Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	CS Beef Packers, LLC	Site Code	2794635
Site name	CS Beef Packers, LLC		
Scope of audit	Slaughter and fabrication of beef carcasses including beef primals, sub primals, beef offal, beef trimmings, and ground beef; bulk, vacuum, and modified atmosphere packaging.		
Exclusions from scope	Rendering and Hides & Traded Goods Module		
Justification for exclusion	Products produced in a different area of the facility. The site elected to exclude the voluntary, Traded Goods Module from the scope of certification.		
Audit Finish Date	2020-09-18	Re-audit due date	2021-09-19
Head Office	No		

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

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Blended Announced
Previous audit grade	AA	Previous audit date	2019-09-19		
Certificate issue date	2020-10-16	Certificate expiry date	2021-10-31		

Number of non-conformities		
	Fundamental	0
	Critical	0
	Major	0
	Minor	3

3.Company Details

Address	17365 South Cole Road Kuna, Idaho 83634		
Country	United States	Site Telephone Number	208 810 7509
Commercial representative Name	Roger Cooper - Operations Manager	Email	Roger.cooper@csbeef.com
Technical representative Name	Matt Thompson - FSQA Manager	Email	matt.thompson@csbeef.com

4.Company Profile

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

Shift Pattern	One Ten-hour shift
Subcontracted processes	No
Other certificates held	Halal
Regions exported to	Asia North America South America Other Africa
Company registration number	USDA 630
Major changes since last BRCGS audit	None

4.Company Profile

Company Description

The facility was built in 2017 and harvest 1700 head per day on average. Their major product was ground beef which started in 2018. The facility consisted of approximately 500,000 sq ft. and employed 750 people. One extended shift had a 6:30 AM start up and ran for approximately 10 hour shifts. Contracted sanitation cleaned the facility overnight. Retail and food service were the primary customer base.

5.Product Characteristics

Product categories	01 - Raw red meat 03 - Raw prepared products (meat and vegetarian)
Finished product safety rationale	Low risk - Finished products were raw required finished product cooking prior to consumption and were stored at temperatures <44.6F

High care	No	High risk	No	Ambient high care	No

Justification for area	Harvest and Fabrication areas were physically segregated and staffed with designated employees. Finished products were raw required finished product cooking prior to consumption and were stored at temperatures < 44.6F.
Allergens handled on site	None
Product claims made e.g. IP, organic	Natural, USDA Grade Claims
Product recalls in last 12 Months	No
Products in production at the time of the audit	Beef carcasses, variety meats, sub-primals, boneless beef trim, ground beef, chubs, bricks and loaves.

6.Audit Duration Details

On-site duration	29 man hours	Duration of production facility inspection	14 man hours

6. Audit Duration Details	
Reasons for deviation from typical or expected audit duration	The facility was well prepared with programs and records easily accessible. Additionally, a significant portion of the square footage was designated as carcass storage where minimal processing activities occurred.
Next audit type selected	Announced

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2020-09-14	08:00	16:00
2	2020-09-15	08:00	14:00
3	2020-09-17	05:00	16:00
4	2020-09-18	07:00	11:00

	Auditor (s) number	Name	Role
Auditor Number	258011	Alyssa McMahan	Lead Auditor
Second Auditor Number	N/A	Sherri Speziale	Observer

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
Steve Cherry/Plant Manager	X			X
Roger Cooper/Operations Manager	X	X	X	X
Matt Thompson	X	X	X	X
Kyle Hand/HACCP-BRC Coordinator	X	X	X	X
Amanda Adair/Fabrications QA Superintendent	X	X	X	X
Brandy Whitehead/Grind Superintendent	X	X	X	X

Present at audit				
Maria Luna/Harvest QA Superintendent	X	X	X	X

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced
2020-09-18	BRC, Food Safety Standard	Announced

Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements				
No.	**Requirement ref.**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**
1	1.1.2	The site did not document the review of the effectiveness of the completed activities and their timescales of the results of the surveys for the food safety and quality culture.	CS Beef Management added a section for Review of Employee Food Safety and Quality Culture to the Monthly Manager's Meeting to ensure that the plan and any updates/timeframes for improvement are communicated at least	Monthly Manager's Meeting notes will be reviewed after every meeting to ensure the Employee Food Safety and Quality Culture Plan has been reviewed.	The root cause of the issue was identified to be human error and a misunderstanding of the identified timescales for review of the Employee Food Safety and Quality Culture Plan.	2020-10-04	Alyssa McMahan

			quarterly to the site's Senior Management.				
2	4.9.2.1	A blue handled box knife was observed in the case sealer area which did not include identification information.	A training on small equipment accountability was conducted to ensure equipment is accounted for in the Case Sealer area.	A Box Shop Small Equipment Check List has been created and implemented to ensure accountability of box knives for Case Sealer area employees. Accountability will be documented daily (start of shift, lunch break and end of shift) on each area employee and verified by the area supervisor.	The root cause was deemed to be lack of proper training for Case Sealer area employees in regards to small equipment accountability (box knives).	2020-10-04	Alyssa McMahan
3	4.11.2	There was no documentation of quarterly cleaning of seven refrigeration units on the Master Sanitation Cleaning Schedule (units 24, 25, 28, 30, 32, 37S and 37N).	A Training was conducted on Master Sanitation Verification to ensure items on the Master Sanitation Schedule are documented correctly.	A Monthly Master Sanitation Verification Check Off Sheet has been created to ensure that the MSS is reviewed and verified as being complete. This document will help to ensure that all MSS items are documented correctly on the Master Sanitation Schedule.	Root Cause was determined to be human error. During the timeframe in question, the Master Sanitation Schedule was revised several times and due to this change, seven refrigeration units were not documented as having been cleaned.	2020-10-04	Alyssa McMahan

Comments on non-conformities

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**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

*The Commitment To Food Safety and Quality was posted throughout the facility in employee common areas and with current signatures by the Plant Manager and Operations Manager. The statement explained the site was committed to producing food products that were safe, legal, authentic, wholesome, and of the highest quality. The site demonstrated continuous improvement through corrective and preventive actions, reviewed operating procedures annually and archived those no longer in use, and properly trained supervisors and operators signed off by plant and operations management. The site conducted employee engagement surveys every two years of food safety and quality culture within each department. Goals listed for the facility included customer complaint index less ≤5 and ≤ 90 non-conformances issued by the USDA. Monthly management review meeting notes reviewed from May and August listed COVID-19 precautions, a new head splitter installed, floors repaired, BRC corrective actions working as intended, customer complaints , USDA non-conformances issued and HACCP reassessments reviewed since the last meeting. Management posted a confidential suggestion box in guard shack for employees to report concerns of food safety, integrity, quality and legality issues. They also communicated this system to the employees during hire and using monitors located throughout the facility as daily reminders. The FSQA Manager reviewed the suggestions and reported them during the management meetings. Employee food safety and quality issues were trended. The following updates were installed since the last audit: Ground Beef grind and packaging lines, grind area cooler racking, railing installed in the stimulator area to streamline the process and the flooring was resealed in the majority of the facility. The company kept informed of scientific and technical developments, new risks identified in raw materials, industry codes of practice and relevant legislation through the USDA website,weekly meetings with the inspectors, and emails, using Meatingplace notifications and industry trade associations. The site maintained hard and electronic copies of the BRCGS Standard Issue 8. BRC re-audits were conducted within scheduled time-frame. The sites most senior production managers attended the opening and closing meetings of the audit certification. Senior management ensured the root causes of non-conformities against the Standard from the previous audit were effectively addressed to prevent recurrence. The facility did not use the BRC logo.

The following minor non-conformity was identified:

1.1.2 - The site did not document the review of the effectiveness of the completed activities and their timescales of the results of the surveys for the food safety and quality culture.

1.2 Organisational structure, responsibilities and management authority

*The organizational chart defined the reporting structure from the Plant Manager to plant employees and was reviewed 9/12/20. The job descriptions and back-ups were identified for essential positions (dated 3/12/20). Position responsibilities for each department manager and FSQA superintendent dated 9/12/20 were reviewed. The FSQA Manager was responsible for overall food safety and quality at the site and reported to the Operations Manager. Employees were given on the job training and reviewed job standard operating procedures (SOP's) using Alchemy training upon hire and annually. Reviewed Fabrication

employee job description and Quality employee SOP's for individual jobs dated 6/10/2020. The organizational chart, responsibilities and job descriptions were reviewed annually or as needed.

Details of non-applicable clauses with justification

Clause/Section reference	Justification
1.1.13	The BRCGS logo was not utilized.

2 The Food Safety Plan – HACCP

The facility operated under three HACCP plans based on Codex Alimentarius: Harvest, Fabrication (Raw Not Ground) and Ground Beef (Chub, Patties, Loafs and Bricks). HACCP Team Members listed were: Plant Manager, Assistant Plant Manager, Operations Manager, Food Safety Quality Assurance (FSQA) Manager, HACCP/BRC Coordinator, Ground Beef Quality Assurance (GBQA) Superintendent, Plant Engineer, Safety Manager, Ground Beef (GB) Manager and Harvest Manager. The HACCP Team Leader was HACCP trained July 17-18, 2017. HACCP certifications were also held by additional Quality Assurance (QA) department personnel. The Team Leader discussed the HACCP Principles with the HACCP team annually. The facility was a cattle slaughter facility, producing beef primals, sub-primals, trimmings, raw ground and offal products. Sold to customers, further processors, grinding facilities, and the general public. The facility operated under Category 1 (Raw products requiring cook prior to consumption, slaughter and primary cutting) and Category 3 (Retail butchery, processing and packing). Prerequisite programs implemented but not limited to: Water Potability, Supplier Approval, Metal Detection, Food Defense, Good Manufacturing Practices (GMP's), Sanitation, Pest Control, Recall Program, Traceability, Foreign Object Control, Residue Program, Sanitary Dressing Monitoring , Chemical Application, Sanitation Standard Operating Procedures (SSOP), Facility Audits, Labelling, Trailer Inspections, Environmental Testing, N60 Plus Procedures, Thermometer Calibration, AQL Program, Returned Product, Certificate of Authenticity (COA) Verification, HACCP Corrective Action, Plant Temperatures, (Manual Sampling Device (MSD) MicroTally Cloth, Lactic Acid Checks, Acidified Sodium Chlorite (ASC) Checks, Spray Chill, Carcass Chilling, Birdshot Carcass, Offal Sampling, Carcass Sampling, Residue Program, HEP, Offal Sponge Sampling, Material Receiving and Quarterly Validation were reassessed annually (at a minimum). HACCP Reassessments were conducted annually, or as needed. Programs were clearly documented. Reassessment dates were listed on the SOP Change Log. Records were reviewed for reassessments conducted on the Slaughter and Fabrication HACCP plans on 1/2/20 and the Ground Beef HACCP plan on 1/17/20 (this reassessment also condensed two previous ground plans into one). HACCP meeting notes were provided from plan reassessments. Product and process descriptions were provided for each plan and included the process category, products covered, product intended use, type of packaging, distribution, labeling instructions, shelf life, consumers, and intended use. Intended use was identified as further processing, retail, and food service sales for consumption by the general public. Flow charts were provided, color-coded and verified by the HACCP team on 1/20/20 (Harvest), 3/12/2020 (Fabrication) and 9/9/2020 (Ground Beef). The steps of the flow charts included receiving live animals/chemicals/packaging materials, CCP's, process inputs/outputs, packaging, storage and shipping of finished products. Hazard analysis identified Biological, Chemical,

Physical and Radiological hazards of concern including: E. coli O157:H7, Non-pathogenic E. coli O157:H7, Salmonella, STEC O24, O45, O103, O111, O121, O145, Specified Risk Materials (SRM), sanitizer, metal, hard plastic, wood, lead shot, antibiotic residue, needles, fecal material, hair, bruises, abscesses, lactic acid and dry ice. The Harvest HACCP plan listed five CCP's. CCP1 – Carcass zero tolerance for E. coli O157:H7 and Salmonella, monitoring for zero visible fecal, milk, and ingesta as defined in FSIS Directive 6420.2 using 50 candlepower lighting, documented once per audit (or at failure) on CCP1 form, CCP2 – Carcass Hot Water Wash/Inspection had a critical limit of 198F at the header, and a visual verification that product passed through the cabinet. Hourly monitoring was conducted of the hot water temperature and visual verification of proper coverage. CCP3 – Carcass Lactic Acid Application had a critical limit of 2-5% solution at the mixing tank and temperature range of 75-150F over the carcass and visual verification the product passes thru the cabinet. CCP4 – Offal Lactic Acid Cabinets had a critical limit of 2-5% solution at the mixing tank and temperature range of 75-150F over the carcass and visual verification the product passed thru the cabinet, and CCP5 – Variety Meats Zero Tolerance (Head/cheek meat) of E. coli O157:H7 and Salmonella. Fecal inspections were conducted by inspecting 30 lbs., of both products, once within the first hour, once within the last hour, and once per period of production. The Fabrication HACCP Plan listed two CCP's: CCP F1 – Cold Storage of sub-primal boxed product with a critical limit of < 44.6F within two hours of final packaging time listed on the product label and CCP F2 – Cold Storage of combo boxed product with a critical limit of < 44.6F within two hours of final packaging time listed on the product label. The Ground Meat HACCP Plan listed CCP G1 - Final grinder product temperature, with a critical limit of ≤ 44.6F within two hours of final packaging monitored once per hour of ground beef production per final grind time listed on the case label. Product temperature monitoring was conducted after the final grinder once per production hour. Monitoring activities were conducted by QA or properly trained designated employees. Verification activities included daily direct observation of monitoring procedures, daily record review, and daily thermometer verification. Corrective actions were in accordance with 9 CFR 417.3(a) requirements. CCP records were reviewed from the week of 5/4-5/8/2020. A deviation was identified for one hour on 5/7/2020 on CCP 5 noting 23 cases of head meat tagged back to the last acceptable check. The failure with plant inspectors resulted in performance coaching of the employee involved in the failure and staff followed up to ensure the employee learned from this incident. The FSQA staff inspected the 30 lb. cases every 30 minutes until four consecutive checks were passed. Validations were conducted quarterly, records were observed for the first three quarters (E. coli O157:H7, and non-E. coli O157:H7). HACCP records were maintained for three years.

Details of non-applicable clauses with justification

Clause/section reference	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

*The site's Food Safety and Quality procedures were maintained in an electronic Quality Manual and hard copy which was fully implemented and available to relevant facility personnel. The procedures and work instructions were legible, unambiguous, translated, as needed, in Spanish, Koran and Swahili and detailed enough for relevant personnel to understand. The hard copies were maintained in the FSQA office and were available for relevant personnel to view. Reviewed the color-coding policy, dated, 2/1/20 and the slaughter work Instruction, dated 3/23/2019.

3.2 Document Control

*Reviewed the Document Control Policy, dated 2/22/2017 which was authorized by the FSQA Manager. A list of controlled SOP's and documents were listed by title, version, date and reason. Their authorization, original date and current version number were listed in the body of each policy. As documents were updated, they were distributed throughout the plant by giving production and QA management hard copies on the slaughter side and removing the old versions from their respective folders. The Fabrication and Ground Beef areas utilized the electronic versions. As these were updated the change was in effect for the next business day. Production did not have access to change the electronic versions of the documents. The electronic documents were password protected, stored securely and backed up daily, to prevent loss.

3.3 Record completion and maintenance

*The Record Completion and Maintenance Policy dated 1/2/2020 was reviewed. Records were legible, maintained in good condition and easily obtained. They were stored securely in electronic form using passwords and authorized access. They were also backed-up daily and retained for 3 years. Errors on manual forms were corrected by placing a single line through the error and initialing. Electronic forms were corrected during the daily document review by typing the correction in the column.

3.4 Internal audits

*The BRC Internal Audit Schedule defined internal audit scheduling and audit requirements, reviewed date 1/2/2020. The frequencies of the audits were based upon risk, activity type and previous audit performance. An internal BRC audit was completed in its entirety annually by covering different sections at least four different times throughout the year. Auditors were independent of their area of responsibility, and maintained internal auditor training certificates from FSNS dated 2/29/12, 1/31/19, and 1/17/19. Completed audit reports were provided of the internal audits conducted against policies developed to meet the BRC standard (Mar, July, August 11 and August 25, 2020). Monthly Housekeeping/Sanitation audits were completed as required by the schedule. Completed reports from the previous twelve months evidenced compliance to 3.4.3 and facility requirements.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

*The HACCP hazard analysis included risk assessments for raw and packaging materials. Supplier approval and monitoring procedures were outlined in the Supplier Approval SOP (QA SOP 8) dated 1/2/20. Suppliers were required to meet all USDA/FSIS requirements and provide third party audit results or supplier audits which include traceability, product safety HACCP review and good manufacturing practices (GMP's), control of non-conforming product, trace system in place, quality and food safety evaluation of product provided, allergen control program, certificate of analysis (COA), new supplier risk

assessment, supplier questionnaire (low risk products), letters of guarantee (LOG) and product specifications. Live cattle suppliers submitted signed Producer's Wholesomeness Certificate and Market/Dealer Certificates every three years. Certificates were verified weekly against the FSIS Repeat Violator List. Approval was based on historical relationships with the site. The site did not purchase from brokers. Supplier approval documents were reviewed and compliant. The site conducted supplier monitoring through the ability to meet company requirements, LOG's, third party audits, supplier questionnaires, HACCP reviews, GMP's and allergen control program compliance. Approved suppliers were listed on the List of Approved Suppliers/Services dated 8/14/20. Exceptions were permitted (in dire situations or products used for research and development)) with corrective actions (CA) in place. Prior to purchasing from non-approved vendors, incoming goods were inspected and verified through testing, if needed. Suppliers were reviewed every three years at a minimum, or as needed.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

*Raw Material and Packaging Receiving and Monitoring Procedures required incoming trailers to be sealed, clean and in good physical condition. Suppliers were verified as listed on the List of Approved Suppliers. The Raw Material Receiving Policy (GB SOP 1), dated 1/2/20, explained the procedures for receiving boneless beef from external suppliers. Meat trailers were maintained ≤40F. Shipments required a COA indicating products were tested for E. coli O157:H7 and found negative. The Material Receiving Policy (CP 24), dated 1/2/2020, listed the procedures for receiving packaging and chemicals. Packaging, raw materials, and ingredients were inspected organoleptically. Live animals were subjected to FSIS ante-mortem inspection. Inspections were recorded on the electronic Receiving Log.

3.5.3 Management of suppliers of services

*Supplier Raw Material Vendor Phone list was viewed showing approved suppliers as active. This list also included the type of material purchased and phone contact. The Service Approval and Performance Monitoring SOP, dated 1/2/20, listed procedures for service supplier approval and monitoring. Suppliers were approved based on historical relationship, required to provide a LOG indicating there was no potential food safety risks associated with the services and a signed contract. Contracted services included pest control, laundry, pathogen laboratory testing, certifying bodies, sanitation, select maintenance services, food vendor and waste removal. Signed contracts provided for sanitation and laboratory services were reviewed and current. Service suppliers were monitored for the quality of services provided.

3.5.4 Management of Out sourced processing

*Processing was not outsourced.

3.6 Specifications

*The Finished Product Specification (QA SOP 18), dated 1/2/2020, explained the process for customer specifications approval. If no formal specifications were agreed upon, then the schedule was the approved specification. Specifications were developed for raw and finished products. Hard copy and electronic versions were maintained. Specifications were reviewed for raw beef trim, dated 1/2/20, (lean point was verified through in-plant testing conducted on every batch of product). Information listed was necessary to manufacture their products, such as: ingredients, UPC code, GTIN, pack size, box type, product weight, container weight, product temperature, shelf-life, boxes per pallet and product packaging. A finished specification was reviewed for Niman Coarse Grind 80L, dated 1/2/20, and contained identification information, product description, ingredients, packaging instructions, package and case weights, labeling instructions, storage, shelf life, and palletizing instructions. Specifications were reviewed every three years, or as needed.

3.7 Corrective and preventive actions

*The SSOP Corrective Actions and HACCP Corrective Actions (CP7), both dated 1/2/2020, were reviewed and detailed the procedures for each program to conduct and document corrective action (CA) and preventive action (PA) investigations. Deviations were reviewed for critical control point (CCP) and non-CCP nonconformances. The site utilized the Five-Why analysis procedure to investigate root cause analysis. The documented CA included date of incident, product involved, or issue, amount of product involved, description of incident, product disposition and corrective and preventive actions. Corrective actions were reviewed for an incident involving cheek meat and an issue with condensation dripping from a cooling unit, no product was affected. Root cause analysis of the CA and trends were reviewed during management review meetings.

3.8 Control of non-conforming product

*Control of Non-conforming product was listed in the QA Hold Tags (QA SOP 4) SOP, dated 1/2/2020. Procedures covered placing non-conforming product, materials, or equipment on hold. Red QA tags were used to identify non-conforming carcasses, boxes or equipment. Tags were released by QA personnel only and verified daily. The QA Hold Tag Log was utilized to document use of such tags, and included the date, QA name, reason for tag, corrective action, release date, and disposition of product (if applicable). The Hold Log from Ground Beef was reviewed and current.

3.9 Traceability

The Recall Program was implemented which identified recall team, roles, responsibilities, and contact information. Processing aids and packaging materials were traced using manufacturers information. Live animals were tracked using producer information. Finished products were traced using product code and production date.

A vertical exercise was completed during this assessment on product code 10701 85L produced on 5/7/2020. The facility produced 15 combos of finished product which shipped to one customer distribution center. Packaging materials were traced using manufacturers lot information which was documented on the Packaging Product Traceability record. Processing aids were tracked using manufacturers lot information and purchase order which was documented on ASC - Carcass Spray Cabinet log, Lactic Acid - Subprimals and Trim log, and CCP monitoring logs. Carcasses entering fabrication were tracked using a carcass identification number placed at harvest hot scale. Live animals were tracked using producer name and ear tag. The auditor initiated traceability exercise was completed in less than two hours with 100% identified and traced.

Mock recalls were conducted a minimum of twice per year with two mock recalls provided from 2019 and 2020. Each exercise was completed within two hours and included live animals, packaging, processing aids, and finished product to the first point of distribution.

Rework was tracked on production logs which included product code, production date, and date reworked.

3.10 Complaint-handling

*Customer Complaint (QA SOP 24) Procedure outlined procedures, responsibility, investigation, and follow-up for customer complaints received. Complaints were received by the FSQA Manager and communicated to management personnel for investigation and corrective action. Documentation was provided for a quality defect (5/12/20) and a Costco defect (6/10/20), and included investigative results

which were reported to the customer. Complaints were tracked through an Excel spreadsheet and trended every time a complaint surfaced. The complaints were reported during the management review monthly meetings. Unaddressed trends were not observed.

3.11 Management of incidents, product withdrawal and product recall

*Emergency Breakdowns (QA SOP 9), dated 1/2/2020, outlined the crisis response team, team objectives and considered situations for fire, water damage, or other facility/building disaster, supply chain deficiencies, electrical power outage, labor shortage, bomb threat, plant evacuation, and water safety issues. The Recall Program outlined the FSQA Manager was the recall coordinator, communication plans, recall procedures, product recall team with responsibilities, external contacts, legal counsel, media contacts, support organizations, customer contact list, and mock notification letters. Recall procedures were tested 6/10/2020 in conjunction with the trace exercise described in section 3.9 of this audit. Procedures included provisions to notify the certification body of a recall within three working days.

Details of non-applicable clauses with justification

Clause/section reference	Justification
3.5.4	Processes were not outsourced.
3.5.4.1	Processes were not outsourced.
3.5.4.2	Processes were not outsourced.
3.5.4.3	Processes were not outsourced.
3.5.4.4	Processes were not outsourced.

4. Site standards

4.1 External standards

The facility was located in a rural area of Kuna, ID. The surrounding areas did not pose a risk to the facility or products produced. Grassy areas and landscaping was maintained and did not create a pest harborage area. External traffic areas were paved and observed in good repair. Pipes through walls from external bulk tanks were sealed to prevent pest entry. Areas for bird roosting were not observed. Openings which might permit pest and contaminant ingress were not observed.

4.2 Site security and food defence

*The Food Defense Plan outlined food security measures, identification of risk, plant security, building access accountability, plant personnel, contractor approval policy, and visitors/delivery. The facility conducted an annual Food Defense Assessment with the most recent dated January 2020. Access to the facility was controlled through locked doors with access codes, security cameras, partial perimeter fencing, and locked external bulk storage. Visitors were required to sign in, read the visitors policy, show identification, and were escorted at all times. Food Defense training for employees was conducted annually through Alchemy. The site conducted Food Defense training in January 2020 with a shelter-in-place exercise on 1/25/20. Training records were reviewed from January 2020. The facility was registered with the FDA Bioterrorism Act ending in 4668. The facility was registered with USDA as Est number 630.

4.3 Layout, product flow and segregation

Site maps indicated the locations of receiving, processing, storage, shipping, risk areas, welfare, and break rooms of the facility. Flow of product, personnel, rework, waste, and inedible materials, were included in the site maps. Access points for personnel, raw materials and packaging materials were identified on the maps. Contractors and visitors were informed ammonia was used on site and were escorted at all times. Sufficient work space was provided for storage and personnel to perform their duties. Temporary structures were not present.

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

Walls were constructed of pre-stressed concrete, easily cleanable and in good repair. Floors were constructed of sealed concrete and slip resistant coatings easily cleanable and in good repair. Floors were sloped to drains to prevent pooled water where wet cleaning was utilized. Drains were easily accessible for sanitation. A drain map was provided to show locations and flow through the facility. Ceilings were observed in sanitary conditions. Stairs to overhead platforms and overhead platforms were equipped with kick plates and bottom plates to protect from contamination of materials or personnel below. Ventilation openings were screened and equipped with backdraft prevention louvers and fans. Glass windows were protected in the processing areas. External personnel doors were self-closing and sealed to prevent pest entry. Dock doors and levelers were observed properly sealed. Lighting was sufficient for cleaning and inspection in the facility. Lights were shielded to protect from breakage. ILTs (insect light traps) were located away from products or packaging material and positioned to prevent attraction of insects from the outside. Ventilation was adequate as condensation and dust accumulation were not observed. There were no suspended ceilings.

4.5 Utilities – water, ice, air and other gases

Water was supplied from wells located on the company property. Quarterly water testing from point of use from the slaughter, fabrication and grinding areas for coliforms and residual chlorine was reviewed from 3/19/2020 with acceptable results. Chemical analysis was conducted annually with results provided for 2020. Sites were alternated throughput the year. An up to date water distribution schematic was provided. Backflow prevention testing was conducted annually. Most recent test was conducted on 4/11/20. Filters were utilized on air compressor units in contact with food at a size of 0.3 microns. Air filters were checked 3/30/20 and were set on a monthly preventive maintenance schedule.

4.6 Equipment

Processing equipment was constructed of stainless steel and other food grade materials and was well maintained. Rough welds, excessive greasing, hollow tubing and metal to metal wear were not observed. Equipment layout and design did not impede maintenance, sanitation or inspections.

4.7 Maintenance

*The Preventive Maintenance Program (QA SOP 26), dated 1/2/20, outlined procedures for maintaining the facility, addressed preventive maintenance, corrective maintenance, the addition of new equipment and procedures for maintaining product safety in the event of unplanned or non-routine maintenance work. Preventive maintenance (PM) was tracked using the Manager Plus (eMaintenance) system. PMs were generated based on the specified frequencies of weekly, monthly, and quarterly inspections based on manufacturer recommendations and facility history. Daily records were reviewed from the Fabrication department (rib, loin line) 8/3, 8/48/12 of various department inspections. Work orders were given to maintenance for work needed each day. Frequencies were adjusted based on inspection results. Temporary repairs were made using approved, cleanable materials and were scheduled for permanent repair as soon as practical as outlined in the Maintenance repair policy. Unplanned work orders required QA inspection prior to release. Tool and part accountability and the restoration of sanitary condition following maintenance on food contact equipment were documented. Tools were cleaned before each task. Food grade greases which did not contain known allergens were used by the maintenance department and segregated from non-food grade greases. Reviewed an allergen letter from Sealed Air for various oils and greases used on their equipment. The maintenance areas were well maintained and organized.

4.8 Staff facilities

Staff facilities included break room, locker room, and toilet areas. Designated changing areas were provided for all personnel. Lockers were provided for storage of outer clothing and personal items for all employees at the facility and inspected daily. Hand wash sinks were provided in restrooms and processing areas. Sinks were equipped with hands free, warm water taps, liquid soap, single use paper towels, waste containers, and hand wash advisory signage. Hand washing was required prior to starting work, after break, eating, smoking, blowing their nose, using the rest room, or other potential contamination. Toilets were provided in sufficient numbers for employees in each department and did not open directly into production areas. Break rooms were provided for employees including shelving for storage of employee lunches. Designated break areas outside were equipped with containers for waste. Smoking including electronic cigarettes was permitted in designated areas equipped with canisters for smokers' waste. Shelves were provided for storage of employee lunches.

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

4.9.1 Chemical control

The Chemical Control Program outlined procedures for purchasing, segregated storage, restricted access, labeling, and use of chemicals in the facility. SDS were available for employee access. Chemicals were handled in compliance with OSHA and EPA requirements. An approved list of chemicals was provided. The FSQA Manager was responsible for reviewing and approving new chemicals. Strongly scented

chemicals were not allowed in the production area during operations. Chemicals were observed properly labeled and securely stored in designated locations throughout the facility.

4.9.2 Metal control

The Foreign Object Control (CP 10) outlined procedures for controlling knives and blades used in the processing areas. The facility only allowed company-issued safety knives in the processing areas. Knives/hooks were issued to employees who were responsible for maintaining the condition and cleanliness. The items were engraved with the employee initials or numbers. Tools were issued as needed to employees in the Grind Room. Inspections were conducted at the beginning of the shift, throughout the shift and end of each shift and documented on the on the operational sanitation form. Documents reviewed from 5/4/20 were compliant. Staples, paper clips, push pins, and snap off blades were not permitted in production areas. Corrective and Preventative Action Reports were reviewed from the Fabrication Room and QA Tag Log documented during inspections. Records reviewed from 5/5/20 were compliant.

The following minor non-conformity was identified:

4.9.2.1- A blue handled box knife was observed in the case sealer area which did not include identification information.

4.9.3 Glass, brittle plastic, ceramics and similar materials

*The Glass and Brittle Plastic Inspection (QA SOP 7) Policy outlined procedures for handling glass and brittle plastic in the facility; breakage procedures included documentation of the incident, responsibility, isolation of the area and potentially affected products, cleaning of the area, inspection and verification to resume production, changing of work wear and inspection of footwear. A Glass and Brittle Plastic List was maintained and included location, type and number of the items present. Daily and monthly inspections were performed to verify the condition of the glass and brittle plastic items. Daily operational records were reviewed from 5/9/20 and monthly recorded inspections were reviewed from the Fabrication Room dated 5/8/2020 and the Ground Beef Room dated 5/4/20. In the Ground Beef Room item G-53 (Pressure gauge) was identified with condensation inside. All records were acceptable. No ceramic steels were used in the production areas. The Glass/Brittle Plastic map was reviewed and found acceptable. Glass training was conducted with the QA Leads and Supervisors on 6/10/20, Training documents were reviewed for plant training from 7/4 and 8/4/20.

4.9.4 Products packed into glass or other brittle containers

*Products were not packed into glass or other hard brittle plastic containers.

4.9.5 Wood

*The Pallet and Spacer Inspection (QA SOP 16) Policy, dated 1/2/20, described the acceptable condition of wooden pallets. Wood was only present in the plant in the form of wooden pallets. Pallets were inspected prior to entry into the production area. Segregated storage was utilized for damaged pallets. Dump stations in the ground beef area were equipped with two stage dumping to minimize the risk of introducing wood into the process.

4.9.6 Other physical contaminants

*Foreign Object Control (CP 10), dated 1/2/20, listed debagging and deboxing procedures outlining methods to prevent raw material contamination due to packaging. The facility used metal detectable pens in processing areas.

4.10 Foreign-body detection and removal equipment

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

*A foreign material risk assessment was included in the HACCP plan outlined in section 2.0. Foreign material detection (Metal Detector Check CP 9 dated 1/2/20) included metal and X-ray detection. Devices were located prior to or after packaging. Device monitoring was conducted at a frequency that met customer requirements. The facility was able to isolate and hold potentially affected product in the event of device failure. Documented checks were reviewed and found acceptable.

4.10.2 Filters and sieves

*Filters and sieves were not present.

4.10.3 Metal detectors and X-ray equipment

Metal was identified as a physical hazard of concern in HACCP hazard analysis. X-ray (Meat Master) detection was utilized on the round line, and the two trim lines in the fabrication area. Equipment was verified hourly using 3.0mm ferrous, non-ferrous, and stainless-steel standards. Metal detection was implemented in ground beef production at initial grind and final grind. Initial grind metal detector was verified prior to use with 7.0 mm ferrous, 8.0 mm non-ferrous, and 9.0 mm stainless steel standards. Final grind line metal detectors were verified hourly using 2.0 mm ferrous, 2.5mm non-ferrous, and 3.0mm stainless-steel standards. Rework ground beef x-ray was also verified prior to passing product through (and hourly while in use) using 0.8 mm ferrous, non-ferrous, and stainless-steel standards. Memory reset of product rejection systems was verified at each test. Records reviewed from the week of 5/4/2020 in association with the vertical audit were properly completed. Checks were compliant with the exception of 5/9/20. The Meat Master went down and product was diverted to a secondary metal detector. Documents were reviewed which indicated the CA and procedures taken to ensure all product passed through a working metal detector. In the event a detection system failed to detect a standard, product was placed on hold to the last acceptable check, product was reworked through a properly functioning system, and additional employees were utilized to perform 100% product inspection.

4.10.4 Magnets

*Magnets were not utilized.

4.10.5 Optical sorting equipment

*Optical sorting equipment was not present.

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

*Product was not packed into glass jars, cans, or other rigid containers.

4.11 Housekeeping and hygiene

The facility was observed visibly clean and maintained in sanitary condition. Sanitation was conducted by a contract sanitation company (PSSI). Sanitors received training at hire and annually on safety, chemical handling, chemical security, titration, allergens, food defense, GMP's HACCP, bacteria control, cleaning

and sanitizing activities, visual inspection, pre-operational inspection, drain cleaning, and equipment specific cleaning techniques. Reviewed employee training documents 6/4-6/6/20 and Supervisor and Lead training on cage security from 5/22/20. Sanitation cleaning instructions were developed and included step-by-step cleaning procedures for cleaning each piece of equipment (including disassembling, if required) or area of the facility. SOP's for the CO^2 mixers for lines 1 and 2, cutting boards and refrigeration units were reviewed. A Master Sanitation Schedule (MSS) was maintained, outlined less than daily cleaning and responsibility. The MSS documented the area cleaned, frequency of cleaning, date cleaned and responsible party. SDS and labels were maintained for each chemical. Reviewed documents for KC-505, liquid alkaline cleaner dated 3/8/2016. Chemical concentrations were monitored daily and weekly by the chemical supplier with titration of each chemical used in the facility. Titration records were reviewed. Chemicals were dispensed using an electronic control panel with recipes for each chemical use and restricted user access. Chemicals could only be transported, mixed, or applied by trained personnel. Sanitation effectiveness was verified through visual inspections of the area/equipment, adenosine triphosphate (ATP) swabbing and microbiological swabbing. Visual inspections were performed on a daily basis following the end of the sanitation shift and documented on the Pre-Operational Inspection form. ATP swabbing of five Harvest, seven Fabrication and five Ground Beef sites was conducted daily. Upper limit was less than three relative light units (RLU's), greater than or equal to three RLU's required corrective actions. CA included re-cleaning and re-swabbing in the event of an ATP failure. Release of the line was conducted after acceptable results. APC swabbing was conducted weekly by sampling five food contact sites from each area (Harvest, Fabrication and Ground Beef). The upper limit was ≤ 100 cfu/cm. CA included re-cleaning and re-swabbing in the event of an APC failure. Records reviewed for the year indicated failures with multiple pieces of equipment involved with the start-up of a grind line on 1/7/20. The equipment was recleaned and resampled with acceptable results. Equipment sampled 5/8/20 and 8/4/20 indicated acceptable results. The air plate action limit was documented at 100 cfu/cm^2 as outlined in the Pre-op policy. Drains were sampled monthly for Listeria and Salmonella. Results from testing were reviewed for the week of 5/4/20. Cleaning equipment was suitable for intended use.

The following non-conformity was identified:

4.11.2- There was no documentation of quarterly cleaning of seven refrigeration units on the Master Sanitation Cleaning Schedule (units 24, 25, 28, 30, 32, 37S and 37N).

4.11.7 Cleaning in place (CIP)

*CIP was not utilized.

4.11.8 Environmental monitoring

*Environmental Testing SOP defined sanitation verification requirements. ATP swabs were collected daily from five contact and non-contact surfaces each in each area, which were selected through a random number generator. Action limit was established at 3 RLU, and corrective actions for swab failures included re-cleaning, sanitizing, and swabbing of tested items. APC swabs were collected from five randomly selected surfaces weekly. Action limit was established at 50,000cfu/sq. cm. Listeria spp. swabs were collected on five randomly selected drains per area per month. Corrective actions in the event of a presumptive positive included intensified cleaning, re-training of sanitation employees, and intensified swabbing. Trending of swab results for 2020 did not identify negative trends. Pre-operational findings, swab failures and results, effectiveness of the environmental monitoring program were reviewed annually, most recently on 1/2/20.

4.12 Waste

Waste was collected in color-coded, dedicated containers and removed from the site on an as needed basis by a third party. A certificate of destruction for SRM product was reviewed from 2/18 and 5/4/20. A license was not required by the state of Idaho for waste removal. Waste flow observed did not pose a product contamination risk.

4.13 Management of surplus food and products for animal feed

Waste collection was provided by a local licensed waste company. A corporate letter regarding the handling of inedible product made into animal feed was provided for review but not required at this site since no products were intended for animal feed. The Surplus Foods and Pet Food Products (QA SOP 12) dated 1/2/20 for customer-branded products explained surplus foods were eligible for plain packaging with generic labels to sell to other customers. Products eligible for employee sale or donation did not meet customer specifications, but met regulatory requirements.

4.14 Pest management

Integrated Pest Management was contracted to Sprague. License, insurance, and certifications were current. Weekly services included interior and ILT traps. Monthly service was provided for exterior bait stations. Interior traps were appropriately located and maintained to prevent contamination. Exterior bait stations were secured and tamper resistant with bait anchored inside. ILTs were appropriately located to prevent contamination of product. A current site map dated 1/14/20 detailed bait stations, interior traps and ILT's. The pest sighting log was maintained including pest, location, additional comments, and action taken. An approved pesticide log, pesticide labels and SDS were available for review. Viewed the SDS and labels for Contract All Weather Blox. Pesticides were not stored on site. An annual survey of the pest control system was conducted by the supervisor of the pest control technician on 1/27/20. The report was reviewed. Service reports included service comments, material summary, open conditions, conditions resolved this visit, pest summary, device summary, area inspections, device inspection details, and material application details. Pest control devices included a barcode for scanning during service. A work request was provided with a corrective action report for recommendations made by the PCO for plant start-up, since then, no issues were identified. Inspections for bird entry points and nesting areas were monitored during monthly inspections. In the event of infestation, or evidence of pest activity action was taken to identify potentially affected product and to minimize the risk of product contamination. Any potentially affected products followed the QA Hold program. Employees received pest awareness training during annual GMP training.

4.15 Storage facilities

The Materials Receiving Policy, dated 1/2/20, defined product, chemical and packaging material storage requirements. Packaging and incoming ingredients were stored separately from finished product. Obsolete packaging materials were tagged and segregated for disposition. Chemicals were stored in totes in the chemical storage area. Carcasses, raw materials and finished products were stored in refrigerated coolers. First in-first-out (FIFO) rotation was verified through the Canopy electronic system. Materials were observed stored off the floor and in racks away from walls. Partially used packaging was returned to the warehouse and properly protected. Each pallet of finished goods was identified with a pallet identification number based on date of production and ensured proper rotation of finished product. Plant Temperatures SOP explained temperatures of refrigerated areas were monitored continuously through an electronic

alarm system. Alarm notifications were received by site management and maintenance technicians in the event ambient temperature parameters were exceeded for more than two hours. Temperatures were visually verified by QA at a frequency of once per production period. Fabrication, offal, and ground beef processing areas were maintained at or below 50F. Product storage coolers and hot boxes were maintained at or below 40F. Storage freezers were maintained at or below 5F. Temperature monitoring and verification records reviewed in association with the vertical audit were within defined parameters.

4.16 Dispatch and transport

*Trailer Inspection Policy (QA SOP 15) dated 1/2/20 outlined trailer acceptability, inspections, general loading requirements, temperatures and product safety prior to shipping and during transport. Trailers were pre-chilled to below 44.6F prior to loading. Trailer conditions were documented on the Trailer Inspection Form. Records reviewed from the week of 5/4/20 demonstrated program compliance. Outbound trailer inspections included temperature monitoring and condition. Forklifts were observed properly maintained to prevent contamination. Temperature monitoring devices were required on trailers depending on customer specific requirements. Transporter agreements outlined securing of trailers during transit, restriction of mixed loads, and actions to take in event or breakdown, accident, or unit failure.

Details of non-applicable clauses with justification

Clause/section reference	Justification
4.3.5	Temporary structures were not present.
4.4.5	There were no suspended ceilings.
4.13	
4.13.1	
4.13.2	
4.13.3	
4.14.3	Pest control was contracted.
4.15.4	Controlled atmosphere storage was not present.

4.15.5	Outside storage was not utilized.
4.9.4.1	Products were not packed into glass or other hard brittle plastic containers.
4.9.4.2	Products were not packed into glass or other hard brittle plastic containers.
4.9.4.3	Products were not packed into glass or other hard brittle plastic containers.
4.10.2.1	Filters and sieves were not present.
4.10.2.2	Filters and sieves were not present.
4.10.4.1	Magnets were not utilized.
4.10.5.1	Optical sorting equipment was not present.
4.10.6.1	Product was not packed into glass jars, cans, or other rigid containers.
4.10.6.2	Product was not packed into glass jars, cans, or other rigid containers.
4.11.7.1	CIP was not utilized.
4.11.7.2	CIP was not utilized.
4.11.7.3	CIP was not utilized.
4.11.7.4	CIP was not utilized.

5. Product control

5.1 Product design/development

*Product Design and Development Policy (QA SOP 11) outlined finished product specification development, new product/changes to formulas, formula maintenance, packaging, and shelf life testing. Initiation of new products were communicated to the site from the corporate sales team. Changes were made by FSQA Manager. Processing trials were conducted during new product development to assess process capability, quality, and safety. HACCP plan review was conducted for new products, ingredients, or changes to existing products. Once approved, trial production and shelf-life testing of sample finished products was conducted. New product shelf life testing included: microbiological, chemical and/or organoleptic criteria. The site had not developed new products in the past twelve months. Records were reviewed from on-going shelf life testing started 2/20/20.

5.2 Product labelling

*The Labeling Products (QA SOP 14) defined the new label approval process and requirements. New labels were approved by USDA/FSIS. Labels were reviewed when changes were made to product specifications, and required approval from the FSQA Manager. Label changes were automatically entered into the electronic printing system. Labels are printed in-house but received from its corporate facility. Label and film verification's were conducted against an approved proof at receiving, once per production period, and at product changeovers. Records reviewed in association with the vertical audit from the week of 5/4/20 and during the facility tour demonstrated program compliance. Label approval was reviewed for Boneless Beef for Cooking Only, dated 6/22/2017 and Natural Beef dated 8/9/2017, records demonstrated compliance.

5.3 Management of allergens

*Allergen ingredients were not utilized at the site. Potential allergen contamination GMP requirements explained hand washing was required after eating and drinking, after using the restroom, and when hands became contaminated. Visitors and contractors received allergen awareness through GMPs at arrival. Risk assessment for potential allergen contamination was included in the HACCP hazard analysis as discussed in section 2 of this assessment.

5.4 Product authenticity, claims and chain of custody

*A vulnerability assessment was conducted on 3/12/2020 for each of the raw materials and ingredients used at the facility. Grade change monitoring form was observed for the period of 5/4 – 5/8/20. Natural products were scheduled first of the day then change-over to regular products. The grades were scheduled starting with highest grade first then allow time for product changes. This is all documented on the grade change form. The assessment included fraud or adulteration, motivations, controls in place, and history of each raw material. The facility kept informed of fraud or adulteration risks through reviewing information from USDA and BIFSCO (Beef Industry Food Safety Council). The facility maintained a Halal Certification, the current certificate was issued by Islamic Society of California. Procedures were implemented to maintain product identity throughout processing. The Carcass Separation Program (SL SOP 1), dated 1/2/20, documented cattle grades as less than/or greater than 30 months and the grading requirements for prime, choice and select. Yields were conducted daily by accounting personnel to ensure

mass balance was achieved. The Beef Vulnerability Assessment was dated 3/12/20 and was reviewed annually, or as needed.

5.5 Product packaging

*Packaging specifications and certificates of conformity were maintained for each packaging material supplier. Packaging materials were verified at receiving by QA and were stored away from ingredients and finished products. Raw material liners used in processing were appropriately colored and tear resistant. Storage Procedures (FAB SOP 17) dated 1/2/20 described obsolete packaging and labels were segregated from use until disposition. No packaging materials were discarded in the past 12 months. Approved supplier Sealed Air documents consisted of GFSI certification, Certificate of Conformance dated 1/19/20, and Letter of Guarantee (LOG) dated 1/12/20. Packaging material supplier BMSI (Veritive distributor) sent COC dated 11/6/2019.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

*Finished product testing conducted included E coli, APC, total coliforms and Salmonella. Microbiological testing for 21 day old 80 Lean Ground Beef was conducted on 2/20/20 and included APC, lactic acid bacteria, organoleptic analysis, appearance, package integrity, color, odor and texture. Records were also reviewed for 7 Day SL 90 Lean Boneless Trim on 2/28/20, 45-day SL Hand trim Shuck Roll. Results were acceptable. Shelf-Life Study (QA SOP 20) outlined the bi-annual requirements (or as needed) of conducting shelf-life analysis. Shelf life testing was conducted on an ongoing basis. Products were evaluated for organoleptic qualities, aerobic plate count (APC), upper limit greater than or equal to 50,000 cfu/cm2, and Lactic Acid Bacteria at pre-determined intervals up to the stated shelf life. Shelf life testing reports supported current shelf life claims. Generic E. coli 1 out of 300 head produced per regulatory requirements was conducted in harvest. Swabs were conducted quarterly on 10 head at hide on, hide off, after pre-wash, before hot water, after hot water, after lactic, after chill, after ASC. Swabs were analyzed for APC and results from 2019 and 2020 quarters were provided for review. Variety meats (hearts, head meat, cheek meat, salivary glands) were sampled for E. coli O157:H7 each lot produced where a lot was a production day. Trim was sampled for E. coli O157:H7 on each bin produced with up to five bins considered as a lot. Ground beef was sampled E. coli O157:H7 per customer request on every 10,000 pounds produced for that customer. APC, coliform, and generic E. coli sampling was conducted per 10,000 pounds of ground beef produced per customer requirements.

5.6.2 Laboratory testing

*The facility utilized a third party laboratory for routine and pathogen testing. Laboratory utilized maintained ISO/IEC 17025:2005 accreditation through A2LA with a certificate valid until 7/31/21. An onsite laboratory was not in use.

5.7 Product release

Products were subject to pre-shipment records review in accordance with regulatory requirements conducted at the end of each production day. If product was not identified out of specification or placed on hold for any reason, it was acceptable to ship. Finished products were released via the On Hold and

Release Policy by QA after record review of CCP monitoring and batch information was completed, and finished product testing was complete. A lot was defined as between one and five combos. Products requiring positive release were head/cheek/salivary glands. Customer requirements dictated sampling. If a positive result was obtained from the lab it was placed on QA hold, if present. If not, product was returned or stopped from delivering. Affected product on hold was then used for cooking only. Once a cooker was found the product was shipped, case counts verified and cooker sends verification of lethality of cook. Record reviewed from 2/19/20 with lethality treatment on 4/3 and 4/6/20.

5.8 Pet Food

Pet food was not produced on site.

Details of non-applicable clauses with justification

Clause/section reference	Justification
5.2.3	Claims were not made.
5.3.2	Allergens were not utilized.
5.3.3	Allergens were not utilized.
5.3.4	Allergens were not utilized.
5.3.5	Allergens were not utilized.
5.3.6	Allergens were not utilized.
5.3.7	Allergens were not utilized.
5.3.8	Allergens were not utilized.
5.8	Pet food was not produced on site.
5.8.1	Pet food was not produced on site.

5.8.2	Pet food was not produced on site.
5.8.3	Pet food was not produced on site.
5.6.2.2	An onsite laboratory was not present at the facility.

6. Process control

6.1 Control of operations

The Validation Study for E. coli O157:H7, Salmonella, and Listeria monocytogenes in Ground Turkey and Beef conducted by R.Y. Murphy et. al involved a cross-functional team from the University of Arkansas, dated 2004 was used to support the decision to note their products were required cooking to 165F. Specifications outlined component assembly, code date, and packaging requirements. Specifications were utilized to communicate processing activities to employees on each line. Product quality audits were completed on each product category. Equipment adjustments were made by authorized individuals. Critical areas were either locked by a key or code access such as metal detectors, x-rays, equipment adjustments, mechanical areas and process computers. Incoming materials were inspected for product integrity. Product changeovers were monitored and recorded on the processing paperwork. Label and code date verification was completed once a period or at each product change over and recorded on the audit form which included a control label. Metal detection, x-ray and scale calibration verification were recorded on operational forms. In the event of a deviation, products were retained and assessed for quality and safety prior to release. Corrective and preventive actions were recorded on the corrective action form.

6.2 Labelling and pack control

Grade Change Policy (QA SOP 34), dated 1/2/20, stated label verification was conducted at receiving for accuracy of information. Labels were also verified when issued to production, change-overs, and end of shift. Line clearance verification was included on the Product Change Monitoring Form. Product change-overs were observed and found acceptable. Labels were removed from the line and the current product label was placed in-line. Records were reviewed from the week of 5/4/20 and acceptable. A Boxed Product Return form, dated 1/2/20, was reviewed from 5/9/20 with documented checks conducted for the day. Production employees documented non-conforming label issues and notified QA for correction with documented release.

6.3 Quantity, weight, volume and number control

Finished product (individual package or case weight) sold as net weight was in accordance with NIST 133 handbook. Net weight verification was conducted every hour of production and documented on the Box Weight Inspection Check (GB SOP 10). Maximum allowable variances (MAV) were established for each finished product weight. When an MAV limit was exceeded products were retained to the last acceptable check. Tares were verified at the beginning of production and at change-overs. Products were required to

meet the stated package weight and labels were pre-printed. Checkweigher verification was performed daily by the maintenance staff. Scale Calibration Check (GB SOP 14), dated 1/2/20, lists procedures to ensure the scales were functioning properly. Records reviewed from the week of 5/4/20 were completed at the established frequency and met product stated weights. A third-party check of the scales was completed annually.

6.4 Calibration and control of measuring and monitoring devices

Equipment Calibration Policy outlined calibration frequencies of thermometers, scales, pH meter, moisture meter, and water meters. Thermometers were calibrated daily using the methods recommended by Kansas State University. The method included using dial and digital thermometers and an NIST certified thermometer. The NIST certification was dated 4/24/20. Scales were calibrated annually, valid through USDA Packers and Stockyards Program, and verified daily using certified weights valid through 3/12/21. The In-line Fabrication Carcass Cabinet pH meter was calibrated quarterly by a third-party vendor utilizing 4.0 and 7.0 buffer solution standards in accordance with manufacturer's directions. Records were reviewed and demonstrated compliance. Product measured with equipment found significantly out of calibration followed the On-Hold and Release Policy. Devices which could not be calibrated were removed from service. Procedures in the calibration policy listed instructions for product assessment in the event a device was found out of calibration.

Details of non-applicable clauses with justification

Clause/section reference	Justification

7. Personnel

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

Training was conducted at date of hire and annually for employees and included good manufacturing practices (GMPs), sanitation, HACCP, chemical control, food defense, allergens, pest awareness, and job specific tasks. Temporary employees were not employed. Visitors were required to sign in, read the visitors policy including GMPs, hand washing procedures and ammonia awareness and show identification. CCP training was conducted annually as job specific tasks. CCP training records were verified for CCP monitors observed during the on-site assessment. Employees related to packaging were appropriately trained. Training records reviewed from 4/13 and 4/14/20 for the Fabrication department, 5/19 and 8/5/20 for Harvest and 6/15-6/22 for Ground Beef. The records included date, trainer, trainee,

duration, and topic. Training competency was assessed through on the job observation and quizzes. Internal training reference materials were maintained.

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

GMP Policy outlined hygiene requirements. Jewelry including watches, false nails, and nail polish were not permitted in the facility. Strongly scented after shave or perfume was not permitted. Hand washing was required before and after work, after every break, including lunch, smoke and restroom breaks. GMPs were monitored daily by QA. Blue metal detectable bandages were provided for employees with minor cuts and covered with a glove. Metal detection checks on bandages were performed and the purchase order number was recorded to enable tracking. Records were reviewed from 7/6/20 and demonstrated compliance with the program. Personal medicines were stored in employee lockers and not permitted on the production floor without a doctor's note.

7.3 Medical screening

QA SOP 1 GMP Policy outlined persons with communicable disease, infected or open boils, lesions and sores were not permitted in production or storage areas. Persons with such symptoms were to report conditions to supervisors or management. Visitor Policy outlined requirements for visitor health requirements. COVID-19 monitoring procedures put in place were: Temperatures monitored by IR, health screening at entrance, hand sanitizer stations installed all over the facility, hygiene/hand washing focus, plexiglass dividers installed in break areas, mask wearing for all employees, barriers in hallway to aid in one-way single file lines, temperature checks at break times and visitor screening/temperature monitoring.

7.4 Protective clothing: employees or visitors to production areas

Protective clothing requirements were outlined in the GMP Policy. Protective clothing was defined as plant coats and uniforms. Color coded frocks were provided with snap closures and without pockets above the waist. Frocks were laundered by a third-party service provider, delivered protected and stored separately from dirty laundry. ATP swabs were conducted on employee frocks daily. Records were reviewed from 9/17/20 with acceptable results. The results were totaled to date and trended. Hairnets and beard nets were required in processing areas. Mustaches were covered per company policy. Protective clothing was changed upon soiling or as needed, at least daily. Employees handling product were required to wear blue plastic disposable gloves. Gloves, arm guards, and aprons were cleaned or changed as often as necessary to prevent product contamination.

Details of non-applicable clauses with justification

Clause/section reference	Justification

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
Low-risk.
8.2 Building fabric in high-risk and high-care zones
Low-risk.
8.3 Maintenance in high-risk and high-care zones
Low-risk.
8.4 Staff facilities for high-risk and high-care zones
Low-risk.
8.5 Housekeeping and hygiene in the high-risk high-care zones
Low-risk.
8.6 Waste/Waste disposal in high risk, high care zones
Low-risk.
8.7 Protective clothing in the high-risk high-care zones
Low-risk.

Details of non-applicable clauses with justification

Clause/section reference	Justification
8.1	Low-risk.

8.1.1	Low-risk.
8.1.2	Low-risk.
8.1.3	Low-risk.
8.1.4	Low-risk.
8.2.1	Low-risk.
8.2.2	Low-risk.
8.3.1	Low-risk.
8.3.2	Low-risk.
8.3.3	Low-risk.
8.4.1	Low-risk.
8.5.1	Low-risk.
8.5.2	Low-risk.
8.5.3	Low-risk.
8.6.1	Low-risk.
8.7.1	Low-risk.
8.7.2	Low-risk.

8.7.3	Low-risk.

9 - Traded Products

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

Voluntary Module not Included.

9.2 Specifications

Voluntary Module not Included.

9.3 Product inspection and laboratory testing

Voluntary Module not Included.

9.4 Product legality

Voluntary Module not Included.

9.5 Traceability

Voluntary Module not Included.

Module 11: Meat supply chain assurance

Scope	

11.1 Traceability

Voluntary Module not Included.

11.2 Approval of meat supply chain

Voluntary Module not Included.

11.3 Raw material receipt and inspection

Voluntary Module not Included.

11.4 Management of cross-contamination between species
Voluntary Module not Included.
11.5 Product testing
Voluntary Module not Included.
11.6 Training
Voluntary Module not Included.

Module 12: AOECS Gluten-free Foods

Scope	
12.1 Senior management	
Voluntary Module not Included.	
12.2 Management of suppliers of raw materials and packaging	
Voluntary Module not Included.	
12.3 Outsourced production	
Voluntary Module not Included.	
12.4 Specifications	
Voluntary Module not Included.	

12.5 Management of gluten cross-contamination
Voluntary Module not Included.
12.6 Management of incidents, product withdrawal and product recall
Voluntary Module not Included.
12.7 Labelling
Voluntary Module not Included.
12.8 Product inspection and laboratory testing
Voluntary Module not Included.

Module 13 FSMA Preventive Controls Preparedness Module

Version 2 July 2018

Item no.	Clause	Module item	Conforms (Y/N) or Not Applicable (NA)	Comments
1	13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.	NA	Voluntary Module not Included.
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping	NA	Voluntary Module not Included.

		systems that discharge waste water or sewage.		
3	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.	NA	Voluntary Module not Included.
4	13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.	NA	Voluntary Module not Included.
5	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.	NA	Voluntary Module not Included.
6	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	NA	Voluntary Module not Included.

		• Unintentional adulterants which affect food safety		
7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine “hazards requiring a preventive control” (i.e., significant hazards).	NA	Voluntary Module not Included.
8	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.	NA	Voluntary Module not Included.
9	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	NA	Voluntary Module not Included.
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.	NA	Voluntary Module not Included.
11	13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7.	NA	Voluntary Module not Included.

		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).		
12	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.	NA	Voluntary Module not Included.
13	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.	NA	Voluntary Module not Included.
14	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	NA	Voluntary Module not Included.

15	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	NA	Voluntary Module not Included.
16	13.1.16	Devices used to verify preventive controls must be calibrated.	NA	Voluntary Module not Included.
17	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.	NA	Voluntary Module not Included.
18	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	NA	Voluntary Module not Included.
19	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.	NA	Voluntary Module not Included.

20	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.	NA	Voluntary Module not Included.
21	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.	NA	Voluntary Module not Included.
22	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.	NA	Voluntary Module not Included.
23	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.	NA	Voluntary Module not Included.
24	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:	NA	Voluntary Module not Included.

		- 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.		
25	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.	NA	Voluntary Module not Included.
26	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	NA	Voluntary Module not Included.

		• Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
27	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.	NA	Voluntary Module not Included.
28	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.	NA	Voluntary Module not Included.
29	13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies.	NA	Voluntary Module not Included.

		Procedures shall include recordkeeping requirements for all monitoring activities.		
30	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	NA	Voluntary Module not Included.
31	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	NA	Voluntary Module not Included.

32	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	NA	Voluntary Module not Included.
33	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	NA	Voluntary Module not Included.
34	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.	NA	Voluntary Module not Included.
35	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.	NA	Voluntary Module not Included.

36	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.	NA	Voluntary Module not Included.
37	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.	NA	Voluntary Module not Included.
38	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	NA	Voluntary Module not Included.

		the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	NA	Voluntary Module not Included.
40	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.	NA	Voluntary Module not Included.
41	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	NA	Voluntary Module not Included.
42	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	NA	Voluntary Module not Included.

		address those potential problems • Responsibilities of the carrier		
43	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.	NA	Voluntary Module not Included.
44	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.	NA	Voluntary Module not Included.
45	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	NA	Voluntary Module not Included.
46	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	NA	Voluntary Module not Included.

		• Correcting problems with harvest containers or equipment		
47	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.	NA	Voluntary Module not Included.
48	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.	NA	Voluntary Module not Included.
49	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.	NA	Voluntary Module not Included.
50	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.	NA	Voluntary Module not Included.
51	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.	NA	Voluntary Module not Included.

52	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.	NA	Voluntary Module not Included.
53	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.	NA	Voluntary Module not Included.
54	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.	NA	Voluntary Module not Included.
55	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.	NA	Voluntary Module not Included.

		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.		
56	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.	NA	Voluntary Module not Included.
57	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.	NA	Voluntary Module not Included.
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	NA	Voluntary Module not Included.
59	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.	NA	Voluntary Module not Included.
60	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.	NA	Voluntary Module not Included.

61	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).	NA	Voluntary Module not Included.
62	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	NA	Voluntary Module not Included.

		• 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		