Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	Tyson Foods - Emporia	Site Code	1424701
Site name	Tyson Foods - Emporia		
Scope of audit	Portion cutting and repacking of fresh sub-primal beef and pork, grinding of beef and Pork, marination of portioned chicken, beef and pork, and ready to cook chicken, seasoning; packaged in corrugated boxes, bulk, brick pack, and vacuum packaging.		
Exclusions from scope	None		
Justification for exclusion	-		
Audit Finish Date	2020-08-20		
Re-audit due date	2021-08-20		

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

Head Office	No

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	A	Previous audit date	2019-04-04		
Certificate issue date	2020-09-23	Certificate expiry date	2021-10-01		

Number of non-conformities	Fundamental	0
	Critical	0

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	Major	0
	Minor	4

3.Company Details

Address	2101 West 6th Avenue Emporia, Kansas 66801		
Country	United States	Site Telephone Number	620 340 1212
Commercial representative Name	Doug Griffin - Director of Operations	Email	doug.griffin@tyson.com
Technical representative Name	Belinda Moore - FSQA Manager	Email	belinda.moore@tyson.com

4.Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	501-1500	No. of HACCP plans	1-3

Shift Pattern	Two eight hour production shifts were operated from 05:45 to 14:15 and from 15:00 to 23:30. Shifts were operated five days per week for raw not ground and six days per week for raw ground. One contract sanitation shift was operated from 00:00 to 05:45.
Subcontracted processes	No
Other certificates held	None
Regions exported to	Asia North America South America

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4.Company Profile

Company registration number	245D, P245D
Major changes since last BRCGS audit	Major changes since the last BRC audit had not occurred.

Company Description

Tyson Foods Emporia was built in 1969 and underwent expansion in the spring of 2002. Factility was restructured in February 2008 when slaguhterhouse operations were removed and prepared meats were introduced. Presently, the plant covers approximately 27,439 square feet on two levels. Products produced included raw ground beef and pork, and raw not ground beef, pork, and chicken products. Products were intended for further processing, retail, foodservice, and cooking by the end consumer. Seven lines were operated including two value added, two grind, one trim, and one customer branded line. Staffing was approximately 1,000 employees including management. Two eight hour production shifts were operated from 05:45 to 14:15 and from 15:00 to 23:30. Shifts were operated five days per week for raw not ground and six days per week for raw ground. One contract sanitation shift was operated from 00:00 to 05:45.

5.Product Characteristics

Product categories	03 - Raw prepared products (meat and vegetarian)				
Finished product safety rationale	Low Risk - Raw meat products were produced, stored and shipped under 45F. Products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.				
High care	No	High risk	No	Ambient high care	No
Justification for area	Low Risk - Facility produced raw meat products intended for further processing or cooking prior to consumption. Differing species and allergen containing products were controlled through production scheduling and pre-requisite programs. Team members were assigned to work in each production area.				
Allergens handled on site	Cereals containing gluten Soya Milk				
Product claims made e.g. IP, organic	Natural (Minimal Processing), Certified Angus Beef, and No Antibiotics Ever (NAE) claims were made on finished raw meat products.				
Product recalls in last 12 Months	No				

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5.Product Characteristics

Products in production at the time of the audit	Facility was producing beef subprimals, ground beef chubs, and bagged roasts.

6.Audit Duration Details

On-site duration	24 man hours	Duration of production facility inspection	12 man hours
Reasons for deviation from typical or expected audit duration	Facility was well prepared with documentation readily available for review.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1	2020-08-18	08:00	17:00
2	2020-08-19	05:00	16:00
3	2020-08-20	07:00	10:00

	Auditor (s) number	Name	Role
Auditor Number	258028	Jay Anderson	Lead Auditor
Second Auditor Number	N/A	N/A	Auditor

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
Doug Griffin / Director of Operations	X			X
Belinda Moore/ FSQA Manager	X	X	X	X

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Present at audit				
Mike Hippen / Sr. Production Manager	X	X		X
Gary Sparks / Warehouse Manager	X	X		X
Fredell Moore / Sr. Production Manager	X	X		X
Chris Singleton / Sr. FSQA Supervisor		X	X	
Pam Purdum / Safety Manager	X			X
Lynn McAllister / Industrial Engineer	X			X
LaDeana Wigton / Human Resources Manager	X			X
Raul Santiago / Sr. Production Manager		X		
Krystal Collier / Controller	X			X
Nelson Ramirez / Sr. HACCP Supervisor	X	X	X	X
Ryan Smith / Sr. Maintenance Manager	X	X	X	X
Robert Pugh / Sr. Maintenance Manager	X	X		

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced
2020-08-20	BRC, Food Safety Standard	Announced

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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**

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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	3.2.1	Issue Sheet Form with a current revision date of 03/06/19 was used to document ingredient and packaging lot identification numbers used in production. After review of the Master Document Listing, the latest revision date was identified as 03/21/19	The electronic folder and paper document folder were reviewed and old forms removed.	The administrative assistant was trained on steps for record keeping to keep paper documents current.	The root cause was identified to be the team member completing the film lot numbers had the correct form while the team member completing the ingredient lot numbers did not have the correct form. The film lot numbers are being	2020-09-08	Jay Anderson

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		indicating the current version was not in use.			typed into the new spreadsheet for tracking. The ingredient lot numbers were being completed on the form by taking the form to the ingredient issue area for documentation completion. The paper folder had not been updated with the updated sheet.		
2	4.6.1	An incomplete weld was observed on the A line auger hopper framework creating a potential microbiological harborage point. The incomplete weld was corrected prior to the closure of the audit.	The bad weld was repaired.	The maintenance training has been updated for identification of good and bad welds.	The bad weld had been completed when repairs to the chute had been done.	2020-09-10	Jay Anderson
3	4.9.1.1	Food grade and non-food grade lubricants were observed co-mingled in a labeled and designated non-food grade area of the lubricant storage cabinet.	The food grade and non-food grade lubricants were located to the correct shelf.	An additional cabinet has been purchased to have separate cabinets for food grade and non-food grade to prevent the co-mingling.	The container had been put onto the shelf for the food grade and non-food grade that was inaccurate.	2020-09-08	Jay Anderson

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4	4.11.3	Pre-Op Sanitizer Verification electronic record from 06/16/20, completed by plant personnel, documented a final sanitizer concentration result that was unacceptable. This verification result was taken from the direct observation of contract sanitation personnel titrating the chemical and their concentration result. Chemical Concentration log for 06/16/20 from the contract sanitation team indicated that the titrated concentration was acceptable. Control limits in the electronic system did not identify the out of compliance result as unacceptable.	The deficiency was reviewed with the FSQA team on 8/21/20.	The sanitizer verification electronic documentation has been modified for an alarm when under or over the ppm limit.	The team member had entered the wrong sanitize level into the electronic system. The incorrect level was over the criteria that would result in a potable water rinse to be completed. No actions were documented.	2020-09-08	Jay Anderson

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Comments on non-conformities

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Additional Modules / Head Office Non-Conformity Summary Sheet

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

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

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

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Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Food Safety and Quality Policy outlined senior management's commitment to producing safe, legal products meeting customer's expectations and assuring product quality through customer expectations, product specifications, regulatory requirements, product wholesomeness, and expected profitability. Policy was signed by the Complex Manager and communicated to employees through posting in common areas of the facility.

Annual Tyson Food Safety Culture Review for 2020 outlined assessment of GMP inspections, reported food safety and quality assurance concerns, product analysis results, training competency, audit outcomes, monthly meeting minutes, and action items. Food Safety Culture Action plan was deemed effective through review but actions were taken including updating GMP training, implementation of weekly training on food safety and quality assurance topics, quarterly newsletter communication for employees, and quarterly workshops targeting training improvement opportunities. The Food Safety Culture Action Plan was evaluated on an annual basis, most recently on 03/02/2020. Published Quarterly Newsletter for June 2020 demonstrated evidence of implementation.

Established Food Safety and Quality Assurance Objectives targeted less than one percent E. coli O157:H7 and STEC prevalence, reduction in quality and customer incidents from prior year, pass all third party audits inclusive of GFSI and customer addendums, and forty million pounds of quality finished products for customers. Goals were reviewed on a quarterly basis, most recently on 07/10/2020 for the third quarter. Objectives were observed met at the time of the audit. For objectives that were not met, underlying reasons were discussed and action plans were determined for mitigation of missed targets.

Meetings were held twice per month for food safety, once per month for quality assurance related topics, and monthly for foreign material review (internal and external findings). Weekly meetings were conducted with the contract sanitation team and FSIS personnel. Agenda items for meetings included review of previous meeting minutes, non-conformance reports, PHR rate, third party and internal audit results, customer complaints, food defense updates, sanitation performance, pre-requisite program review, HACCP, SSOP, and SPS updates, pest control, and new equipment or facility modifications. Meetings included action items and estimated completion dates. Records from June 2020 to date evidenced compliance. Quality meetings discussed follow up issues from previous meetings, pending processing changes, and claim investigations. Meeting minutes from May and June 2020 demonstrated compliance.

A confidential reporting hotline and email contact were established for anonymous reporting of food safety and quality assurance concerns. Signage was present in common areas communicating contact information to employees. Concerns reported through the system were documented and forwarded to the Ethics and Compliance Department for review. Concerns were then sent to relevant department managers for investigation. At the time of the audit, food safety and quality assurance concerns had not been reported.

Financial resources provided for 2019 to 2020 capital improvement included a new header for the hot water system, make up air unit, facility modifications in response to the pandemic, and replacement of x-ray systems for foreign material detection on sub-primal processing lines. FSQA department was staffed

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with twenty four employees for implementation and monitoring of food safety and quality assurance programs.

Senior management was made aware of food fraud updates and regulatory changes through weekly emails from Corporate FSQA Management. Weekly meetings were held with USDA-FSIS personnel discussing updates to relevant regulations. FSQA management maintained email subscriptions with USDA-FSIS and relevant industry subscriptions. Weekly emails shown from May 2020 demonstrated compliance.

Physical and electronic copies of the standard were available. Director of Operations was present in the opening and closing meetings. Certification audit occurred in the required time frame from the certificate extension. Recurring non-conformances were not observed. BRC log was not used.

1.2 Organisational structure, responsibilities and management authority

Emporia Organizational Chart depicted management reporting structures from the Senior Vice President to the technician level. FSQA Manager reported to the Associate Director of FSQA. Organizational Structure, Responsibilities, and Management Authority outlined the deputy reporting structure in cases of absence. FSQA Manager was backed up by the Senior HACCP Coordinator.

Employees were made aware of their responsibilities through Job Safety Analysis (JSA) documents detailing area, equipment used, potential hazards, control methods, personal protective equipment, and any specialized training. JSAs for Boxing and Palletizing Boxes Operator and Blender Operator demonstrated compliance. JSAs were provided at new hire orientation and reviewed with employees as part of an annual refresher training.

Details of non-applicable clauses with justification

Clause/Section reference	Justification
1.1.13	BRC log was not used.

2 The Food Safety Plan – HACCP

A multi-disciplined HACCP team was established for management of fourteen Codex Alimentarius based HACCP plans. Plans were very similar including grinding of beef and pork, and not ground beef, pork, and poultry products. HACCP Team included the Complex Manager, Maintenance Superintendent, Production Managers, Material Handling Superintendent, Processing Managers, HACCP Coordinator, FSQA Superintendent, Safety Coordinator, Industrial Engineer, Plant Engineer, Human Resources Manager, Health Services Manager, General Foreman, and Project Engineer. Team was led by FSQA Manager whom was qualified through external HACCP certification and years of experience. Pre-

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Requisite Programs supporting the HACCP plans included: SPS Program, E. coli O157:H7 Testing Procedure, Raw Material Receiving, Returned Goods, Foreign Material Control, Product Testing, Supplier Approval, SSOPs, Allergen Control, Maintenance, and Temperature Control. Monitoring procedures, corrective actions, and forms were defined within each pre-requisite program.

Process Category Descriptions included common name, composition, intended use, packaging requirements, shelf life, intended customer, intended consumer, labeling instructions, and distribution controls. Intended use included general population with reference to products labeled for allergy sufferers. Flow diagrams were established depicting the process from raw materials to finished products including processing inputs, outputs, steps, rework, inedible/waste, and critical control points. Flow diagrams were verified for accuracy on an annual basis through onsite-review and documented as part of the HACCP reassessment. Accuracy verification from January 2020 demonstrated compliance. Hazard analysis and critical limit support was based on FSIS regulations, directives (7120.1, 10010.1) internal decision making documents, and scientific validations (Olsen, 1998 for foreign material control, Tompkins Study for temperature). Process steps for the HACCP plans including receiving of previously tested negative (E. coli O157:H7) beef raw material, receiving of pork and poultry, storage, dumping/ deboxing, grinding/ portioning, packaging, storage, and shipment of finished product.

Hazard analysis was conducted with Codex Alimentarius -based logic decision trees determining that the following chemical/allergen, physical, microbiological hazards were likely to occur: refrigerants, cleaning compounds, sanitizers, plastic, metal, wood, paper, bones, paper, rubber, BSE/SRM, STEC, E. coli O157:H7, Salmonella, Campylobacter jejuni/coli lubricants, allergens (milk, soy, wheat), ASC, and PAA. Radiological hazards were determined not likely to occur. Fraud assessment was outlined in section 5.4 of the audit. Malicious contamination controls were outlined in section 4.2 of the audit.

Critical Control Points were determined necessary for the control of physical and microbiological hazards identified in the fourteen HACCP plans:

Raw Not Ground:

Beef and Pork NG1 - Raw material surface temperature with a critical limit of less than 45F. Six temperatures were taken prior to the start of the shift by trained QA personnel or designee.

Beef and Pork NG2 - Internal Product Temperature with a critical limit of less than 45F. Internal product temperatures were taken twice per production period by trained QA personnel or designee.

Beef NG3 - Raw material surface temperature with a critical limit of less than 45F. Six temperatures were taken prior to the start of the shift by trained QA personnel or designee.

Beef NG4 - Disposition of Positive Trim with a critical limit of non-negative product. Product was distributed to an approved FSIS establishment with validated lethality treatment. Product amounts were reconciled for verification.

Beef NG6 - ASC application with critical limits of concentration 500 ppm to 1200 ppm and pH of 2.3 to 2.9 pH, greater than or equal to 12 seconds of dwell time in the ASC cabinet, and minimum flow rate of 0.9 gallons per minute monitored once per period per shift by trained QA personnel or designee. Points were identified on the product belt for determination of dwell time with a NIST stopwatch.

Beef NG7 Primals Subprimals intervention - ASC application with critical limits of concentration 500 ppm to 1200 ppm and pH of 2.3 to 2.9 pH, greater than or equal to 12 seconds of dwell time, and 0.9 gallons per minute flow rate monitored once per period per shift by trained QA personnel or designee.

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Poultry NG5 - Raw material surface temperature with a critical limit of less than 45F. Six temperatures were taken prior to the start of the shift by trained QA personnel or designee.

Raw Ground

Beef GB2, Beef and Pork RG1, and RG3 - Metal Detection - with critical limit of rejection at 2.5mm ferrous, 3.5mm non-ferrous, and 5.0mm stainless steel. Metal detectors were checked prior to shift and hourly after by trained QA personnel or designee.

Beef RG2 - Metal Detection - with critical limit of rejection at 1.0mm ferrous, 1.5mm non-ferrous, and 3.0mm stainless steel. Metal detectors were checked prior to shift and hourly after by trained QA personnel or designee.

Pork RG4 Brick - Metal Detection - with critical limit of rejection at 2.5mm ferrous, 3.5mm non-ferrous, and 5.0mm stainless steel. Metal detectors were checked prior to shift and hourly after by trained QA personnel or designee.

Corrective actions for Critical Control Point deviations were taken in accordance with 9 CFR 417.3(a) and included that the cause of the deviation was identified and eliminated, CCP was brought under control after corrective actions were taken, measures to prevent recurrence were established, and that product injurious to health did not enter commerce. Corrective action taken for concentration critical limit deviation on 04/07/2020 identified root cause, corrective actions, investigation details, established preventive measures, and verification of corrective action completion.

Verification activities included calibration of thermometers once per shift, hourly calibration of pH meters, direct observation or monitoring activities once per week, direct observation of corrective actions at the time of occurrence, daily record review, and daily pre-shipment review in accordance with 9 CFR 417. Records included electronic CCP monitoring records, corrective actions, and electronic pre-shipment review. CCP monitoring was conducted electronically with use of tablets. Monitoring records reviewed in association with the vertical audit discussed in 3.9 of this report included date, time, result of monitoring activities, and initials of the monitoring personnel. Reassessments were conducted on an annual basis or when changes occurred and documented on the HACCP/SSOP Change Log. Beef HACCP Reassessments dated January 2020 and Pork HACCP dated May 2020 demonstrated compliance.

Details of non-applicable clauses with justification

Clause/section reference	Justification

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3. Food safety and quality management system

3.1 Food safety and quality manual

Food Safety and Quality Procedures were retained in physical and electronic form and available upon request. Electronic system records and procedures were backed up on a nightly basis. Procedures reviewed during the vertical audit were authentic, legible, and clear. Procedures were translated into Spanish as needed. Employees were made aware of their responsibilities through JSA (Job Safety Analysis) documents detailing area, equipment used, potential hazards, methods of control, personal protective equipment, and any specialized training. JSAs for Boxing and Palletizing Boxes and Blender Operator positions demonstrated compliance. JSAs were provided at new hire orientation and reviewed as part of an annual refresher training.

3.2 Document Control

Record Keeping Policy outlined control requirements for food safety and quality assurance documents. Documents were labeled with confidentiality indication and a header. Header identified each document by name, revision date, and approval. FSQA Manager was responsible for the approval of documents. Revision log was maintained with each procedure that included revised date, reason for revision, and authorization. Obsolete documents were destroyed when changes were made. An Electronic Master Document Listing included forms used for food safety and quality assurance by document name, revision date, and revision reason. Electronic forms were stored on a secured network server backed up on a nightly basis.

The following non-conformity was identified:

3.2.1 - Issue Sheet Form with a current revision date of 03/06/19 was used to document ingredient and packaging lot identification numbers used in production. After review of the Master Document Listing, the latest revision date was identified as 03/21/19 indicating the current version was not in use.

3.3 Record completion and maintenance

Record Keeping SOP outlined completion requirements for food safety and quality assurance records. Use of correction fluid was prohibited. Alterations were made with a single line through the error and initialed authorizing the mistake. Pencil was not permitted on records. Records reviewed during the vertical audit were genuine, legible, and readily accessible. Changes to electronic records required a password authorization. Records were retained for three years at minimum with the longest product shelf life at 180 days. Retention schedule was in compliance with customer requirements.

3.4 Internal audits

Tyson Internal Audit Program Assessment outlined the risk based schedule for audits conducted. Audits were required on an annual basis at minimum with exception of GMP audits conducted on a monthly basis. Internal Audit Program outlined requirements for internal audits. Auditors were internally trained and were independent of the areas that they audited. Trained auditors included the Senior HACCP Specialist, Director of FSQA Beef Division, Divisional Manager of FSQA Beef Division, and Qualified Plant FSQA Manager Beef/Pork/Poultry division. An annual Food Safety Review (FSR) was conducted on 01/20/20 to 01/21/20. Template included clause, requirement, response, and evidence used to support conformance or non-conformance. Four audit dates included audits completed in January 2020, May 2020, June 2020, and July 2020.

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Corrective Actions were documented in the Corrective Action Log that included section, clause, deficiency, root cause, action plan, and responsible personnel. An annual Food Fraud Assessment was conducted by Corporate FSQA Management. Additional audits conducted included an annual Quality System Review (QSR) conducted from 07/29/20 to 07/31/20, monthly Allergen Management Program Verification Audit from 6/28/2020, monthly food security audit from 6/26/2020, night sanitation audit on a monthly basis from 6/25/2020, SSOP monthly verification from 06/26/2020, monthly SPS audit verifying sanitary conditions in accordance with 9 CFR 416. Audits included clause, requirement, level of conformity, and objective evidence reviewed for compliance. Audit scopes included HACCP, Pre-Requisite Programs, food defense, and procedures implemented for BRCGS compliance.

A Monthly GMP audit was conducted reviewing production, storage, and exterior areas for potential sources of product contamination, insanitary conditions, or housekeeping observations that could contribute to a food safety hazard. Inspection record from 06/26/2020 demonstrated compliance. Audit included corrective actions, identification if an issue was a recurring issue, and estimated completion dates.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Risk assessments for raw and packaging materials were conducted in conjunction with the HACCP hazard analysis. Approved Supplier Procedures outlined approval and monitoring of suppliers. Suppliers were initially and continually approved based on receipt of a third party GFSI audit and/or questionnaire and letter of guarantee. Suppliers approved based on questionnaire results submitted third party audit results, certificate(s), and corrective actions taken for deficiencies noted. Questionnaires included traceability system verification and were updated every three years at minimum. Questionnaire for the Sodium Erythorbate supplier demonstrated compliance. Supplier Approval was completed by Corporate Strategic Personnel. Brokers were not used. An Approved Supplier Listing was available in the electronic FoodLogiq system including documentation used for approval. Monitoring was conducted on an annual basis at minimum including review of documentation and supplier performance. Emergency supplies were approved by Corporate FSQA Management and included requirements for letters of guarantee and a 60 to 90 day monitoring period of supplier performance. Customer branded product vendors provided required packaging materials and ingredients through emails and internal procedures. Third party audits and letters of guarantee for ingredients and packaging materials reviewed during the vertical audit demonstrated compliance.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Food Ingredient and Packaging Suppliers Policy outlined acceptance of incoming raw materials. Incoming materials were received with COAs demonstrating negative E.coli O157:H7 testing results for beef raw materials intended for raw ground use, and were verified on a trailer that was clean, in acceptable condition, with seals, and without any hazardous chemicals present. Records for incoming deliveries from the vertical audit demonstrated compliance. Raw Material receiving log documented trailer inspections including trailer condition and products received. For raw meat receipts, one temperature was taken for each pallet of product with an acceptable limit of 40F or less. Approved supplier listings were provided to receiving personnel when changes occurred. Materials were sourced from approved suppliers with internal restriction of purchase order creation until suppliers were approved. Live animals were not received.

3.5.3 Management of suppliers of services

Outsourced services included sanitation, transportation, pest control, waste removal, laundry, and catering. Suppliers were initially and continually approved through Corporate Strategic Sourcing requiring contractual agreement on file. Contracts for sanitation, waste removal, and pest control demonstrated

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compliance with applicable regulations. Suppliers of services were monitored through service reports, swabs, audits, and overall satisfaction of services rendered.

3.5.4 Management of Out sourced processing

Processing was not outsourced.

3.6 Specifications

Supplier approval for raw, chemicals, and packaging materials received required letters of guarantee demonstrating evidence of agreed specifications. Finished product specifications were maintained in an electronic database and included raw material requirements, trim specifications, formulation requirements, procedures for production, acceptable limits for brine uptake, target temperatures, and packaging material requirements. Specifications were reviewed every three years at minimum or when changes occurred. Specifications for customer branded products were agreed through procedures and email communication. Specification revision logs included date of revision, and revision reason. Specification for the Corned Brisket and Flats traced during the vertical audit demonstrated compliance.

3.7 Corrective and preventive actions

Corrective Actions Procedure outlined that corrective action requirements were included within each procedure and were documented within electronic monitoring software when taken. Corrective actions for CCP deviations were outlined in section 2 of the audit. Corrective action documentation for food safety failures included root cause analysis conducted using the Ishikawa Diagram or Five Why methods. Corrective action taken for concentration critical limit deviation on 04/07/2020 identified root cause, corrective actions, investigation details, established preventive measures, and verification of corrective action completion. Corrective action trends from Plant View documentation were reviewed on a monthly basis during the Senior Management Team meetings. Negative trends were not observed.

3.8 Control of non-conforming product

FSQA Hold Policy outlined procedures for physical and electronic tagging and holding of products preventing shipment. Electronic Inventory Management system had the capability to hold product and prevent picking or shipment. Physical hold tags were individually numbered for tracking and included product name, quantity, date, reason, and personnel placing product on hold. Products placed on hold were documented on the Hold Log including the product, quantity, date, code, reason, tag number, corrective actions taken, and final product disposition. Final product disposition was included on the Hold Log and was made by FSQA Management. Hold Tag Number 9862386 for a combo bin placed on hold demonstrated compliance during the vertical audit. Vendors for customer branded products were notified of out of specification incidents and final product disposition.

3.9 Traceability

Traceability of products was managed through an electronic warehouse management system and physical documentation. A traceability exercise was initiated as part of the vertical audit for 100 cases, 3,991.2 pounds of Corned Beef, product code 07346MWL, produced on 06/16/20. Exercise was initiated at 8:58am to 10:44am. Documentation provided traced finished product forward to the end customer and back to the raw material receiving dates. Packaging materials and processing aids were included and were traced back to receiving dates. Emporia Job Order Tracking was generated for each production date for planned products including formulations, ingredients, and water to be used. Issue Sheet documented

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ingredients and packaging materials in production and included the lot identification number, product number, run number, quantities used, and monitor initials. Raw meat products received were provided a label and identification number at receipt. Raw materials including ingredients, packaging materials, and processing aids were traced back to the received date and supplier lot identification numbers. Finished product bills of lading documented products shipped including case identification numbers, production dates, and product codes.

Mock recalls were conducted twice annually with a requirement of 100% of raw materials, rework, finished product, packaging, and processing aids reconciliation within two hours. Effectiveness of the mock recall scenario was based on 100% reconciliation within the two hour time frame. Mock recall scenario conducted on 08/17/20 demonstrated reconciliation of product and traceability of packaging, rework, ingredients, and processing aids within two hours. Exercise was initiated at 7:35am and concluded at 9:35am.

Rework and Partial Procedures outlined requirements for reworking products including ground beef, primals, sub-primals, and partials. Rework materials were re-introduced prior to foreign material detection devices under sanitary conditions. For ground beef, rework was introduced into the subsequent blender but not exceeding 5% of what remained in the blender. Primals and subprimals were scanned electronically to a "Rework" identification in the system including the original production date. Primals and sub-primals were required to be reworked same day. Partials were documented on the Partial Log including original production date, product code, quantity, date put into finished product code and any carryover.

3.10 Complaint-handling

Customer Complaints Procedure outlined requirements for customer and consumer complaints received. Complaints were forwarded through notification to the Consumer Relations Department and issued to FSQA and Operations Management for investigation. Serious Consumer Complaint Policy stated the requirements for handling food safety related complaints where product recovery actions were potential. Complaints received were forwarded to Corporate FSQA management and the Legal Department. FSIS was notified within 24 hours. Investigation included complaint details, who was involved, records reviewed, retention of product, corrective actions determined, preventive measures established, root cause analysis, and unforeseen HACCP hazard reassessment. Complaints were trended and reviewed during the monthly Senior Management meetings. Trends of recurring issues were not observed. Complaint Log from 2020 was reviewed demonstrating complaints received, investigation, corrective actions, and preventive measures.

3.11 Management of incidents, product withdrawal and product recall

Emergency Product Protection Plan outlined actions taken in case of power loss, natural disasters, or malicious contamination. FSIS and Corporate FSQA personnel were notified of emergency situation, potentially affected products were placed on hold and actions taken were documented. Corrective actions included chilling of products using dry ice, organoleptic inspections of product, and additional monitoring or room temperatures.

Tyson Emporia - Covid 19 2020 Information outlined Senior Management's actions taken as result of the pandemic. Actions included temperature screening of employees prior to entry with a required temperature of 100.4 or less with alarms triggered for employees testing out of compliance, additional screening questions asked at entry, restriction of visitors, additional hand sanitizer stations placed in common and traffic areas, implemented social distancing with floor markings, implemented dividers at work stations, required mask use for all employees, additional sanitation of door handles and contact surfaces,

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installation of dividers at break area tables, and implementation of a red/green card system for identifying necessary cleaning.

Emporia Recall Action Plan documented the recall team members, responsibilities, contact information, initiation, reconciliation, and termination of the recall. Recall Plan included communication and record keeping templates. Certification body was required to be notified with 24 hours of the initiation of a product recall. Mock recalls were outlined in section 3.9 of the audit.

Details of non-applicable clauses with justification

Clause/section reference	Justification
3.5.1.5	Brokers were not used.
3.5.4	Processing was not outsourced.
3.5.4.1	Processing was not outsourced.
3.5.4.2	Processing was not outsourced.
3.5.4.3	Processing was not outsourced.
3.5.4.4	Processing was not outsourced.

4. Site standards

4.1 External standards

Facility was located in an industrial area of Emporia, Kansas and surrounded by paved roads observed in adequate condition. Surrounding businesses were not observed creating potential for product contamination. Vegetation was minimal and building was observed adequately sealed preventing pest ingress. Bird roosting sites were not observed.

4.2 Site security and food defence

Food Security Plan Checklist documented internal assessments of the Food Security Program on a monthly basis. Audits verified management plan, outside security measures, general inside security, processing security, storage, shipping and receiving, water and ice security, mail handling, and personnel security. Vulnerabilities were not identified from audit conducted on 06/26/2020. Raw material or finished

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product vulnerabilities were not identified. An annual assessment was conducted using the FSIS Industry Self-Assessment Checklist, most recently on 01/17/20. Facility Food Defense Plan included the Food Security Management Team, Food Security Coordinator, emergency contact information, and security measures implemented. Implementation included complete fencing perimeter with signage, guard stations staffed around the clock, security cameras, individually assigned badges, management presence on the production floor, locking of external carbon dioxide tanks, and restricted access to designated personnel. Visitors upon entry into the facility were required to sign in and review Visitor Good Manufacturing Board for GMP requirements. Visitors were escorted by plant personnel when onsite. Employees were trained on food defense annually. Facility was registered with USDA-FSIS under Establishment Number 245D, P245D.

4.3 Layout, product flow and segregation

Maps of the facility were provided depicting personnel flow with access points, welfare areas, smoking areas, raw material, ingredient, waste, and rework flow, production process flows, compressed air drops and potable water lines. Visitors upon entry into the facility were required to sign in and review Visitor Good Manufacturing Board for GMP requirements. Visitors were escorted when in the facility. Areas were defined as low risk with allergen and species product movement production controlled through scheduling. Team members were dedicated in each production area. Adequate space was observed for manufacturing and inspection activities. Temporary structures were not present.

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

Walls were comprised of sealed freezer or stainless panels and concrete in adequate condition permitting cleaning. Floors were comprised of sealed brick and concrete in adequate condition and sloped facilitating cleaning. Drains were adequate in number and size for prevention of accumulated water or waste. Equipment and wash sinks were observed directly piped to drains. Ceilings and overheads were observed in adequate condition and comprised of sealed concrete or freezer panels. Suspended ceilings and roof voids were not observed in production areas. Elevated walkways were equipped with toe boards, catch pans, and were located away from exposed products. Windows or roof glazing were not observed. Doors, including personnel and dock doors, were adequately constructed of insulated paneling or stainless steel and observed with adequate seals for prevention of pest ingress. Lighting was adequate for manufacturing and inspection activities. Fans and overhead cooling units were observed operational. Condensation and dust buildup was not observed.

4.5 Utilities – water, ice, air and other gases

Water used for cleaning and production activities was sourced from the municipality of Emporia, Kansas. Municipal testing was conducted on an annual basis for chemical, microbiological, and radiological analyses in accordance with 40 CFR 141 National Primary Drinking Water Regulations. Potability was verified on a quarterly basis through Total Coliform Count (TCC) microbiological sampling. Results from 08/13/20 demonstrated compliance and confirmation of potability. Backflow prevention was included on the water drops in the facility, tested on an annual basis most recently on 07/31/20. Potable water lines were documented on facility maps indicating sample collection points. A boil advisory was issued on 02/26/2020 for high turbidity by the municipal water department. Incident details were documented and included the closure of the incoming water lines from the city. Product was placed on hold pending further evaluation. Testing results of incoming water demonstrated potability. Finished product release was made by Corporate FSQA personnel. Steam and wet ice were not used. Carbon dioxide was used for the chilling

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of raw meat products. Certificates of conformance from August 2020 demonstrated compliance. Compressed air was filtered through two stage filtration with a 0.1 micron filter at the point of use.

4.6 Equipment

Equipment was comprised of stainless steel, ultra high molecular weight plastics, and food grade product belting maintained in accordance with 9 CFR 416. Surfaces were smooth and permitted cleaning. New equipment was assessed by FSQA Management using the AMI Sanitary Design Checklist and HACCP reassessment prior to use in production. Equipment assessment included review for any hazards present and for ease of sanitation.

The following non-conformity was identified:

4.6.1 - An incomplete weld was observed on the A line auger hopper framework creating a potential microbiological harborage point. The incomplete weld was corrected prior to the closure of the audit.

4.7 Maintenance

Notification of Repair Policy outlined the preventive and corrective maintenance program. Preventive and Corrective Maintenance activities were scheduled and documented in an electronic maintenance system. Preventive maintenance tasks were based on facility history and manufacturer's recommendations including sign-off for accountability and reconciliation of tools and parts. PMs for the weekly air filter change-out from August 2020 demonstrated compliance. Maintenance Work order Requests were initiated for corrective maintenance requests. Equipment was inspected during pre-operational sanitation for condition. Notification of Repair Cards documented verification of sanitation activities after work was performed. Documentation included date, equipment, parts accountability, cleaning and sanitizing of product surfaces, and sign-off by supervision and QA. Records from July and August 2020 demonstrated compliance. Temporary Repair SOP outlined requirements for temporary repairs. Temporary repairs made were required to be made in sanitary condition and monitored during operational SSOP inspections. Work orders were entered for temporary repairs made documenting estimated completion date for the permanent repair. New equipment was assessed by FSQA Management using the AMI Sanitary Design Checklist and HACCP reassessment prior to use in production. Equipment assessment included review for any hazards present and for ease of sanitation. Food Grade lubricants were stored in a secured and labeled cabinet. Food grade lubricant reviewed during the vertical audit was confirmed NSF-H1 status and free of allergens. Maintenance shop was observed clean and organized with boot brushes as mitigation for debris transfer.

4.8 Staff facilities

Employee welfare areas included break rooms, restrooms, and locker rooms. Lockers were adequate in size for storage of personal items and protective clothing was hung on a hook outside of the personal locker for prevention of contact with personal clothing. Locker rooms had direct access to production areas. Restrooms did not open directly to production areas and were equipped with hand washing facilities. Hand washing facilities included warm water from hands free taps, foam soap, single use towels, hand dryers, waste containers, and signage prompting hand washing. Hand washing facilities at entrances to production areas included warm water from hands free taps, foam soap, single use towels, hand dryers, waste containers, and signage prompting hand washing. Smoking was permitted in designated areas at the exterior of the facility. Smoking areas were observed equipped with adequate waste removal. On-site

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cafeteria was operated by an approved third party vendor inspected by the Kansas Department of Public Health. Health certificates were on file. Racking systems were provided to employees for storage of personal lunches. Break rooms and cafeterias were observed clean and tables were sectioned off with partitions in response to the pandemic. Vending machines were observed operational.

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

4.9.1 Chemical control

Chemical Review and Approval System included requirements for the approval of new chemicals. Review included regulatory compliance review and review for potential product contact. Chemical Control Program outlined the requirements for chemical use. Chemicals were required to be approved prior to receipt into the facility. Personnel handling chemicals were trained on an annual basis at minimum. Chemicals for cleaning and sanitation activities were stored in a locked cage with restricted access to designated personnel. List of approved chemicals was on the MSDS Online system. NSF-H1 lubricant reviewed during the vertical audit was verified on the approved chemical listing. SDS binders were present around the facility including chemicals used. Strongly scented chemicals were prohibited from production areas.

The following non-conformity was identified:

4.9.1.1 - Food grade and non-food grade lubricants were observed co-mingled in a labeled and designated non-food grade area of the lubricant storage cabinet.

4.9.2 Metal control

Foreign Material Control Policy outlined requirements for the prevention of foreign objects. Equipment was inspected during pre-operational sanitation for condition. Knives, blades, and needles were inspected once per period at minimum for condition. Band saws and skinner blades were inspected prior to installation. Imaxx Needle Form documented the inspection of injection needles once per period for condition. Foreign Material Control Inspection Records from August 2020 demonstrated compliance. For blades or needles found damaged during inspection, product back to the last acceptable check was placed on hold and reworked with foreign material devices capable of detecting the potential reject. Snap off blades, staples paper clips, and drawing pins were prohibited from production areas. Break time Checklist documented the inspection of equipment at break time for condition. Grinder Plate Check documented the condition of grinder blades once per period for condition. Belt Inspection Checklist documented condition of product belting at the start and end of the production shift. Records from June 2020 demonstrated compliance. Packaging materials received were not observed with potential foreign materials. Monthly Foreign Object Report reviewed internal plant findings, external findings, consumer complaints, and FSIS district notifications.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Foreign Material Control Policy stated that glass other than sources of lighting was not permitted in production areas. Lighting was required to be protected with a shatterproof shield. A register was maintained of materials including location, number, type, and condition. For breakage, products and areas affected were placed on hold and quarantined, affected areas were cleaned, change out of work wear or footwear, and documentation of the incident on Operational SSOP records. Glass breakage incidents had not occurred since the last certification audit. Employees involved with glass and brittle plastic breakage cleanup were trained on an annual basis. Glass breakage incidents had not occurred since the last certification audit. An inspection of glass and brittle plastic materials was conducted on a quarterly basis

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and included item, type, number, product contact zone, condition, and any corrective actions taken. Records from July and August demonstrated compliance. Ceramic Steels Verification Log for 245D included the inspection of ceramic steels on a daily basis for condition. Corrective actions taken for damage were recorded on the form. Records from August 2020 demonstrated compliance. Glass windows were not observed.

4.9.4 Products packed into glass or other brittle containers

Products were not packed into glass or other brittle containers.

4.9.5 Wood

Wood used in the facility consisted of pallets that were inspected prior to use in the facility. Pallets with damage or pieces missing were rejected and disposed. Prior to placement into combo dumpers, wooden pallets were wrapped with plastic wrap for prevention of foreign material introduction into product. Wood handled tools were not permitted.

4.9.6 Other physical contaminants

Foreign Material Control Policy outlined requirements including Metal Detectable Writing Utensils. Metal detectable pens were assigned to QA personnel and Management for control. Job Safety Analysis (JSA) Procedures defined requirements for de-bagging of primals, sub-primals, and ground products preventing foreign material contamination. JSA for Rework Chubs demonstrated compliance.

4.10 Foreign-body detection and removal equipment

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

Assessment of physical hazards was included in the HACCP plan hazard analysis. Metal was identified as a hazard likely to occur and controlled through critical control points. Metal detectors were verified during critical control point monitoring by QA personnel prior to start of production. Verification included memory reset by challenging detection systems with 2.5mm ferrous, 3.5mm non-ferrous, and 5.0mm stainless steel standards. Monitoring and corrective actions was outlined in section 2 of the audit. After initial functionality verification, metal detectors were verified on an hourly basis. X-Ray systems were verified on an hourly basis using 2.5mm ferrous, 3.5mm non-ferrous, and 5.0mm stainless steel standards. Rejection mechanisms included belt stop and product divert. When foreign materials were detected, a Foreign Material Incident Form was completed including description, affected product, assessment for hazard determination, and disposition of final product. Incident from 08/12/2020 demonstrated compliance. Findings were trended; negative trends were not identified. Corrective actions were implemented in the event a device failed to detect a standards, which included placing product on hold to the last acceptable check, and testing product through properly functioning equipment.

4.10.2 Filters and sieves

Filters and sieves were not used.

4.10.3 Metal detectors and X-ray equipment

Assessment of physical hazards was included in the HACCP plan hazard analysis. Metal was identified as a hazard likely to occur and controlled through critical control points. Metal detectors were verified during critical control point monitoring by QA personnel prior to start of production. Verification included memory reset by challenging detection systems with 2.5mm ferrous, 3.5mm non-ferrous, and 5.0mm stainless steel

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standards. Monitoring and corrective actions was outlined in section 2 of the audit. After initial functionality verification, metal detectors were verified on an hourly basis. X-Ray systems were verified on an hourly basis using 2.5mm ferrous, 3.5mm non-ferrous, and 5.0mm stainless steel standards. Rejection mechanisms included belt stop and product divert. When foreign materials were detected, a Foreign Material Incident Form was completed including description, affected product, assessment for hazard determination, and disposition of final product. Incident from 08/12/2020 demonstrated compliance. Findings were trended; negative trends were not identified. Corrective actions were implemented in the event a device failed to detect a standards, which included placing product on hold to the last acceptable check, and testing product through properly functioning equipment.

4.10.4 Magnets

Magnets were not used.

4.10.5 Optical sorting equipment

Optical sorting equipment was not used.

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

Products were not packed into glass jars, cans, or other rigid containers.

4.11 Housekeeping and hygiene

Cleaning and sanitation activities were performed by an approved third party vendor. SSOPs for the daily cleaning of food and non-food contact surfaces were developed and included cleaning procedures, frequencies, responsibilities, chemicals used, cleaning equipment, equipment disassembly, and pictures of equipment. Dedicated color coded black brushes were used for drains. A Master Sanitation Schedule was implemented that included non-routine cleaning activities conducted on a weekly, bi-weekly, and monthly basis for overheads, belts, overheads, locker rooms, walls, and catwalks. Records from June 2020 demonstrated compliance. SDS sheets were available for chemicals and sanitizers used and included regulatory letter demonstrating acceptability of use as a no-rinse sanitizer. Rotational sanitizer program was implemented rotating peroxyacetic acid and quaternary ammonia based sanitizers. Chemicals including detergents and sanitizers were titrated on a daily basis, including the chemical, acceptable limits, chemical used, corrective actions for out of specification concentrations. Records from June 2020 demonstrated compliance. Sanitation review was conducted on a monthly basis for implementation of SSOPs, previous action items, and corrective actions taken. Record of inspection from 06/25/2020 demonstrated compliance. Sanitation training was conducted upon new hire, equipment specific procedures, and on an annual basis. Records from January and August demonstrated compliance. Training topics included seven steps of sanitation, GMPs, foreign material control, food defense, food safety principles, and chemical application. Meetings were conducted on a weekly basis discussing equipment plans for cleaning and any corrective actions taken for cleaning activities. Cleaning equipment used included wall mounted foamers, secondary chemical containers, drain brushes, and single use scrub pads. Sanitation verification included visual pre-operational sanitation inspections of 100 percent of equipment and ATP rapid test swabs. Corrective actions for visual failures included re-cleaning of the surface and re-inspection. ATP testing was outlined in section 4.11.8 of the audit.

Bio-luminescence Swab for Pre-Op Procedure outlined the risk based environmental monitoring program utilizing rapid test ATP swabs for verification of sanitation activities. ATP swabs were collected on a daily basis from ten food contact surfaces, two per area. Swabs targeted presence of organic residue and were taken from a four inch by four inch area prior to sanitizer application. Acceptable limit was defined as less than 175 RLU and corrective actions taken in accordance with 9 CFR 416.15(b) included re-cleaning of the surface and re-testing until a passing result was achieved. Results were recorded in the electronic

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system, trended on a monthly basis, and reviewed during the monthly Senior Management meetings. Records from June 2020 demonstrated compliance.

CIP was not used.

The following non-conformity was identified:

4.11.3 - Pre-Op Sanitizer Verification electronic record from 06/16/20, completed by plant personnel, documented a final sanitizer concentration result that was unacceptable. This verification result was taken from the direct observation of contract sanitation personnel titrating the chemical and their concentration result. Chemical Concentration log for 06/16/20 from the contract sanitation team indicated that the titrated concentration was acceptable. Control limits in the electronic system did not identify the out of compliance result as unacceptable.

4.11.7 Cleaning in place (CIP)

CIP was not used.

4.11.8 Environmental monitoring

Bio-luminescence Swab for Pre-Op Procedure outlined the risk based environmental monitoring program utilizing rapid test ATP swabs for verification of sanitation activities. ATP swabs were collected on a daily basis from ten food contact surfaces, two per area. Swabs targeted presence of organic residue and were taken from a four inch by four inch area prior to sanitizer application. Acceptable limit was defined as less than 175 RLU and corrective actions taken in accordance with 9 CFR 416.15(b) included re-cleaning of the surface and re-testing until a passing result was achieved. Results were recorded in the electronic system, trended on a monthly basis, and reviewed during the monthly Senior Management meetings. Records from June 2020 demonstrated compliance.

4.12 Waste

Waste removal was contracted with an approved third party vendor. License for waste removal on file demonstrated compliance with Kansas Department of Health and Environment requirements. Compactor was emptied three times per week and inedible material was transferred to an off-site sister rendering facility three times per week. Trash compactors were observed secured and sealed. Color Coding Policy outlined the color coding scheme including inedible, edible, and trash materials. Disposal of unsafe materials was identified as a CCP and discussed in section 2 of this assessment.

4.13 Management of surplus food and products for animal feed

Products designated for employee sale were subjected to pre-shipment review and release in accordance with 9 CFR 417. Customer branded product was removed from original packaging and placed into generic packaging. Color Coding Policy outlined the color coding scheme including inedible, edible, and trash materials. Inedible products were sent to a sister rendering facility for processing.

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4.14 Pest management

Pest control activities were outsourced to an approved third party vendor. Facility did not undertake pest control activities. Contract Service included routine monitoring activities for rodent and insect activity. Twenty five exterior rodent stations were serviced on a monthly basis, sixty interior rodent control stations serviced on a monthly basis, thirteen exterior snap traps on a weekly basis, interior fly light traps were serviced on a monthly basis for April and November, bi-weekly during May and October, and weekly from June to September. Bird roosting areas were not observed. An equipment diagram depicted trap location by type and area. Traps were individually carded with documentation of service present in each trap. On a monthly basis, five interior and five exterior station cards were verified by plant personnel. Service reports included services and findings, thresholds exceeded, and chemical usage. Chemical usage documented quality applied, active ingredient, EPA registration number, targeted pest, and area applied. SDS sheets and labels were located in the electronic system. Pest observations in the facility were recorded on the Pest Sightings Log and included corrective actions taken by the PCO. Client Actions documented recommendations reported by the PCO including documentation of closure by the plant. Recommendations had not been made since November 2019. Trends were conducted on a weekly basis for activity. PCO license was valid to January 2022, business license was valid to January 2021, and insurance was valid to January 2021. Pest Management Program (pest control survey) was reviewed on a quarterly basis, most recently on 07/23/2020, for effectiveness. Recommendations were not identified. Interior light traps were glue board in nature with bulbs protected by a wire mesh frame. Toxic baits were used at the exterior of the facility in secured bait stations. Bait stations opened had anchored bait. Interior traps were observed operational and present on both sides of doors. Pest control traps were located away from exposed products and finished product areas. Employees were trained on pest awareness and reporting annually. Contact information for the PCO was provided in the event of an infestation.

4.15 Storage facilities

Storage and Transportation Policy outlined the physical monitoring of storage temperatures once per period by QA personnel. Acceptable limits were defined as 32F to 36F for coolers, less than 50F for production rooms, 28F to 30F for warehousing and storage areas, and less than 0F for freezers. Records from June 2020 demonstrated compliance. Frozen products were not permitted on the shipping dock for more than two hours. Packaging materials were stored in ambient conditions. Partial packaging materials were observed covered. Raw materials, ingredients, and finished products were stored in established racking systems off the ground and away from walls facilitating pest ingress inspections. Allergenic ingredients were required to be stored under non-allergenic materials. Actions taken for loss of refrigeration were outlined in section 3.11 of the audit. Electronic systems utilized FIFO product date management for raw materials and finished products. Controlled atmosphere storage was not performed. Outside storage was not performed.

4.16 Dispatch and transport

Shipping docks and product storage warehouses were enclosed and climate controlled. Storage and Transportation Policy outlined requirements for the shipment of finished products. Trailers were required pre-chilled and inspected for cleanliness and condition prior to loading. Trailers were required to be free of odors, in good repair, and free from contamination. Inspections were documented on the Loadout Stacker Sheets. Records from August 2020 demonstrated compliance. Trailers were equipped with automated temperature recorders that were able to be interrogated upon request. Use of additional temperature recording devices based on customer requirements were included on shipment forms. Devices were stored in the shipping office. Inspections for forklifts and pallet jacks were conducted on a daily basis for operation and cleanliness and documented in the Infolink System. Inspection included daily disinfection of

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surfaces. Records from June 2020 demonstrated compliance. Transportation agreements outlined requirements for third party transporters including trailer security, restriction of mixed loads, actions to take the event of theft, an accident, or breakdown.

Details of non-applicable clauses with justification

Clause/section reference	Justification
4.4.5	Suspended ceilings and roof voids were not observed in production areas.
4.4.7	Windows or roof glazing were not observed.
4.14.3	Facility did not undertake pest control activities.
4.15.4	Controlled atmosphere storage was not performed.
4.15.5	Outside storage was not performed.
4.9.3.4	Glass windows were not observed.
4.9.4.1	Products were not packed into glass or other brittle containers.
4.9.4.2	Products were not packed into glass or other brittle containers.
4.9.4.3	Products were not packed into glass or other brittle containers.
4.10.2.1	Filters and sieves were not used.
4.10.2.2	Filters and sieves were not used.
4.10.4.1	Magnets were not used.

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4.10.5.1	Optical sorting equipment was not used.
4.10.6.1	Products were not packed into glass jars, cans, or other rigid containers.
4.10.6.2	Products were not packed into glass jars, cans, or other rigid containers.
4.11.7.1	
4.11.7.2	
4.11.7.3	
4.11.7.4	

5. Product control

5.1 Product design/development

Fresh Meats Product Request (FMPR) Management Procedure covered requirements for changes to product formulation, packaging, or methods of production. Research and Development activities were conducted on the Corporate level. A FMPR was initiated and included assessment of hazards, affected plants, label review, allergen risk assessment, controls implemented, and effective date. FSQA Manager signed off on the FMPR requests demonstrating approval. FMPR from 06/29/20 for Butcher Block sub-primals demonstrated compliance. Initial product shelf life and production trials were managed through Corporate Research and Development Personnel.

5.2 Product labelling

Corporate FSQA Management personnel were responsible for the review and approval of product labels. Changes to labels were included in the Fresh Meats Product Request (FMPR) Management Procedure and required sign-off for relevant personnel acknowledging changes. Finished product labels were submitted to USDA-FSIS for approval or generically approved based on previous label approvals. USDA-FSIS label approval for CAB Corned Beef Brisket with Spice Packet label approval from 10/30/19 demonstrated compliance. Finished products included inspection legends and Safe Handling Instructions in accordance with USDA-FSIS regulations. Nutritional claims were not made. Cooking instructions were not provided. Third party companies were provided product specifications to ensure accuracy of labels. Labels were verified for accuracy upon receipt and approved by designated personnel

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5.3 Management of allergens

Assessment of allergens was conducted in conjunction with the HACCP Hazard Analysis identifying milk, soy, and wheat allergens used in finished products. Suppliers provided letters of guarantee and allergen statements. Allergen Control Policy outlined Allergen Management requirements. Controls included label verification at receipt, production scheduling, rework restrictions, storage controls use of color coded tools (red and blue), protective equipment and production lines dedicated for use with allergen products. Production was scheduled for non-allergenic products to be produced before non-allergenic products. Allergen Control Grids defined the wash down requirements between products. Rework was permitted into the same products and was not permitted to be carried over to the following production day. Allergen Management Checklist outlined the monthly verification audit for facility procedures and requirements. Audit verified allergen control and protocols, separation of tools and ingredients, and production scheduling, label verification, and change-over practices. Audit performed on 06/28/2020 demonstrated compliance. Verification of allergen declarations on finished product labels was outlined in section 6.2 of the audit. Five allergen swabs were collected on a quarterly basis for verification of sanitation activities. Allergen swabs from March 2020 for gluten, casein, and soy demonstrated compliance. Allergen based claims were not made.

5.4 Product authenticity, claims and chain of custody

Senior management was made aware of authenticity and fraud updates through industry subscriptions, email alerts, and communication from the Corporate FSQA team on a weekly basis outlined in section 1.1.8 of the audit. Food Fraud Vulnerability Assessment was conducted on an annual basis, most recently on 01/08/20, reviewing ingredients and packaging materials according to history of food fraud, country of origin sourcing, detection ability, economic factors, and likelihood of food fraud. Ingredients and packaging materials were identified as low risk and vulnerabilities were not present. Claims made included Certified Angus Beef (CAB), Natural (Minimal Processing), and No Antibiotics Ever (NAE). Species Separation Procedures SSOP outlined production scheduling requirements for species separation. Changeovers were minimized to prevent contamination. Label Verification Log 245D documented hourly verification of removal of packaging materials and labels from the production line after product changeovers. Records from August 2020 demonstrated compliance. CAB products were received from plants that had G Schedule AMS approved Phenotype Angus Verification Programs in place. Mass balance exercises were conducted every six months for products labeled with claims. Mass balance exercise for CAB Inside Rounds conducted on 05/06/2020 demonstrated 100% reconciliation of product. Claims for methods of production were not made.

5.5 Product packaging

Packaging materials were sourced from approved third party vendors and included letters of guarantee for approval. Letters of guarantee demonstrated compliance with applicable regulations and suitability for use with finished products. Letters of Guarantee for films and Cryovac bags demonstrated compliance. Product liners and bags were approved for contact use, resistant to tearing, and differing in color (yellow or green) to products produced. Label and Pre-Printed Packaging Destruction outlined requirements for the destruction of obsolete labels and packaging materials. Obsolete materials were disposed through shredding, burning, denaturing, soaking in water, or puncturing until labels and materials were unusable. Record of destruction was maintained. Materials disposed were recorded on the Packaging Disposition Log.

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5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

A schedule of analytical and microbiological tests was maintained. Acceptable Quality Limit (AQL) testing was conducted every 30 minutes for 50 trim types and every 60-90 minutes on lean trim types of 70 point of lean or higher. On a weekly basis, five combo bins were sampled for APC and ECC. Limits were included in the program. Fat analysis was conducted on each batch of ground beef produced. Samples were collected by USDA-FSIS on a routine basis for ground beef (MT43) and bench trimmings (MT65). Samples were collected from products intended for raw ground and tested for E. coli O157:H7. Microbiological testing for specific customer requirements was conducted per batch and included APC, TCC, ECC, and Staphylococcus Aureus. Acceptable limits were defined by the customer as APC < 500,000 cfu/g, TCC < 1100 cfu/g, < 500 ECC cfu/g, < 200 cfu/g Staphylococcus Aureus.

Shelf life Testing was conducted on an annual basis for boneless, bone-in, and ground beef products. Products were evaluated product according to organoleptic principles and microbiological testing verifying shelf life limits. Results from April 2020 demonstrated compliance. Laboratory results were reviewed on a daily basis as a component of pre-shipment review, trended, and included in the Monthly Senior Management team meetings and Food Safety and Quality Assurance Objectives.

5.6.2 Laboratory testing

Onsite laboratories were not used. Microbiological and Analytical testing were subcontracted to an offsite company laboratory certified to ISO 17025:2017 and accredited through A2LA. Certificate was valid to 12/31/20. Laboratory testing procedures were included in their certification scope and were AOAC approved. Products intended for raw ground were subjected to positive release for E. coli O157:H7. Non negative products were subjected to Critical Control Point NG4 Disposition for Non Negative Products and dispatched to a USDA-FSIS establishment for lethality treatment. APC testing procedures were derived from AOAC Official Methods 17th Edition 990.12. ECC and TCC testing procedures were derived from AOAC Official Methods 18th Edition 998.08. Laboratory wastes including products tested for pathogens were autoclaved or destroyed using a quaternary ammonia based sanitizer. Proficiency testing was conducted on an annual basis and were based on Z-Scores. Record from June 2020 demonstrated compliance. Laboratory results were reviewed on a daily basis as a component of pre-shipment review, trended, and included in the Monthly Senior Management team meetings and Food Safety and Quality Assurance Objectives.

5.7 Product release

Finished products were subjected to pre-shipment review in accordance with 9 CFR 417 verifying HACCP, SSOP, and pre-requisite program records. Products intended for raw ground were subjected to positive release for E. coli O157:H7 testing. Non negative products were subjected to Critical Control Point NG4 Disposition for Non Negative Products and dispatched to a USDA-FSIS establishment for lethality treatment. Records of reconciliation were maintained.

5.8 Pet Food

Pet food was not produced.

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Details of non-applicable clauses with justification	
Clause/section reference	**Justification**
5.2.3	Nutritional claims were not made.
5.2.5	Cooking instructions were not provided.
5.3.7	Allergen based claims were not made.
5.4.5	Claims for methods of production were not made.
5.8	Pet food was not produced.
5.8.1	Pet food was not produced.
5.8.2	Pet food was not produced.
5.8.3	Pet food was not produced.
5.6.2.2	Onsite laboratories were not used.

6. Process control

6.1 Control of operations

Emporia Job Order Tracking was generated for each production date with established formulations for the ingredients and water. Specifications for finished products included raw material, trim specifications, formulation, procedures for production, acceptable limits for brine uptake, target temperatures, shelf life, labeling, and packaging material requirements. Marinade Pick Up Percentages documented net weight and pump weight evaluating for weight gain. Form included procedures for brine mixing and temperature requirements. Marinade pick up sheet for product reviewed during the vertical audit demonstrated compliance. Critical Control Point monitoring was outlined in section 2 of the audit. Environmental testing was outlined in section 4.11.8 of the audit. Foreign material control devices were outlined in section 4.9 and 4.10 of the audit. Temperature control was outlined in section 4.15 of the audit. Metal detectors and

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scales were secured, access controlled to designated personnel, and protected from modification. For equipment found out of specification, product was placed on hold back to the last acceptable check pending further disposition. Chemical Control Program outlined chemical titration procedures for PAA used on primals and sub-primals. Quaternary ammonia sanitizer dip tank concentrations were verified once per shift with an acceptable limit of 200 to 400 ppm. Process controls and validation were discussed in section 2 of this assessment.

6.2 Labelling and pack control

Specifications outlined labels and packaging materials required for production. Labels and packaging materials were physically pulled and transferred to production based on production schedule. Issue sheets documented lot identification numbers for labels and packaging materials issued to production. Label Verification Log 245D documented hourly verification of removal of packaging materials and labels from the production line after product changeovers. Records from August 2020 demonstrated compliance. FSQA Label Control Verification reviewed labeling of value added food service products verifying safe handling instructions, ingredient statements, allergen declarations, UPC codes, best by dates, USDA inspection legend, date coding, and declared net weight for each batch. Ground Beef Retail Label Verification reviewed chub stamps including establishment, Julian date, physical copies of the chub stamp, and best before or freeze by dates at the start of production, product changeovers, and any time maintenance was taken on the printer. Retail Label Verification Procedure - Procedure A verified retail labeling for sub-primal cuts verifying product name, sell by date, retail per pound, per price pack, net weight, tare weight, safe handling labels, nutritional statement, allergen declaration, UPC coding, and physical copies of the labels at the beginning of the shift and after any product changeover. Line Retail Label Verification was conducted at the beginning of the shift, after break, and after any product changeover verifying physical copies of the label, safe handling instructions, allergen declarations, inspection legend, and sell by/freeze by dates. Packaging Audit was conducted on an hourly basis reviewing number of bags, number of pieces, presence of leakers, product of USA, production date, inspection legend, ingredient statement, weight of individual package, and use by date. Label Verification Records from June and August 2020 demonstrated compliance. Online verification equipment was not used. Changeover was not available for observation during the assessment.

6.3 Quantity, weight, volume and number control

Quality Program for Net Weight outlined the verification of twenty boxes once per period at the case sealer, one chub per k-pak line each hour, ten brick pack packages every thirty minutes, and three random value added product codes each hour. Acceptable limits were defined within the program and were +/- 0.01 pounds. For out of specification weight, product back to the last acceptable check was placed on hold for rework. Scale present in the case sealer area verified each case of boxed beef prior to labeling. Weights and tares were electronically verified based on product and were kicked out if out of specification. Packaging tare weights were maintained in the electronic system by Corporate Management. Net weight verification documentation demonstrated compliance with NIST Handbook 133 requirements.

Scales were certified on an annual basis by an outside vendor in accordance with NIST Handbook 44 and the Kansas State Department of Agriculture, most recently on 07/22/20 and 06/09/20. Weight price scales were verified prior to production, bulk scales were verified twice per day, in motion test was conducted per day for case sealer scales. Check-weighers were verified on a daily basis by trained technicians through the preventive maintenance program. Weights used for verification of scales were certified on an annual basis by the Kansas Department of Agriculture, most recently during January and February 2020. Out of

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specification scales were removed from production, serviced by a third party vendor, and verified prior to issue back into production.

6.4 Calibration and control of measuring and monitoring devices

A list of calibrated equipment was provided which included equipment location and method of identification. Calibration SOP outlined the calibration of equipment including thermometers used for HACCP critical control point monitoring were calibrated prior to use and after the completion of the task against an NIST certified thermometer with an acceptable limit of +/- 2F. Thermometer calibration procedures were based on the Kansas State Methodology. NIST thermometer calibration was valid to 12/10/2021. Thermometer Calibration Records for June 2020 demonstrated compliance. Thermometers for quality tasks were calibrated on a weekly basis. pH meters were subjected to a two point calibration with 2.0 and 4.0 buffers on an hourly basis and recorded in the electronic system. Buffers were changed out on a weekly basis. Flow meters were identified through serial numbers and NIST calibrated by the vendor. Flow meter was valid to 08/29/20. Flow meters were replaced when expired. NIST stopwatches were used for verification of dwell time and were valid to two years. NIST calibration for stopwatch used was valid to 08/05/2021. Fat analyzers were verified on an annual basis for functionality by the Manufacturer, most recently on 09/09/2019.

Scales were certified on an annual basis by an outside vendor in accordance with NIST Handbook 44 and the Kansas State Department of Agriculture, most recently on 07/22/20 and 06/09/20. Weight price scales were verified prior to production, bulk scales were verified twice per day, in motion test was conducted per day for case sealer scales. Check-weighers were verified on a daily basis through the preventive maintenance program. Weights used for verification of scales were certified on an annual basis by the Kansas Department of Agriculture, most recently during January and February 2020. Out of specification scales were removed from production, serviced by a third party vendor, and verified prior to issue back into production.

For equipment found out of calibration, products were placed on hold back tot the last acceptable check. Corrective actions for CCP monitoring equipment were taken in accordance with 9 CFR 417.3(a).

Details of non-applicable clauses with justification

Clause/section reference	Justification
6.2.4	Online verification equipment was not used.

7. Personnel

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

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Employees were trained upon hire and as part of required annual refresher training. Training topics included: Allergen control, GMPs (handwashing, pest control, glass and brittle plastic policy), chemical awareness, hazard communication, food defense, and HACCP. Records from August, September, and October 2019 demonstrated compliance. Training records documented date, start time, completion time, trainer, course contents, and name of the trainee. Translators were available for Spanish speakers. Personnel monitoring Critical Control Points were trained during new hire and on an annual basis. Employee signed off on CCP monitoring procedure acknowledging requirements. Competency was verified during direct observation of monitoring activities. Emporia FSQA Technician Training Activity Book included training for FSQA personnel performing labeling and packaging verification. Records from August 2020 demonstrated compliance. Production personnel received Quality Systems Training for Labeling and Packaging, most recently on April 2020. Visitors upon entry into the facility were required to sign in and review Visitor Good Manufacturing Board for GMP and allergen requirements.

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

Personnel Hygiene and GMP's Policy outlined product handling requirements including that hands were washed after leaving the restroom, after handling allergenic ingredients, and any time they may have become contaminated. Personnel were not allowed to touch hair, nose, mouth or any potential insanitary condition. Fingernails were required to be short and clean without false nails or polish. False eyelashes were not permitted. Jewelry including watches and piercings were not permitted with the exception of a plain wedding band without stone. Hairnets and beard nets were required to be worn in food production and storage areas. Food, drink, and tobacco products were not permitted to be consumed in production areas. Excessive perfume and aftershave were not permitted. Personal medications were required to be stored in personal lockers. Bandages for cuts were blue, metal detectable in nature, and tested on each metal detector confirming rejection. Records from 07/20/20 demonstrated compliance. Bandages were required to be covered. GMP compliance was monitored on a daily basis as part of Operational SSOP monitoring activities. Records from June 2020 demonstrated compliance.

7.3 Medical screening

Personnel Hygiene and GMP's Policy stated that employees with communicable diseases were not permitted to work in the facility. Plant Admittance Registry and Access Agreement required visitors to notify plant management if suffering from infectious disease, communicable illness, or have open cuts or sores prior to entry into the facility. If suffering, visitors and contractors were not permitted access. Additional screening requirements as part of the Covid-19 pandemic were outlined in section 3.11 of the audit.

7.4 Protective clothing: employees or visitors to production areas

Personnel Hygiene and GMPs Policy outlined protective clothing requirements including wearing of hairnet and beard nets, aprons, and frocks in production areas. Frocks covering personal clothing were laundered by a third party on a daily basis and did not include outside pockets. Visitor Safety Requirements outlined protective clothing requirements for visitors and contractors entering the facility. Protective clothing was required to be removed prior to entering break rooms, restrooms, maintenance shops, and outside of the facility. Chain mail, mesh gloves, and arm guards for skinners and bandsaws were required to be cleaned at the end of each production shift. Laundry services were contracted with an approved third party vendor. Clean garments were placed into a protective clothing bag and hung on the exterior of each employee's locker. Soiled garments were placed into a segregated container and covered during entry into the facility. Third party audit verifying HACCP practices was conducted on 01/19/19 demonstrating review of laundry vendor procedures and pre-requisite programs. Gloves for product contact included cotton and green

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colored nitrile (latex and powder free) gloves observed without loose fibers or damage. Gloves were required for product contact with change out requirements when damaged or heavily soiled.

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

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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 raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.1.1	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.1.2	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.1.3	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.1.4	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.2.1	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.2.2	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.3.1	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.3.2	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.

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8.3.3	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.4.1	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.5.1	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.5.2	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.5.3	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.6.1	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.7.1	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.7.2	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.
8.7.3	Low risk raw meat products were intended for further processing or cooking prior to consumption and labeled with Safe Handling Instructions.

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9 - Traded Products

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

Voluntary Modules not Included

9.2 Specifications

Voluntary Modules not Included

9.3 Product inspection and laboratory testing

Voluntary Modules not Included

9.4 Product legality

Voluntary Modules not Included

9.5 Traceability

Voluntary Modules not Included

Module 11: Meat supply chain assurance

Scope	

11.1 Traceability

Voluntary Modules not Included

11.2 Approval of meat supply chain

Voluntary Modules not Included

11.3 Raw material receipt and inspection

Voluntary Modules not Included

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

Module 12: AOECS Gluten-free Foods

Scope	
12.1 Senior management	
Voluntary Modules not Included	
12.2 Management of suppliers of raw materials and packaging	
Voluntary Modules not Included	
12.3 Outsourced production	
Voluntary Modules not Included	
12.4 Specifications	
Voluntary Modules not Included	
12.5 Management of gluten cross-contamination	
Voluntary Modules not Included	

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12.6 Management of incidents, product withdrawal and product recall
Voluntary Modules not Included
12.7 Labelling
Voluntary Modules not Included
12.8 Product inspection and laboratory testing
Voluntary Modules 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 Modules not Included
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	NA	Voluntary Modules not Included
3	13.1.3	All food contact surfaces of plant equipment and utensils used in	NA	Voluntary Modules not Included

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		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.		
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 Modules 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 Modules 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 • Unintentional adulterants which affect food safety	NA	Voluntary Modules not Included
7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine “hazards	NA	Voluntary Modules not Included

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		requiring a preventive control" (i.e., significant hazards).		
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 Modules 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 Modules 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 Modules 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. 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	NA	Voluntary Modules not Included

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		(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 Modules 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 Modules 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 Modules 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	NA	Voluntary Modules not Included

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		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		
16	13.1.16	Devices used to verify preventive controls must be calibrated.	NA	Voluntary Modules 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 Modules 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 Modules 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 Modules 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)	NA	Voluntary Modules not Included

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		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.		
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 Modules 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 Modules 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 Modules 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: - During holding, human food by-products for use as animal food must be accurately identified.	NA	Voluntary Modules not Included

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		* 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 Modules 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 • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring,	NA	Voluntary Modules not Included

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		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 Modules 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 Modules 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. Procedures shall include recordkeeping requirements for all monitoring activities.	NA	Voluntary Modules not Included

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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 Modules 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 Modules not Included
32	13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever	NA	Voluntary Modules not Included

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		• 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		
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 Modules 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 Modules 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 Modules 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	NA	Voluntary Modules not Included

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		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.		
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 Modules 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 the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.	NA	Voluntary Modules not Included

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39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	NA	Voluntary Modules 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 Modules 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 Modules 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 address those potential problems	NA	Voluntary Modules not Included

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		• 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 Modules 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 Modules 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 Modules 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 • Correcting problems with harvest containers or equipment	NA	Voluntary Modules not Included
47	13.5.3	One or more supervisors or individuals responsible for the	NA	Voluntary Modules not Included

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		operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.		
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 Modules 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 Modules 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 Modules 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 Modules 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 Modules not Included

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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 Modules 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 Modules 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. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris).	NA	Voluntary Modules not Included

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		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 Modules 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 Modules not Included
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	NA	Voluntary Modules 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 Modules 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 Modules 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	NA	Voluntary Modules not Included

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		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).		
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 • Clean and sanitize the affected and surrounding areas	NA	Voluntary Modules not Included

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		• 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		

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