2022-06-21	Audit Finish Date	2022-06-23
Re-audit due date	2023-07-11	Head Office	No

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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	2021-06-22	
Certificate issue date	2022-07-14		Certificate expiry date	2023-08-22	
Number of non-conformities			Fundamental	0	
			Critical	0	
			Major	0	

2. Audit Results

	Minor	2

3. Company Details

Address	4637 Port Royal Spring Hill, TN 37174		
Country	USA	Site Telephone Number	931-451-7808
Commercial representative Name	Charles Andrews	Email	Charles.amndrews@armadanutrition.com
Technical representative Name	Moriah Seibert	Email	Moriah.seibert@armadanutrition.com

4. Company Profile

Plant size (metres square)	>25K sq.m s	No. of employees	51-500	No. of HACCP plans	1-3

Shift Pattern	2 shifts – A shift-11-hour shifts, 4 days/week M-TH 6 am -4:30 pm, B shift 7:30 pm-6:00 am 2 shifts – C& D shift- 12 hours, 3 days/week F-Sat-Sun 5 am-5 pm, 5 pm-5 am.
Subcontracted processes	Yes
Other certificates held	Kosher, Halal, Gluten Free, Non-GMO, and Organic
Regions exported to	None
Company registration number	FDA Registration #:xxx2864, Health Canada Foreign Site Reference #: 5000410, Tennessee Department of Agriculture #: NFRY-A9FKD8EU FEI #:300293075
Major changes since last BRCGS audit	none

4. Company Profile

The site was originally built in 1999 and was originally an automotive warehouse. In 2014, Capstone Nutrition leased this site. Armada Nutrition purchased the assets in July 2016 and started its operations. Armada Nutrition is a contract manufacturer for high quality nutritional powders dedicated to providing customers with innovative formulations and turnkey products. The facility has approximately 445 employees currently with approximately 230 working on the first shift. 2 shifts – 11-hour shifts, 4 days/week M-TH 5 am -4:30 pm, 6 pm-5:30 am 2 shifts – 12 hours, 3 days/week F-SU 5 am-5 pm, 5 pm-5 am. Total square footage of this facility to carry out manufacturing and warehousing is 30,769 sq. meters. Primary operations have been Measuring and Blending, with secondary operations in Powder Fill and Capsule Fill at this facility. The site is a contract manufacturer, the site does not export any product. Products are manufactured for retail sale. A second manufacturing site is planned in Utah.

5. Product Characteristics

Product categories	15 - Dried food and ingredients
Finished product safety rationale	Finished product and ingredients have a water activity of less than 0.7, products stable at ambient temperatures.

High care	No	High risk	No	Ambient high care	No

Justification for area	Low Risk-The low water activity of ingredients and finished product will not support the growth or survival of pathogens. Appendix 2 of the BRC Food Safety Standard Guidelines was used to define production risks.
Allergens handled on site	Cereals containing gluten Crustaceans Egg Fish Peanuts Nuts Soya Milk Sulphur dioxide and Sulphites
Product claims made e.g. IP, organic	Claims made by customers: Certified Vegan, Keto Certified, Non-GMO, Organic. Gluten Free, Halal, Kosher, Organic, Informed Choice/Informed Sport, Certified for Sport.
Product recalls in last 12 Months	No
Products in production at the time of the audit	Protein powders in 2 pound containers, pet bone broth in flexible 146g packs, Pre-workout drink mix in jars

6. Audit Duration Details			
Total audit duration	24 man hours	Duration of production facility inspection	11 man hours
Reasons for deviation from typical or expected audit duration	none		
Next audit type selected	Announced		

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1	2022-06-21	08:00	16:00
1	2022-06-22	20:00	22:00
2	2022-06-22	08:00	16:30
3	2022-06-23	08:00	14:00

Audit Team	Auditor number	Name	Role
Lead Auditor	21358	Colette Thiel	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
Brent Laffey, President				x
Charlie Andrews, General Manager	X			X
Moriah Seibert, Director of Quality	X	x	x	X
Tina Spelta, Director, Human Resources	X			x

James Havican, Director of Quality Control Laboratory	X			X
Scott Tate / Production Manager-Primary	X	x		X
Ron Wasko, Maintenance Manager	X			X
Jordon Skelton Operations Analyst	X			x
Jackie Lotz, Director of Commercial Development				x
Tony Word, Senior Financial Director				x

GFSI Post Farm Gate Audit History		
Date	Scheme/Standard	Announced/Unannounced
2021-06-22	BRC Food Standard Ed 8	Announced

Document control			
CB Report number	ID:8705.		
Template Name	F834 Food Safety Audit Report Template v11		
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	4.9.3.2	The records for the weekly glass inspections of the production area could not be located during the audit.	All inspection reports are being scanned into Quality immediately after completion versus previously being kept only in a binder in the production office. Attached you'll find the inspections that have been completed post audit.	Audits will be conducted electronically through Redzone to ensure proper documentation. Redzone audits will be live and replacing paper inspections by 8/1/22	The binder was misplaced prior to the start of the audit. Since the original records had not been scanned in, electronic records could not be produced.	2022-07-12	C. Thiel
2	7.1.1	During the second shift plant tour, at Line 4, several employees were observed inserting their fingers into the product jars.	Annual facility GMP training was conducted 7/2/22 & 7/5/22 for all 4 shifts with a heavy focus on food contact surfaces and proper bottle handling. Training records are attached.	Training and ongoing process verification will be conducted via the internal audit program. Employees not following the process will receive coaching and/or corrective action if observed to be not following the established procedure.	Accountability to follow facility GMP procedures was not in place.	2022-07-12	C. Thiel

Minor							

Comments on non-conformities
NIL

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

A Food Safety and Quality Commitment Policy has been developed and has been endorsed by the Company President, Quality Systems Manager, Director of Quality, Plant Manager, Director of Finance and Human resources (2022-1-11). It is displayed at the entrance and document system. The policy outlines the commitment management has made to follow and maintain the principles of HACCP and foster an environment of continual improvement through training and reviews (posted throughout the site in English).

Food Safety Culture Plan: The Plan has strategic initiatives to enhance quality culture (EX: non-conformance Charter-an in-depth look at the non-conformance system to seek improvements). The launch of the Red Zone data collection system is another quality culture project.

Management Review is conducted quarterly (2022-01-06). The meeting. was attended by President, General Manager, Director of Supply Chain, Human Resources Director, Maintenance Manager, Primary Production Manager, Director of Quality and Senior Director of Finance. Old business, non conformances from internal, second and third-party audits, complaints and, Key Performance Indicators. The main objectives are: [redacted]

Monthly Management communication for Quality and Operations Summit meetings (2021-06-03) HACCP and Food Safety meeting is the 16th of each month

Monthly HACCP/Food Safety Team meetings (May minutes were reviewed) Audit results, Customer complaints and sanitation issues were reviewed

Weekly Vital Signs Meeting issues that surface within the production week

Daily Vital Signs Meeting -issues that surface within the production day

The facility is kept informed of any changes in scientific and technical knowledge through contact with FDA.gov, Food Safety magazine, Food Navigator, Customer product information etc.

Confidential Reporting System: There is a designated toll-free number (in English or Spanish) that connects to the Human Resources Department.

A copy of BRC standard was available electronically and hard copy.

The audit was completed within the audit window.

The 5 non-conformances from the previous audit were effectively closed (4.9.1.1, 4.9.6.2, 4.15.1, 7.1.1 and 7.4.5)

1.2 Organisational structure, responsibilities, and management authority

There is an Organizational Chart on file (dated June 2022). President is at the top of the Organizational Chart, with Vice President and Senior Director of Finance and 9 other executive team members reporting to him.
The Quality Department manages food safety, quality, and regulatory aspects of daily plant operations. Job descriptions for Director of Quality, Senior Production Manager and Quality Assurance Manager are on file.

In the case of absences, there are designated back-up personnel (this is defined on the Organizational Chart-the person listed below is a back-up). The Director of Quality is backed up by the Quality Systems Manager. The General Manager is backed up by Quality Systems Manager and Production Manager.).

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

2 The Food Safety Plan – HACCP

HACCP team: The facility has a documented HACCP team (the Team Leader is the Food Safety Team Coordinator, PCQI training, 2022-01-14). Other Team Members include Operations, Maintenance, Sanitation, Warehouse, Quality Systems, Training, Regulatory and Quality There is one food Safety/HACCP Plan at this site.

The facility has a Pre-requisite Program with 7 elements: Receiving, Shipping, Pest Control, Sanitation, Maintenance, Training, Calibrations, Allergens, Calibrations, and Foreign Material.
The HACCP plan was reviewed 2021-12-06.

Products: The products are protein powders and functional foods. The products are shipped and stored at ambient temperatures. The intended consumers are the public.

Process flow steps: The flow chart of the process from receiving, testing, Blending, Testing, Bottling, Induction Sealing, Labelling, Packaging, and shipping. There are four CCPs identified on the process flow chart. Rework is performed at this site. The process flow chart was reviewed 2021-11

Hazard analysis and Hazards:

Chemical-ingredient potency, pesticide residue, aflatoxins, heavy metals, allergens and radiological,

Physical-foreign materials wood, metal plastic and glass

Microbiological -Coliforms, E. coli and Salmonella.

Fraud and malicious hazards were addressed as part of a risk assessment conducted 2021-12-10.

CCPs and critical limits: (The HACCP Decision Tree was used to determine the CCPs).

There are four CCPs:
1.) Screens
2.) X-ray/metal detection
3.) Induction
4.) Labelling
Corrective actions are documented when the critical limit has been exceeded on critical Limits. There is a Deviation Log to track Food Safety/HACCP issues.

Records for all Critical Control Points were reviewed for 2021-07-07, 2022-04-05 and 2022-06-03.

Validation methods of CCPs CCP #1 and CCP #2 the FDA555.425. Product trails dated for seal, burn and Induction: Seal Manufacturing Recommendation.
4

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

3. Food safety and quality management system

3.1 Food safety and quality manual

The Food Safety System manual is maintained in hard copy and in electronic version (on a password protected server, backed up with an offsite server in Illinois). The hard copy is available upon request.
The manual consists of tables relating the sections in the BRC Guidance. Each section of the BRC Standard is addressed.
The program is communicated to the staff a minimum of annually during the annual review. The Manual is in English (all employees speak English).

3.2 Document Control

The facility has a document control register for corporate policies forms and SOPS used at the site. The Master List includes the revision history, effective dates, and next review date. The Department head and Quality Assurance review and approve all food safety and quality related documents. All changes in documents are recorded in a document change log along with reason and date of change. Documents are reviewed every 2 years.

3.3 Record completion and maintenance

There is currently a conversion taking place to move recordkeeping into the Red Zone document system. (It is in the early phases). Usernames and passwords are used to access the records.

There are sign offs required at the bottom of each form by the Supervisor. Records were retrieved from 2021-07-06, 2021-10-05, 2022-01-05 and 2022-04-05 for sanitation, pre-operative inspections, daily production records (line 3) and receiving records. These records were gathered in a reasonable time, and were complete, neat, and orderly. Records are reviewed and initialed by the Quality Assurance Technician or Production ManagerRecords are maintained in a legible manner. Records are maintained for five years (maximum shelf life is 3 years).

3.4 Internal audits

Internal audit Program scope and schedule:

The company has an “Internal Audit” procedure that covers all elements of the HACCP and Food Safety programs including the prerequisite programs. The audits are tracked on the “Audit Schedule 2022”. The internal audit is conducted quarterly (EX: On 2022-04-25 the Management systems portion of the BRC audit was conducted. There were 2 non-conformances, 4.11 and 5.3. The non-conformances were closed out in a timely manner; 4.11.1 and 5.3 on 2022-06-01). There is also an additional audit system based on 21 CFR 111, for Dietary Supplements (this is certified through a third party audit).

Auditor competence and training:

The Director of Quality performs audits (Trained through American Society for Quality-CQA 2012). Internal audit refresher training was conducted August 2020 for 10 individuals who perform audits.

Site Inspections**:**

The program includes monthly Good Manufacturing Practices inspections for the interior and exterior of the site. Records for January – March 2022 were reviewed. (EX: On 2021-09-23, residue build up on chains was addressed the same day. On 2022-03-13, cardboard was sitting on the dock- and was addressed the same day).

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

A documented supplier approval program (Supplier/Manufacturer Approval, Monitoring and Disqualification) is in place which requires letter of guarantee, allergen statement, completed questionnaire, specifications Etc. (EX: the manufacturer of mushroom powder was examined, they are FSSC 2200 certified with a current certificate, and other required documents on file). The policy requires a new questionnaire every 3 years. A current list of all approved suppliers was examined, and the supporting documents were organized by supplier and ingredient. The site has a data base that contains all information to approve a supplier. The DocuWare program tracks the expiration of documents, program is reviewed Corporate Regulatory Compliance.

Depending on the risk assessment result, incoming material may be tested, require a Certificate or Analysis, or be inspected. The program is reviewed annually
No brokers are used to purchase materials at this site.
.
In an emergency, supplier approval is conducted with the same requirements, but with expedited testing. Questionnaires are reviewed every three years with an ongoing status performance reviewed conducted by Regulatory Dept.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

The facility has performed a risk assessment for raw materials to identify potential risks to product safety, legality, and quality. The risk assessment is based on likelihood of occurrence and severity. Based on the ranking in the risk assessment the material may be tested, inspected, or use a COA (EX: On 2022-06-17 sucralose was received with a Certificate of Analysis. Flexible film packaging received on 2022-06-22 on the second day of the audit, with a Certificate of Conformance is sampled and verified by the Quality Assurance Technician). Receiving operators check the incoming materials for damage, seals, and Certificates of Analysis. The Receiving Operator inspects and records trailer condition; this inspection procedure was observed and explained by the operator).

3.5.3 Management of suppliers of services

Contracts and agreements were available for Uniforms, Pest Control and Waste Management. Reviewed the agreements which were current with open ended contracts. Uniform contracts are signed (2021-08-09). Audit of the uniform supplier was conducted 2020-06-05 (audit score was 100%).

3.5.4 Management of Out-sourced processing

The site uses out-sourced processing for blending and packaging. The contracted site is used for overflow production that can't be fitted into the production schedule in time to meet customer requirements. The contracted site is Dietary Supplement certified on 2021-05-26. The Quality Assurance Director conducted in-house audit and watched the first production run. The site has a documented HACCP program as noted in the Dietary Supplement. The products are returned, and testing is conducted beginning, middle and end of the production runs (using the ISO 17025 laboratory at this site).

3.6 Specifications

There are specifications on file for raw and packaging ingredients (EX.: cherry flavor specification was checked, 2021-07-08), packaging materials (EX.: the plastic scoop specification was checked, 2009-04-16), Specifications are stored in DocuWare. Each incoming raw material is tested before it is released to production.

The facility has documented finished product specifications; (EX: Pineapple pre-workout drink, reviewed 2022-04-26). Specifications are reviewed as needed, or annually. The site does not produce branded products.

3.7 Corrective and preventive actions

Corrective actions are documented from Internal audits and monthly self-inspections on the Smartsheet Non-conformance Records. Corrective actions are required to be completed within 30 days. There is a weekly Corrective and Preventive Action Meeting used for the documentation and correction of non-conformances; Correction, Root Cause, Verification, Finding, and e-mail with within the data base.

3.8 Control of non-conforming product

The plant follows an SOP for the Control of non-conforming Product. that controls the non-conforming ingredients, packaging material and finished product (TAQA.325). Products are placed on physical hold with a hold placard placed on the product. Senior Management (Production Management, Quality Control

Management, Warehouse Management, and Inventory Control Management) may take items off Hold status. Hold log (Smart Sheet data base) was reviewed (EX: Chocolate protein powder was on Hold for possible metal shavings,134 bags, lot #693865. Root cause was determined to be rubbing of the auger, there was a broken screw). The Chocolate Protein Powder was seen in the warehouse, it had been released from hold and was in the racks).

3.9 Traceability

Trace System:

Trace exercises are performed at least once per year (this includes food contact packaging, ingredients, and finished goods). The Product Recall Process is followed. The trace is performed semi-annually using the JD Edwards based inventory management system.

Client traces conducted, timings and mass balance across product range
Trace exercises of a trace were reviewed: on 2021-06-23, Grape Flavor, lot # 202012230037 (240 KG) was traced. 3941 bottles of blue raspberry functional food powder were produced, and all product was sent to one customer. 3.75 KG of Grape Flavor is still in the warehouse. Product was traced with 100% recovery in 1 hour and 15 minutes, from receipt to production and warehousing. No rework was used in this production.

Trace exercise conducted during the audit
A trace exercise was performed during the audit. A trace of 13 cc product scoops (item# 71969) which was received on 2021-06-16 lot# 20210616002 (10,200 scoops). This scoop was used in 2 products, manufactured on 2021-08-02 (used 9975 scoops). 225 are left in stock. Finished products made with these scoops were traced through the production process, to the distribution centers that they were shipped to.

Recovery was 100% in 2 hours.

3.10 Complaint-handling

The facility has a documented Customer Complaint Handling Policy. The Quality Staff records the complaint information, into the non-conformance electronic tracking spreadsheet. The Non-Conformance form is used to record customer complaint issues. Complaints were reviewed, the main complaint [redacted]

3.11 Management of incidents, product withdrawal and product recall

There have been no withdrawals or recalls in the last 12 months.

The “Product Recall Process” defines the responsibilities and procedures for Recalls and Withdrawals. The certification body, SAI Global, must be contacted within 3 business days. There is a key contact list. Trace recalls are performed (last mock recall was performed on 2021-06-23).

The “Crisis Management Policy and Crisis Management Effectiveness Check define the emergency procedures at this site. There is aCrisis Management Team, with contact information (the President, plus the HACCP/Food Safety Team). The Crisis Management Team and their contact information and responsibilities were available.

There is an annual test of the Crisis Management (this year a bad storm in the middle of the night was the scenario used). The EHS Manager is the point of contact for emergency services, and Director of Quality and General Manager will assess the food safety risks.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.9.4	The facility does not conduct rework

4. Site standards

4.1 External standards

The site is in a rural area with a residence on one side and vacant land on the other two sides. The site has paved areas around part of the building and well-tended grass on the other sides. There is a paved perimeter around the building. The building exterior is very well-maintained. The inspection of the exterior grounds during the audit verified that there were no observations of conditions that could cause contamination to the facility.

No standing water or debris seen during the on-site assessment.

4.2 Site security and food defence

A comprehensive Security Assessment (FDA Food Defense Plan Builder) was conducted and documented in 2021-06-10. They also have a current Security Policy in place. The FDA updates the template as new threats and risks emerge. Ongoing review is conducted quarterly.
The plan has a raw materials assessment (fraud and intentional adulterations) for raw materials at risk. Botanicals are a concern and testing is performed at the site to verify authenticity. Materials are sent to outside lab for HPLC identification. The results are used as a reference standard.
The site has armed security for the after house on the weekends.
The main entrance is kept locked and is access is controlled by a key card access, which all employees must use. Contractors and visitors are greeted by a receptionist and must sign in, review the Visitor Policy, and show ID prior to entry. Visitors are always accompanied by an employee. There is a fence around the property, doors are kept locked and other security measures are in place.
Delivery drivers wait near their trailers while being loaded or unloaded and do not have direct access to the production areas.

The site is registered with the FDA for the Bioterrorism Act xxx 2864

Employees receive Food Defense Training as part of the annual refresher training.

4.3 Layout, product flow and segregation

There are site maps (dated November 2021) that include production zones, storage zones, security and food risk, ventilation and air movement, emergency exits and routes, GMP zones, water and sewer distribution, staff facilities, personnel movement, trash, and production set up for each product line.
There is sufficient working space and storage in the facility to enable all operations to be carried out properly under safe hygienic conditions.

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

The external and walls are poured concrete. The internal walls in processing are sanitary, washable sheeting material covered with epoxy. The floors are cement. The ceilings are open beam metal ceiling. The lights in processing and storage areas are shielded. The drains have metal grates.
A suspended ceiling is present in the small pack room. The void over the dropped ceiling is inspected. There are no windows that can be opened in process or warehouse. The docks levelers were observed properly sealed against pests and well maintained. All external doors are self-closing and well-sealed against pests. Doors were observed to be in a good condition and easy to clean. Incoming air filters are maintained and exchange by the maintenance department when required monthly and daily for the GMP areas.

4.5 Utilities – water, ice, air, and other gases

The potable water for hand-washing and cleaning is supplied by the City of Spring Hill, TN. No water is used in processing. The site tests the municipal water in-house for coliforms monthly (no issues were noted).
Water testing (Heavy metals) is completed every year (2022-06-22). The last water test results were reviewed. The accredited laboratory is certified (against 17025:2005; the certificate is valid until 2024-01-31. No steam directly contacting food or food contact surfaces is used at this site. The last back flow test was completed on 2022-01-24 by approved service supplier.
Coliforms are tested in the municipal water at the ISO 17025 approved laboratory on-site (results for 2022, January through May were reviewed, and all samples were within specification).
Compressed air is used in the optical and laser sorters. Compressed air filters are 0.1 micron at point of use. Tests were conducted for Total Plate Count and) and yeast and mold (records for 2022, January through May were reviewed all samples were within specification). The facility has dedicated air system filters that are changed or checked daily for the rooms. The general air system filters are changed monthly (8.0 micron filters).

4.6 Equipment

All food contact surfaces are constructed of food grade stainless steel and food grade plastics. All equipment was in good working condition, appearing to meet all operational and regulatory requirements. No new equipment has been commissioned in the last 12 months.

4.7 Maintenance

There is a preventive maintenance program (E-Maint) that undertakes regular checks and repairs, per the Preventive Maintenance and Maintenance Program (rev 2.3). Equipment is included, following the manufacturer's recommended inspection schedule [redacted]. Preventive Maintenance checks are up to date.
All maintenance activities were recorded on Work orders. The Preventive Maintenance sheet was completed to verify, parts, tools and lubricants were removed following task completion A full clean of the production equipment is performed after repairs, by production employees.

No temporary repairs were seen in the plant.

Only food grade lubricants are used. The allergen status of all lubricants is on file (EX: Food Grade Gear Oil and Cinco Super Lube, these are all synthetic lubricants)

There is a monthly Good Manufacturing Practices audit and pre-operative inspections to check on the condition of equipment and the building exterior and interior. The maintenance shop was maintained in good condition.

4.8 Staff facilities

The separate staff support areas are clean, large enough in size for the number of employees and separated from the processing areas. The break room was clean, with microwave ovens, a sink (hands-free) with warm water, a refrigerator, tables, and chairs, plenty of light and ventilation in the lunchroom. The rest rooms were clean, with warm water, soap, paper towels, waste bins and signs to remind employees to wash their hands (the rest rooms open into a hallway). There are lockers are provided for employees' personal items, and for changing uniforms. Separate uniform storage is provided.

Smoking is only allowed in designated smoking area (100 feet from the employee entrance). There is no catering service at this site.

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

4.9.1 Chemical control

An approved list of chemicals was reviewed. It includes cleaning chemicals, lab chemicals and maintenance chemicals. SDS were available for all items [redacted]. All chemicals were labelled and stored in the original container. There are no strongly scented materials used in the plant. Reviewed the approved chemical list each chemical goes through an approval prior to introduction to the facility

4.9.2 Metal control

Metal detection, X-ray and magnets are used to detect any metal in the finished products. Metal detection is monitored approximately every two hours by trained employees. Production Records were reviewed in 3.3 and were complete.

The policy for controlling knives limits cutting tools to company provided tools. Knives are used at the bag dumping station; these are checked daily and identified with numbers on them (this was seen on the second day of the audit during the afternoon plant tour). Knives are checked in and out daily with an assign number controlled by Quality Assurance. No snap-off knives are used, knives are inspected.

4.9.3 Glass, brittle plastic, ceramics, and similar materials

The Glass Policy Brittle Plastics Policy (version 3.2) is on file. There is a glass/plastic register. The Policy describes product quarantine and glass clean up protocols. The site conducts weekly inspections of production area). The site conducts monthly inspections (warehouse area records of the last inspections were reviewed, 2022-03-30, 2022-05-12 and 2022-06-15.

In the event of a breakage a determination would be made as to whether product was affected, and a clean-up of the area would be initiated. There have been no breakage incidents in the last 12 months

4.9.3.2- Minor non-conformance-The records for the weekly glass inspections of the production area could not be located during the audit.

4.9.4 Products packed into glass or other brittle containers

No products are packed into glass or brittle containers at this site.

4.9.5 Wood

All pallets observed were clean (stored indoors). Pallets are sorted for condition before use. Incoming wooden pallets are inspected and stored in the pallet storage area. The pallets are also inspected again at pre-shipment review.

4.9.6 Other physical contaminants

Pens are metal detectable and kept segregated away from open product areas. No staples, paper clips or pins are used in open product areas.

4.10 Foreign-body detection and removal equipment

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

Foreign body risk assessment has been conducted and the controls include screens, magnets, X-ray, and metal detectors (in use on all finished product lines). During a plant tour, the operator demonstrated the procedure for challenging the metal detector. At a later plant inspection, the X-ray was challenged. Any finished product rejected is sent immediately to the lab for analysis

4.10.2 Filters and sieves

There are screens ( ). Line Operators inspect the screens before and after each run This is CCP 1, records reviewed in 2.0).

4.10.3 Metal detectors and X-ray equipment

Metal detection, the CCP is used for finished product. The detector is located just prior the end of the process (before lids are applied). A stop conveyor is the reject mechanism. The check was demonstrated on the second day of the audit by the line operator, who described the procedure The X-ray check was demonstrated on the second day of the audit by the line operator, who described the procedure.

4.10.4 Magnets

There are two magnets used at this site used during bulk packing (screener and blenders). These magnets are inspected checked annually. Magnet pull tests are conducted annually (records of 2022-06-03 were reviewed).

4.10.5 Optical sorting equipment

There is no optical sorting equipment at this site.

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

Plastic finished product containers are received in a sanitary sealed condition (stored upside-down). All containers are checked with visual inspection by operators for cleanliness and foreign material, prior to filling.

4.11 Housekeeping and hygiene

There is a Master Cleaning Schedule for each area of the plant (Powder Full, Stick Pack, Capsule and Bottle etc., and weekly drains and grounds cleaning). The records 2022 were reviewed, and all records are up to date. The facility was found to be maintained in a clean and hygienic condition. Detailed cleaning procedures are in place (EX: Blending Room Cleaning Guide). This instruction contains chemicals used and concentrations, procedures, and personal protective clothing.

There is a weekly chemical concentration check by the sanitation staff. Chemicals are dispensed through a dilution unit for employees (the use of the dispensing unit is password protected).

Pre-operative inspections are performed every day before the start of production by the Quality Assurance staff (records reviewed in 3.3) The pre-operative inspection takes place after every cleaning, which occurs at the changeover of products. The cleaning could be a dry clean (if the changeover is same to same) or wet clean (if there is a formula change). Each line has a self-contained packaging room that is segregated by strip curtains and contains the moisture to a small area.

ATP swabbing is used to check for cleanliness after a wet cleaning (EX: on 2022-01-04, a wet clean was checked with 5 ATP swabs, all swabs passed).

4.11.7 Cleaning in place (CIP)

There are no CIP at this site.

4.11.8 Environmental monitoring

The site has a documented environmental program. The Environmental Monitoring Program dictates the procedures, sampling protocol and target organisms, and allowable limits (Listeria, Salmonella, Aerobic Plate Count, and yeast and mold). No positives for pathogens have been recorded since the last audit. Records for Blend, Powder, Bottling, Stick, Measuring and Sampling were reviewed (2021-12-07,2022-04-16).
Listeria, Salmonella and APC tests are conducted monthly. All tests were negative for fore testing in Zones 2-4. There is a program in place for monthly drain swabbing, for (testing for Listeria and Salmonella).

Pathogens testing for environmental monitoring is tested by a third party ISO 17025 accredited laboratory (certificated valid until 2024-01-31).

4.12 Waste

Trash is placed in a compacter; it is picked up by a hauler licensed by the state of Tennessee. The compactor is well sealed from pests is used to contain trash until it is picked up. The area around the compacter was clean during the audit. Cardboard recycling is being started.

4.13 Management of surplus food and products for animal feed

There are no materials sold as animal feed at this site. There is no surplus donated food.

4.14 Pest management

There is a contract pest control service used at this site (weekly). There is a contract that defines the services of the pest control company (2022-02-21), and management of pests. There are up to date licenses, insurance, map (2022-03-14), with icons identifying the locations of the devices, pest sighting log, list of approved chemicals and Safety Data Sheets (Terad3 AG Blox was used on 2022-04-11 for rodents, the SDSs were available in the front of the binder). Hard plastic bait stations are used. There is a plan for a response to pest issues in the front of the pest control binder; action thresholds are stated. No pest issues were seen during any of the plant tours.

There are annual program reviews, with trending (records of 2022-05-04 was reviewed). The report, showing that there is limited pest activity, are updated by the pest company. The records of pest control activities, licenses and review report are all on file.

4.15 Storage facilities

All storage is under ambient conditions; areas were clean and well maintained.
The raw materials are separated from the finished product storage. The allergen raw material and finished goods storage is isolated in racks away from other storage. During the audit, storage areas were observed well maintained, with clean floors, product stored on pallets away from walls and properly labeled. FEFO (First Expired, First Out) inventory management was maintained and verified during the audit
Inventory is managed base on customer specific requirements and is controlled manually and electronically.

4.16 Dispatch and transport

The plant uses third party trailers and customer trailers to ship finished goods (contracted by the customers). Trailers are inspected for damage, foreign contamination including odors, insects, residues and seals on inbound loads and before loading outbound trailers. Outbound trailers are locked and sealed. The process of shipping was observed and explained by an operator on the second day of the audit

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
4.2.3	The facility does not have any external storage tanks silos or opening for the storage of raw materials
4.3.5	There are no temporary storage structures
4.3.5	There are no temporary storage structures
4.4.7	There is no roof glazing or windows in product areas
4.4.8	There were no glass windows in product areas.

4.5.3	Non-Potable water is not used
4.8.8	No Catering is conducted on site
4.9.1.2	No strong scented or taint forming material are present
4.9.4	There are no products packed in glass or brittle containers
4.10.5	No optical sorting is conducted
4.10.6	There are no products packed in glass jars or cans
4.11.7	There is no CIP in use
4.12.3	There are no unsafe products or substandard trademarked materials transferred to a third party for destruction or disposal
4.13.3	There are no products intended for animal feed
4.14.3	The site does not undertake its own pest control
4.15.4	There is no controlled atmosphere storage with gasses
4.15.5	There is no outside storage
4.16.3	There is no temperature control required for transport
4.16.6	There are no 3rd party contractors for storage and distribution

5. Product control

5.1 Product design/development

All product changes and new product trial runs are reviewed by R&D/New Product Team. Customer Account Managers manage how new products are introduced and handled; costs, Hazards associated with new ingredients, labelling, processes, and products are assessed before a new product is introduced on production lines. Claims are the responsibility of the customer who contracts this co-packing site. Samples are developed and sent to the customer for approval. The New Product Development Form is used to track all the developmental information. The facility reviews the label (artwork is provided by the customer) as part of the specification check to verify that the product makes the claims the customer has intended for the product. All new formulations and products are verified by the Regulatory Supervisor. The

customer must sign off on the completed finished product specification (includes clams, nutritional panel, pallet pattern, packaging, labels) before production begins.

5.2 Product labelling

The Label Review and Approval Process SOP was on file. Labels are reviewed for all finished product labels (aligned with FDA's 21 CFR 111-117, Dietary Supplement Health Education Act and Food Allergen Labelling and Consumer Protection Act and International Regulations). Regulatory Supervisor has the knowledge and expertise on International regulatory compliance requirements on export products, made at this facility for its customers.

The Project Management Team will send the label approval and customer approval of formula and specification to the Regulatory Team for their review using the Label Approval Checklist. (Label Review notes need to be filled out if any changes to label are required. This is forwarded to the Research and Development Team and a Flavor Application Scientist, who perform a review. Once review process is complete, Regulatory Supervisor scans the approved label into the DocuWare (label management system) and sends to Project Management team to communicate back to customers and purchase the labels.

When changes are required, a Change Control Form is used. Additional testing or label changes will be performed to fulfil the customer request. The change must be signed off by the management staff. Three Change Control Forms were reviewed.

5.3 Management of allergens

Raw material assessment is conducted for allergens as part of the supplier questionnaire. The potential risks and ranking of vulnerabilities are calculated on a matrix. Risk assessment was reviewed 2021-12-06.

Each line is segregated and operated as an independent unit. Production rooms for each line are compartmentalized using strip curtains. The Cross Contact Prevention document (rev 4.2) defines the procedures for maintaining segregation.

Color coded stickers are applied to identify different allergens (site handles whatever allergens the customers require). These stickers were observed in the warehouse area and are used to check the correct storage of allergens (seen on the first day of the audit). Site has produced dietary supplement products to be sold in USA and overseas. Production Quality Assurance performs ATP swabs (limit of detection is 17 ppm) to check allergen cleaning effectiveness on processing equipment. SOP TAQA 335 describes swabbing procedures was on file. The allergen procedures include segregation of processing utensils, allergen rework and labeling. The allergens handled by the facility are milk, egg, soy, tree nuts, fish, peanuts, shellfish, crustaceans, wheat gluten ingredients and Sulphites. Validations are conducted after every wash down between products. Allergen products are based on what the client sends to be packed.
Dedicated lab coats, gloves, shoe covers, and hairnets are used for each job. Each production room is wet cleaned whenever there is a formula change. Visual inspection and Hygiena- ATP testing is being used to validate cleanliness after sanitation. If a swab is above the limit, the area must be re-cleaned prior to start up.

5.4 Product authenticity, claims and chain of custody

The facility conducts in house testing to verify against the COA for economic fraud, using the Global Food Fraud Database. The facility has conducted an assessment to determine risks of 12 categories such as Botanicals, Amino Acids and proteins are of risk of fraud.

An Assessment was conducted using Trello in June 2021. The site conducts a supplier vulnerability review of raw materials before implementation of testing prior to production. Botanical Risks are provided by American Botanical Society, Botanical Adulterants Monitor. Botanicals are a high risk for adulteration and substitution; Bilberry, Saw Palmetto and Alpha Yohimbine.
Kosher-Orthodox Union (expires 2023-05-31). All product is Kosher.
Certified for Sport- (expires 2025-01-25).
Halal certified by Islamic Nutritional Council of North America (expires 2023-04-30).
Organic Certified through Quality Assurance International as a Handler (Processor). Cert # C0349582-NOPHPC-2 (last audit 2022-06-14).
Non-GMO (product specific and customer specific)
Gluten Free Gluten Intolerance Group (expires 2022-05-31). The audit is due soon.

5.5 Product packaging

For all packaging, a third-party audit certificate, questionnaire, allergen statement and assessment, and a letter of continuing guarantee (to ensure FDA approved materials are used) is obtained from all packaging suppliers
Finished products are inert to these packaging materials. All products are stored in the original receiving containers. Labels were stored in a secured cage and controlled by a designated individual. Label verifications are checked at receiving and in production. Specification package includes labelling.

Traceability information for all packaging materials is maintained (see 3.9). The plant destroys obsolete packaging materials following customer requirements

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

All finished product testing is specified by customer. The in-house Quality Assurance laboratory testing includes. moisture, pH, bulk density, sieve analysis and organoleptic, ROTAP granulation, visual comparison, water activity, pH 1% solutions test., Heavy Metals, Color Staph, microbiological purity testing, dissolution, Caffeine and Amino Acid. The facility's Quality Assurance laboratory is segregated from processing areas.

Testing results include a cover sheet that has testing methods and if third-party was used for testing.

Some testing is conducted by outside laboratory (ISOI 17025 Accredited with expiration of 2023-12-31).

Environmental monitoring tests are conducted (see 4.11.8)
Microbiology testing is conducted as per customer requirements. Raw materials received on-site are accepted, based on supplier provided COA and additional verifications carried out in-house.
The site does not conduct shelf life assessment**.** Shelf life studies are the responsibility of the customer.

5.6.2 Laboratory testing

The facility has a documented Good Laboratory Practices Program and laboratory staff have been trained on it. AOAC test methods are used to perform required analytical testing. Finished product tests and specifications are determined by the customer. All test results reviewed were seen to be within specifications.
In-house laboratory performs proficiency testing to satisfy ISO 17025 requirements. (EX: pH Testing was conducted 2021-10-26. Samples for microbiological purity and minerals are used in the program are also tested for proficiency (2021-10-23)

The laboratory has a separate dedicated air and water supply.
Security is maintained with pass swipe card with lick and key with badge access. The lab has a pass window.

5.7 Product release

Product that requires specific tests to comply with customer specifications is placed on Hold until testing is successfully completed. Raw materials are tested and released. For finished goods, the Quality Assurance staff changes the status of the material in the materials management system and issues a Certificate of Analysis when requirements are met.

5.8 Pet Food

No pet food is manufactured at this site.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
5.3.5	There is no allergen rework undertaken
5.6.2.3	There are no analyses conducted that are critical to product safety or legality

6. Process control

6.1 Control of operations

The facility has detailed and documented SOPs describing the procedures for blending product.
The facility does not have any automated in-line process controls,
Measuring of powdered ingredients, blending, packaging (bottles, gusset bags, and single serving stick packets) are all measured by hand. There are no process parameters controlled by in-line monitoring devices.

Weights are monitored with each unit. Metal detection, X-ray, screen checks, magnet checks for the bulk pack and retains are maintained for each lot produced. Label checks are verified prior to production and labels are verified on the production floor. Label is attached to the production records.

Humidity of the rooms being recorded at the start and end of the runs, to avoid clumping defects. Mixing instructions are kept in the blending rooms. Pre-production checklists are made for blending rooms.

6.2 Labelling and pack control

All client supplied labels are locked and stored in a secured cage, administered by the Quality Assurance staff. Labels and label artwork are supplied by the client. Production gets exactly the quantity of labels that they need to use, with only the current production labels at the production line. When production is finished, any remaining labels are returned to the label cage. Label review is conducted and signed off by Quality Assurance.
A Clearance check list is used to verify line clearance and signed off by Quality Assurance (EX: On the second day of the audit, Line 1 had a product change over form pet bone broth for one customer to pet bone broth for another customer. All product and packaging materials were removed from the production room, and a dry clean was performed. The room was totally emptied and cleaned. When the cleaning was completed, new labels, packaging film and product were brought into the production room to start up the second bone broth product).

6.3 Quantity, weight, volume, and number control

Small packages are conveyed on a checkweigher (over and under-weight units are rejected). Filling of 5 oz. flexible packaging was observed to verify correct weight control procedures. Weight checks were verified during the audit to verify checks were documented.
Weight checks are checked prior to incidentals (scoop and moisture preserver) added after weight checks. Weight checks are performed hourly.

6.4 Calibration and control of measuring and monitoring devices

The facility has documented calibration program for equipment.
metal detectors-annually. 2021-08-12
X-ray unit-annual 2021-08-12.
Timers and thermometers are purchased annually with a certificate of calibrations.
Humidity meter (annual) 2022-05-17
Lab scales, (annual) 2022-06-17
flukes calibrated annually calibrations were conducted September 2021.
Certified weights (4) were calibrated 2021-06-21.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
6.1.2	There are no equipment settings that are critical to controlling food safety or legality.
6.1.4	There are no process parameters or product quality that are controlled by in-line monitoring devices
6.1.5	There is no variation in processing conditions that occur within equipment critical to the safety or quality of products
6.2.4	There is no in-line vision used to check labels

7. Personnel

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

Quality Assurance is responsible for training. Orientation training is given to all new hires (EX: on 2021-12-13- the newly hired packaging operator was trained on Good Manufacturing Practices, Company policies Hygiene Food Safety Allergen Security, SOP video). There are employees that are trained to conduct CCP checks (HACCP training records for 2021-04-02 were reviewed). There is a computer database that lists the date and time of training and quiz completion.

Training is performed annually, including quizzes. Records for 2021 were reviewed.

7.1.1-Minor non-conformance-During the second shift plant tour at Line 4, several employees were observed inserting their fingers into the product jars.

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

Personal Hygiene is included in the annual training of all employees. Employees observed during the plant tour were seen to be following Good Manufacturing Practices (All employees were wearing clean uniforms. All employees were wearing hair nets and beard nets, if required). All employees were washing their hands whenever necessary. Good Manufacturing Practices are checked through the monthly plant audits (records for 2021-2022 were reviewed).

There are hand wash stations at the entrances of the processing areas; employees were seen to be correctly washing their hands upon entry. Gloves are worn when handling food contact surfaces.

Metal detectable band aids and ear plugs were checked quarterly on 2021-07-06 and 2022-03-17 Medicines are not allowed in the production area.

7.3 Medical screening

Drug screenings are taken for new employees and in case of accident. Disease Control training is part of supervisors training. GMP's encourage employees to inform their supervisor if they feel ill. This was verified during employee interviews during this audit.

7.4 Protective clothing: employees or visitors to production areas

Company's policy on clothing is followed by all employees. Employees wear eye protections, smocks, hair nets, beard nets and gloves. Clothing procedures and signs are posted at entrance to processing areas. Compliance with the requirements are checked and documented daily by supervisor and monthly by Quality Assurance auditor During the plant tours, all employees were seen wearing clean uniforms and correct PPE.

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

7.4.6	The are no items of personal protective clothing used unsuitable for laundering

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

There is no High-Risk, High-Care and Ambient High-Care production at this site

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

There is no High-Risk, High-Care and Ambient High-Care production at this site

8.3 Maintenance in high-risk and high-care zones

There is no High-Risk, High-Care and Ambient High-Care production at this site

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

There is no High-Risk, High-Care and Ambient High-Care production at this site

8.5 Housekeeping and hygiene in the high-risk high-care zones

There is no High-Risk, High-Care and Ambient High-Care production at this site

8.6 Waste/Waste disposal in high risk, high care zones

There is no High-Risk, High-Care and Ambient High-Care production at this site

8.7 Protective clothing in the high-risk high-care zones

There is no High-Risk, High-Care and Ambient High-Care production at this site

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
8.1 – 8.7	There is no High-Risk, High-Care and Ambient High-Care production at this site

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 wastewater 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

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14.2 Environmental Monitoring

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14.3 Product inspection and laboratory testing

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14.4 Protective clothing: Employees or visitors to production areas

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