Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
11756 | 94519

AUDIT RATING

Excellent

DECISION DATE
10/24/2019

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
08/23/2020

AUDIT DATES
09/09/2019 - 09/12/2019

EXPIRATION DATE
11/06/2020

ISSUE DATE
10/24/2019

Facility & Scope

Smithfield Packaged Meats Corp. (45735)
Smithfield Packaged Meats Corp. - Martin City
13825 Wyandotte Street
Kansas City, MO 64145
United States

Food Sector Categories:
8. Processing of Manufactured Meats and Poultry

Products:
Ham

Scope of Certification:
Ham

Certification Body & Audit Team

Mérieux NutriSciences Certification
111 East Wacker Dr
Suite 2300
Chicago, IL 60601
United States

CB#: CB-1-Mérieux
Accreditation Body: JAS-ANZ
Accreditation Number: Z3720906AB

Lead Auditor: Bonner, Curtis (10129)
Technical Reviewer: Luttrell, Sandra (132944)

Hours Auditing: 22
Hours Writing Report: 8

Non-Conforming

11.7.5 Control of Foreign Matter Contamination

The facility follows the written "09-Foreign Material Control" policy to establish methods to prevent foreign material contamination. The policy also establishes the requirements for foreign material identification and detection programs. Foreign material prevention methods are established and communicated to employees during GMP training. All employees are encouraged to report any sources of foreign material or contamination. Foreign material includes insects, rust, insulation, flaking paint, wood, metal, and glass. Minor: The auditor observed several spiral slicers in the RTE area that had peeling safety stickers. The peeling material could be a source for foreign material contamination. Comment: Methods to control include the glass control policy and foreign material control policies. Pre-operational inspections are performed daily. Area SSOP checks are also done daily. Equipment and areas are checked to make sure they are in good condition and free from contaminants. Facility pre-op inspection records were reviewed for November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. Records were found to be complete and initialed or signed by the person responsible for making the check. Proper corrective actions were noted for any deficiencies found during the pre-op process. The "Foreign Material Control" policy establishes methods to prevent foreign material contamination. Included in the Foreign Material Control policy are requirements for glass and brittle plastic. Glass and brittle plastic inspections are done bi-annually and recorded on the facility glass and light audit report. The last was completed on 6/28/19. The facility has a list identifying the location of all the glass and brittle plastic. The facility uses wooden pallets in the palletizing area. Wooden pallets were observed to be well maintained and in good condition. No loose metal objects were observed above the processing equipment. Knives and cutting instruments were clean and controlled. No snap-off blades are used in the facility.

11.7.5.2 Inspections shall be performed to ensure plant and equipment remains in good condition, equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: MINOR

EVIDENCE: Minor: The auditor observed several spiral slicers in the RTE area that had peeling safety stickers. The peeling material could be a source for foreign material contamination.

ROOT CAUSE: Stickers begin to peel after heavy chemical use

CORRECTIVE ACTION: Maintenance has added sticker checks to their routine maintenance program and we will maintain these in stock. We have also met with sanitation to cut/remove loose stickers. We have also added this to our slicer tracking sheet

VERIFICATION OF CLOSEOUT: The auditor reviewed the program for maintenance to monitor the stickers on equipment and deemed this acceptable. CB

COMPLETION DATE: 09/25/2019 **CLOSEOUT DATE:** 09/26/2019

11.10.1 Grounds and Roadways

The exterior of the facility is included in the monthly GMP audit. All areas of the facility grounds were well maintained to minimize dust and are kept free of trash and debris. Minor: The auditor observed several areas of standing water in the truck parking zone and in front of the shipping / receiving areas. The facility had brought gravel in to fill the low spots, but wet ground and truck traffic has caused the gravel to sink down and pot holes formed again. Comment: The facility grass and green areas were well maintained. Equipment stored outside the facility was well organized and did not present a hazard. The facility has concrete and hard surface walkways leading to the facility entrance.

11.10.1.2 The grounds and area surrounding the premises shall be maintained to minimize dust and kept free of waste, accumulated debris or standing water so as not to attract pests and vermin.

RESPONSE: MINOR

EVIDENCE: Minor: The auditor observed several areas of standing water in the truck parking zone and in front of the shipping / receiving areas. The facility had brought gravel in to fill the low spots, but wet ground and truck traffic has caused the gravel to sink down and pot holes formed again.

ROOT CAUSE: Heavy truck traffic has caused the parking lot to be in disrepair

CORRECTIVE ACTION: The plant has dedicated a value per month for parking lot repairs. During repair times, standing water will be vacuumed out of low areas as needed

VERIFICATION OF CLOSEOUT: The auditor accepts the corrective action of vacuuming out the water until the allocated monies are available for complete repair. CB

COMPLETION DATE: 09/25/2019 **CLOSEOUT DATE:** 09/26/2019

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Jacob Davenport
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** jdavenport@smithfield.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Jacob Davenport: FS/QA Manager, Cierra Bielinski: FS Technician, Brent Vernon: Plant Manager, Scott Hickman: Operations Manager, Jeff Hines: 1st Shift Operations, Darin Wadkins: Maintenance Planner, John Sims: Maintenance Manager, Curtis Bonner: Auditor.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** The auditor recommends that the facility be re-certified upon completion and acceptance of corrective action for the non-conformances identified in this audit.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Jacob Davenport: FS/QA Manager, Cierra Bielinski: FS Technician, Brent Vernon: Plant Manager, Scott Hickman: Operations Manager, Jeff Hines: 1st Shift Operations, Darin Wadkins: Maintenance Planner, Mason Halfert: QA Technologist, Curtis Bonner: Auditor.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** Smithfield Foods, Martin City, MO was built in 1972 and is located in an industrial / business area of Martin City, MO. The facility is USDA FSIS inspected (Est. # 509K) and operates under a current grant of inspection. The facility is approximately 125,000 square feet and includes one RTE slicing /packaging area with three packaging lines, one formulation room for bone-in hams, two dry storage areas, cooking house area with 9 smokehouses, five chill coolers, and one raw material cooler. The facility employs approximately 380 people working two production shifts, one sanitation shift on 3rd, 5 days per week. The facility has one HACCP plan with one CCP and one Quality Plan with 6 CQPs. The facility produces fully cooked, not shelf stable cured and naturally cured ham. Pre-op sanitation activities start at 6:45 AM in the RAW areas and at 5:00 AM in the RTE areas. The auditor observed pre-op sanitation activities in the RTE area on the second day of the audit. Corrective actions from the previous audit were still effective. The facilities current SQF certificate expires November 6, 2019.

Section Responses

2.1.1 Food Safety Policy

The Plant Policy Statement was signed by the Plant Manager of the facility and was dated August 1, 2019. The statement assures food safety and quality of all products through the strict adherence to product quality attributes. The Statement is posted in the employee common areas and in the front office. The Policy Statement is posted in English, Spanish, French, and Burmese.

2.1.1.1	Senior site management shall prepare and implement a policy statement that outlines as a minimum the: i. The site's commitment to supply safe food; ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; and iii. The site's commitment to establish and review food safety objectives. **RESPONSE:** COMPLIANT
2.1.1.2	The policy statement shall be: i. Signed by senior site management; ii. Made available in language understood by all staff; and iii. Displayed in a prominent position and effectively communicated to all staff. **RESPONSE:** COMPLIANT

2.1.2 Management Responsibility

The facility has an Organization Chart that is stored in the SQF Manual. It lists the reporting structure and identifies the positions responsible for the quality and food safety at the facility. The Organizational Chart is electronic and updated as needed. The culture of Food Safety and Quality is reflected in the written job descriptions. The job descriptions for Quality Assurance Technologist, Food Safety Technologist, Quality Assurance Supervisor, Food Safety & Quality Assurance Supervisor, and Food Safety & Quality Assurance Manager include provisions to ensure and maintain food safety and quality practices. The SQF Practitioner at the facility is Jacob Davenport. Jacob is the facility Food Safety & Quality Assurance Manager. The SQF Practitioner communicates to relevant personnel information essential to the implementation and maintenance of the SQF Edition 8 system through general Food Safety and Quality training. Food Safety training, SQF training, and GMP training is performed annually using the electronic program Qualtrax, plus Power Point presentations, videos, and paper hand outs. A computerized training register (Excel) was available for review showing all employees and dates of training. The facility's SQF Practitioner is responsible for validating, verifying, and maintaining the company's Food Safety Plan and the Quality Plan. The facility's SQF practitioner is a full time employee, completed a HACCP based training course on 9/7/17 and SQF Training on 8/15/17. Jacob understands the SQF Quality Code and the requirements to implement and maintain the facility's SQF System. The facility follows the written policy "37-Food Safety & Quality Employee Training" Doc No. 1405 dated 6/4/19 that ensures all employees shall receive appropriate training to perform their jobs. New hires receive food safety and quality training at time of hire. Training includes the following topics: GFSI, HACCP, Allergens, GMPs, Quality Plan. Then all employees receive retraining on an annual basis. The facility Senior Management commits the availability of resources to achieve all the Food Safety and Quality objectives and to support the development, implementation, maintenance and ongoing improvements of the SQF system. The Senior Management provides a trained SQF Practitioner that has the authority and responsibility to do the following: 1). Oversee the development, implementation, review and maintenance of the SQF system. 2) Maintain the integrity of the SQF system. 3). Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System. 4). Determine the proper training needs of the facility based on the current programs at the facility. 5). Training will be documented in a training register maintained by the SQF Practitioner. The employee GMP and Food Safety training specifically directs employees to report problems, both quality and food safety, to personnel with authority to initiate action. The Martin City facility written job descriptions list the designated back-up in case of absence. Hourly employees are cross-trained to cover the absence of key operators. The facility demonstrates a continuous improvement program by utilization of Corrective Action (CA) to complete observations and deficiencies of internal and external audits. Specific Quality KPIs and performance data is shared with the upper management group on a daily basis. This information demonstrates the effectiveness of the quality management System. The facility is aware of black out dates for unannounced audits.

2.1.2.1 The reporting structure describing those who have responsibility for food safety shall be identified and communicated within the site.

RESPONSE: COMPLIANT

2.1.2.2 The senior site management shall make provision to ensure food safety practices and all applicable requirements of the SQF System are adopted and maintained.

RESPONSE: COMPLIANT

2.1.2.3 The senior site management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System.

RESPONSE: COMPLIANT

2.1.2.4 Senior site management shall designate an SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF System, including food safety fundamentals outlined in 2.4.2, and the food safety plan outlined in 2.4.3. ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.1.2.5 The SQF practitioner shall: i. Be employed by the site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code for Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2.7 Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements of the SQF Food Safety Code for Manufacturing, and are informed of their responsibility to report food safety problems to personnel with authority to initiate action.

RESPONSE: COMPLIANT

2.1.2.8 Job descriptions for those responsible for food safety shall be documented and include provision to cover for the absence of key personnel.

RESPONSE: COMPLIANT

2.1.2.9	Senior site management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement. **RESPONSE:** COMPLIANT
2.1.2.10	Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities. **RESPONSE:** COMPLIANT
2.1.2.11	Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed upon unannounced audit. **RESPONSE:** COMPLIANT
2.1.3	**Management Review** Company senior management reviews the SQF system and documents the findings in an annual letter. The last review was dated 9/10/18. The Martin City facility senior staff conducted the review of the SQF system. The review included SQF Policies; Internal and External audit findings; Corrective actions and their investigations and resolutions; and any system changes that would have an impact on the supplier's ability to deliver safe quality food. The SQF Practitioner meets with the Senior Staff on a weekly basis to discuss facility quality KPIs, NRs, Foreign Material Complaints, Quality Complaints, Internal and External Audit findings, and GMP and Labeling trends. Records of the weekly meetings are maintained by the SQF Practitioner. Food Safety Plans, GMP, and other aspects of the SQF System shall be reviewed when any changes made have an impact on the ability to deliver safe food products. All records of the SQF system review are maintained and a SQF Change History Log is available on the facility share drive.
2.1.3.1	The senior site management shall be responsible for reviewing the SQF System and documenting the review procedure. Reviews shall include: i. The policy manual; ii. Internal and external audit findings; iii. Corrective actions and their investigations and resolution; iv. Customer complaints and their resolution and investigation; v. Hazard and risk management system; and vi. Follow-up action items from previous management review. **RESPONSE:** COMPLIANT
2.1.3.2	The SQF practitioner (s) shall update senior site management on a (minimum) monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented. The SQF System in its entirety shall be reviewed at least annually. **RESPONSE:** COMPLIANT
2.1.3.3	Food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be reviewed and updated as needed when any potential changes implemented have an impact on the site's ability to deliver safe food. **RESPONSE:** COMPLIANT
2.1.3.4	Records of all management reviews and updates shall be maintained. **RESPONSE:** COMPLIANT
2.1.4	**Complaint Management** The company's corporate office receives customer complaints for in-house label products produced at Smithfield Martin City facility. Complaints are then sent to plant (FS / QA Manager) for investigation. Corrective actions are included in the investigations. The facility follows the written policy "10-Customer and Consumer Complaint" Doc No. 24240 dated 1/24/19, for handling consumer and customer complaints. The facility's Food Safety / Quality Manager is responsible for quality complaints and food safety complaints. Customer complaint investigation is lead by the FS/QA Manager. Corrective actions are included in the investigations. The corporate Customer Complaints System (CCS) database trends customer complaints by location. Complaints are investigated, tracked, and the results are communicated back to the customer. The facility has received 117 consumer complaints to date in 2019. The auditor reviewed random customer quality complaints that had been received: Texture, slicing and fat were the leading complaints. Proper corrective actions were noted on the complaints. Records of complaints are maintained for an indefinite period of time on the corporate share drive.
2.1.4.1	The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities, arising from products manufactured or handled on site, shall be documented and implemented. **RESPONSE:** COMPLIANT
2.1.4.2	Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents. **RESPONSE:** COMPLIANT
2.1.4.3	Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.5. **RESPONSE:** COMPLIANT
2.1.4.4	Records of customer complaints and their investigations shall be maintained. **RESPONSE:** COMPLIANT

2.1.5 Crisis Management Planning

The facility follows the written "32 - Crisis Management & Continuity Planning " procedure Doc No. 24256 dated 3/20/18 that explains the methods and responsibility the Smithfield will implement to cope with a business crisis that may impact their ability to deliver safe food. If the facility has a crisis event that affects the production at the facility, then production would be moved to a sister plant making similar products. In the event of a business crisis decision making , oversight and initiating actions would come from the Plant Manager. The crisis management team consists of the Senior Management group at the facility. Any controls implemented to ensure a response to an emergency will be monitored by the Crisis Management Team to ensure product safety is not negatively affected. The product affected during a crisis would be the raw materials, ingredients, packaging material, WIP, and finished products. Finished product can be easily identified by the printing or label on the box. Raw materials used in producing the finished product can be identified by the bar code information on the label, visual appearance and storage location. Any required isolation of product or raw materials will be done by the plant Quality Department. Any product released will be inspected by the Quality Department for acceptability. A SQF Crisis Contact List is located in the front of the Crisis Manual. The crisis contact list was dated 6/19/19. The crisis manual includes contact information for the CB and SQFI. Sources of legal and expert advice will be directed by our corporate office. Internal communications depending on the circumstances may be from the Plant Manager. Who communicates with authorities, external organizations and the media will depend on the circumstances. It could be the responsibility of the Plant Manager, company Human Resources or the company Legal Department. The facility did Management Group training on 8/1/19 (mock test for a water main break with very low water pressure). The team assessed that since there was no boil order, minimal product was affected. The team assessed the measures that would be taken to verify the acceptability of product prior to release; determine who would be responsible for internal communication with authorities; and assess the amount of time the facility would be affected. The Crisis Management Plan was dated August 20, 2019. Records are maintained by the Quality Department for at least 2 years. Training for the crisis team members is accomplished through the mock crisis test and also with a mock recall.

2.1.5.1 A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis.

RESPONSE: COMPLIANT

2.1.5.2 The crisis management plan shall include as a minimum: i. A senior manager responsible for decision making , oversight and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure a response does not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations and media.

RESPONSE: COMPLIANT

2.1.5.3 The crisis management plan shall be reviewed, tested and verified at least annually.

RESPONSE: COMPLIANT

2.1.5.4 Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System

The facility has a documented food safety management system that is stored electronically on the company share drive and in hard copy in the SQF binder. The food safety plan is available to relevant staff and includes the facilities food safety policies, the quality policy, the organizational chart, the scope of certification, a list of products covered under the scope of certification, all food safety procedures, pre-requisite programs, and the HACCP plans. Any changes to the food safety plan, the product safety manual, and GMPs will be validated or justified by the SQF Practitioner.

2.2.1.1 A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the organization will use to meet the requirements of the SQF Food Safety Code for Manufacturing , be made available to relevant staff and include: i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The scope of certification; iv. A list of the products covered under the scope of certification; v. Food safety procedures, pre-requisite programs, food safety plans; and vi. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

RESPONSE: COMPLIANT

2.2.1.2 All changes made to food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be validated or justified.

RESPONSE: COMPLIANT

2.2.2 Document Control

The facility follows the written "03 – Document & Record Management" policy Doc No. 24234 dated 1/15/19 that defines the specific requirements for producing and retaining food safety / quality and related documents. All documents pertaining to the SQF system shall be controlled by the SQF Practitioner. A request for a revision may be made by any employee. It will be reviewed by the appropriate senior management personnel. If the change is approved then the SQF Practitioner will make the revision. Affected employees shall be made aware and trained on all changes to the procedure. The facility has a SQF Master List of Records that includes the Policies and Procedures (documents) for the facility. Each policy and procedure (document) has a revision date. The document register is electronic and is updated as needed. Documents are controlled and distributed by the SQF practitioner.

2.2.2.1 The methods and responsibility for maintaining document control and ensuring staff have access to current documents shall be documented and implemented.

RESPONSE: COMPLIANT

2.2.2.2 A register of current SQF System documents and amendments to documents shall be maintained.

RESPONSE: COMPLIANT

2.2.2.3 Documents shall be safely stored and readily accessible.

RESPONSE: COMPLIANT

2.2.3 Records

The facility follows the written "03 - Document & Record Management" policy Doc No. 24234 dated 1/15/19 that defines the specific requirements for producing and retaining food safety / quality and related documents. Food Safety or Quality Assurance Managers are responsible for insuring that all employees performing recordkeeping duties are trained on the procedure before completing any records. Department Supervisors are responsible for enforcing proper recordkeeping procedures in their areas, reviewing all paperwork as required by plant protocol prior to delivering the record to the Food Safety or QA area. Records are stored on site for at least 2 years plus the current year. Records are retained according to the written "Record Retention Schedule". The auditor reviewed the following records: Pre-op Inspection, Metal Detector Check, CCP 1, CQP 1 - 6, Cook Lot Tracking, Nitrite Log, Thermometer Calibration Log, Product Receiving Inspection, Scale Check, Daily Operations Sanitation Check, Operational SSOP, Pre-shipment Review, Label Verification, Product / Room Temperature Verification, Scale Verification, Percent Pump Log, Net Weight Verification, GMP Monitoring, and Incoming and Outgoing Trailer Inspection for November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. Records were complete and signed or initialed by the person making the check.

2.2.3.1 The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.3.3 Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations.

RESPONSE: COMPLIANT

2.3.1 Product Development and Realization

The facility has a written policy, "19 - Product Development Start-Up" Doc No. 24248 dated 7/6/16 that outlines the steps involved in product development. The Corporate Product Development Manager plus Research and Development are responsible for product development. The R&D department does testing at the pilot plant before the initial production at the plant. The Quality Assurance and the Food Safety Managers (or designee) establishes, maintains, implements, and monitors design change control over baseline requirements, documentation and deliverable products. All tests are documented with a test form and archived. This effort is supported by a Food Safety (HACCP) Hazard Analysis designed to find the important Food Safety, Quality, and Process Control characteristics necessary to deliver a safe and quality food product. During scale-up production of a new product, these factors are measured and monitored by the appropriate personnel. New products or product formulation changes, changes in equipment or processes are validated by facility trials, shelf life trials, and product testing. The R&D department does testing at the pilot plant level before the initial production of a new product. Smithfield Product Development policy describes the procedures and responsibilities for validating and verifying new products. Shelf Life trials for new products are validated through the "43 – Smithfield Packaged Meats Shelf Life Protocol" Doc No. 29183 dated 1/18/19. Product shelf life determines the number of days from date of pack that it takes for degradation of the product below its acceptable quality threshold. Food Safety factors are evaluated separately from the shelf life protocol. The acceptable quality is measured by organoleptic evaluation (visual, odor, flavor, and texture), chemical tests (pH change, oxidative rancidity), or microbiological testing. Necessary consumer storage and handling requirements will be determined during the product testing stages. Shelf Life testing is completed at the facility. Food Safety and Quality Plans are prepared and reviewed before and during a product scale-up by the Food Safety / Quality Assurance department. Initial product development records are maintained at the R&D facility. Plant test records and subsequent documentation is stored on the share drive. Shelf life records were available for review. Samples were tested at 75%, 100%, and 125% of shelf life code. Testing results showed that the established shelf life was accurate.

2.3.1.1 The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.1.2	Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by site trials, shelf life trials and product testing. **RESPONSE:** COMPLIANT
2.3.1.3	Shelf life trials where necessary shall be conducted to establish and validate a product's: i. Handling, storage requirements including the establishment of "use by" or "best before dates"; ii. Microbiological criteria; and iii. Consumer preparation, storage and handling requirements. **RESPONSE:** COMPLIANT
2.3.1.4	A food safety plan shall be validated and verified for each new product and its associated process through conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food safety. **RESPONSE:** COMPLIANT
2.3.1.5	Records of all product design, process development, shelf life trials and approvals shall be maintained. **RESPONSE:** COMPLIANT

2.3.2 Raw and Packaging Materials

Specifications for raw materials, ingredients, and packaging materials that impact the safety of finished product are maintained by the Corporate QA/FS Compliance Manager. The specifications are stored on-line in PMDM. The auditor reviewed the specifications for Pre-Trimmed Bone IN Ham dated 2/15/17 and for Sodium Nitrite dated 4/2/09. All raw materials, ingredients, and packaging materials used at the facility comply with relevant legislation. Letters of guarantee from suppliers for ingredients and packaging materials are maintained on line in iCIX. Certificates of analysis are received for ingredients used at the facility. Functionality of packaging material is validated to ensure product safety is not compromised and that the material is fit for its intended purpose and suitable use. Packaging Materials, ingredients, and meat supplies are only purchased from approved suppliers. Receiving personnel have a list of the approved suppliers and cross check all incoming product. The auditor reviewed the Continuing Letter of Guarantee from Saratoga Food Specialties (3 oz. Honey Glaze Packet), North American Salt Corporation (salt), and Flavor Seal (Netting). The facility follows the written "24 – Labeling and Code Date Verification" policy for a consistent and accurate labeling process. Label formatting and approval is the responsibility of Corporate Services Regulatory Affairs. Label approval files are maintained by the corporate labeling group. Copies of the labels are maintained at the facility. The raw material, ingredients, packaging, and label registers are computerized and are updated when changes occur.

2.3.2.1	Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety shall be documented and kept current. **RESPONSE:** COMPLIANT
2.3.2.2	All raw and packaging materials and ingredients shall comply with the relevant legislation in the country of manufacture and country of destination, if known. **RESPONSE:** COMPLIANT
2.3.2.3	The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented. **RESPONSE:** COMPLIANT
2.3.2.4	Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, or certificate of analysis, or sampling and testing. **RESPONSE:** COMPLIANT
2.3.2.5	Verification of packaging materials shall include: i. Certification that all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained. **RESPONSE:** COMPLIANT
2.3.2.6	Finished product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel. **RESPONSE:** COMPLIANT
2.3.2.7	A register of raw and packaging material specifications and labels shall be maintained and kept current. **RESPONSE:** COMPLIANT

2.3.3 Contract Service Providers

Contracts for services that could affect finished goods safety are maintained electronically. They include the description of service and relevant training. All contract service providers entering the facility are required to read and sign a copy of the GMP policies and then follow the requirements at all times. The facility contracts services for pest control, security, laundry service, Trash removal, scale certification, and sanitation. The facilities contract services register is maintained by the engineering department, is electronic, and updated as needed. There was a printed copy of the register in the SQF binder that was dated 10/26/18.

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

RESPONSE: COMPLIANT

2.3.3.2 A register of all contract service specifications shall be maintained.

RESPONSE: COMPLIANT

2.3.4 Contract Manufacturers

N/A - The facility does not have any contract manufacturers.

2.3.4.1 The methods and responsibility for ensuring all agreements relating to food safety and customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not have any contract manufacturers.

2.3.4.2 The site shall: i. Verify compliance with the SQF Food Safety Code for Manufacturing and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the site or other third party agency to confirm compliance to the SQF Food Safety Code for Manufacturing and agreed arrangements; and ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not have any contract manufacturers.

2.3.4.3 Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not have any contract manufacturers.

2.3.5 Finished Product Specifications

Finished product specs are documented, current and approved by the company and their customer. The finished product specifications contain microbiological and chemical limits, labeling and packaging requirements, and quality attributes. The finished product specifications are available to the appropriate staff at the facility. The facilities finished product specification register is electronic and stored on PMDM. The finished product specification register is updated as needed. The auditor reviewed the finished product spec for Bone-in Fully Cooked Spiral Sliced Ham Halves- Hickory Smoked - With Natural Juices. The spec was last updated on 8/23/18.

2.3.5.1 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include: i. Microbiological and chemical limits; and ii. Labeling and packaging requirements.

RESPONSE: COMPLIANT

2.3.5.2 A register of finished product specifications shall be maintained.

RESPONSE: COMPLIANT

2.4.1 Food Legislation

Upon shipment of products, the facility assures that food supplied complies with all legal and USDA requirements. Smithfield has a corporate Research, Development and Quality Department which leads all development of new products and changes to existing products. The facility may obtain information from trade associations, USDA updates and/or suppliers to be kept informed of the latest technology, regulations and industry best practices. Smithfield will notify SQFI and Mérieux NutriSciences Global Certification Services in the event of a food safety incident such as a withdrawal or recall that has to be communicated to the public. The notification contact information is included in crisis contact list.

2.4.1.1 The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of use or sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen and additive labeling, labeling of identify preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices

The Good Manufacturing Practices (GMPs) described in module 11 of this Food Safety Code were observed to have been appropriately applied. The site had not requested or been granted an exemption for the GMP requirements of the SQF Food Safety Code with the exception of allowing water in paper cups in the smokehouse area (2013). Plant programs used to support the food safety plans included; Sanitation Standard Operating Procedures (SSOPs), pest control program, suppliers letter of guarantee, receiving ingredients and packaging materials, receiving fresh products procedure, facility/product temperature monitoring program, Pickle Room procedures, potable water supply and testing program, thermometer calibration procedure, returned product procedure and metal detection.

2.4.2.1 The site shall ensure the Good Manufacturing Practices described in modules 3, 4, 9, 10 or 11 (as applicable) of this Food Safety Code are applied, or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

RESPONSE: COMPLIANT

2.4.2.2 Those Good Manufacturing Practices applicable to the scope of certification that outline how food safety is controlled and assured shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan

The food safety system includes but is not limited to – HACCP program, Pre-Operational Sanitation program, Operational Sanitation Program, Allergen Control Program, Environmental Testing, Pest Control Program, and a Product Recall Program. All food safety programs meet or exceed the applicable USDA/FSIS requirements as stated in 9 CFR. At a minimum, all food safety plans are reassessed annually. The facility has one HACCP plan - Fully Cooked – Not Shelf Stable Cured and Naturally Cured Hams. The facility has multi-disciplinary HACCP team that is lead by the FSQA Manager. The scope of the HACCP plan and the hazard analysis of the plan includes the start and end-point of the manufacturing and all relevant inputs and outputs. The HACCP plan includes a flow chart and lists the Critical Control Point for the plan. A hazard analysis has been completed for the HACCP plan. The HACCP plan identified one Critical Control Point (CCP). The food safety plan includes product descriptions for all products included in the scope of the plan. The intended use of each product is also included in the plan. The food safety team has determined and documented the Critical Control Point (CCP) and pre-requisite programs that must be applied to control all significant hazards. The HACCP plan Fully Cooked – Not Shelf Stable Cured and Naturally Cured Hams has identified one CCP. CCP 1B Cook (minimum internal product temperature 150 degrees F.) The facility has documented procedures for monitoring the CCP and records are maintained. HACCP trained personnel monitor the CCP. Verification is done by a Supervisor or a trained designee. The facility has identified corrective actions to take if a CCP deviation occurs. The food safety team shall develop and document procedures to monitor the CCP to ensure is remains within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency. Annual reassessment of the HACCP plan was completed on 1/14/19. The plan meets both Codex and food regulatory requirements.

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. Feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

RESPONSE: COMPLIANT

2.4.3.2 The food safety plan shall be effectively implemented and maintained and outline the means by which the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

RESPONSE: COMPLIANT

2.4.3.3	The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant products and associated processes. Where the relevant expertise is not available on site, advice may be obtained from other sources to assist the food safety team. **RESPONSE:** COMPLIANT
2.4.3.4	The scope of each food safety plan shall be developed and documented including the start and end-point of the processes under consideration and all relevant inputs and outputs. **RESPONSE:** COMPLIANT
2.4.3.5	Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.5.1) plus any additional information relevant to product safety, such as pH, water activity, and/or composition. **RESPONSE:** COMPLIANT
2.4.3.6	The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative use of the product. **RESPONSE:** COMPLIANT
2.4.3.7	The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw material, packaging material, and service inputs (e.g. water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation. **RESPONSE:** COMPLIANT
2.4.3.8	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs. **RESPONSE:** COMPLIANT
2.4.3.9	The food safety team shall conduct a hazard analysis for every identified hazard, to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT
2.4.3.10	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure. **RESPONSE:** COMPLIANT
2.4.3.11	Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e. a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure. **RESPONSE:** COMPLIANT
2.4.3.12	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard(s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1). **RESPONSE:** COMPLIANT
2.4.3.13	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT
2.4.3.14	The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure. **RESPONSE:** COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.16 Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5)

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4 Approved Supplier Program

The facility maintains an Approved Supplier Program that ensures all incoming goods shall be purchased from approved suppliers listed on the Approved Supplier register. The Register is maintained electronically. The written "22 – Vendor Approval" policy Doc No. 24664 dated 1/28/19 has a provision for substitution of vendors. Unapproved vendors will not be accepted without a review and approval of the required compliance documents by the Corporate FSQA Department. Substitution of vendors, if approved, will only be allowed for a time period of 60 days. After that time, the vendor must go through the formal approval process before further products will be accepted from the vendor. Approval of suppliers is a corporate function. A primary objective of Smithfield is to market safe products of consistent quality that meet or exceed their customer and consumer expectations and comply with the HACCP and GFSI requirements. To accomplish this, it is important that the suppliers have the same objective. Smithfield follows the "22-Vendor Approval" policy to help meet the objective. This is to include all product contact packaging, raw meat material, and non-meat ingredient vendors. These items are equally high risk items as they become the product that is consumed or are in direct contact with the product. Suppliers must maintain registration with the vendor management system and store COAs, LOGs, and copies of 3rd party audits (performed in the last 395 days) in the database. The auditor reviewed the Certificate of Analysis from Saratoga Food Specialties, Bolingbrook, IL for Sweet Ham Glaze dated 4/3/19 and from North American Salt dated 6/22/19. The auditor reviewed the 8/8/20 BRC audit for Saratoga, Bolingbrook, IL and the FSSC audit dated 12/19/19 for North American Salt. Suppliers must provide a COA for each shipment received. The documented food defense plan includes requirements for trailers to be sealed or locked at the time of delivery. Employees are screened at time of hire and the facility is fenced. Employees and visitors must pass by security to gain entrance to the building. Employees are trained to inform supervision if they see something suspicious. Incoming product labels are reviewed by the receiver and a supervisor. Smithfield Foods completed a Self Assessment for Food Fraud Vulnerability on 11/20/18. The assessment included all ingredients, packaging, labels, and protein suppliers for fresh meat. The results of the self assessment are located on Qualtrax and available to all Smithfield facilities.

2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification (refer to 2.3.2) and be supplied by an approved supplier.

RESPONSE: COMPLIANT

2.4.4.2 The receipt of raw materials, ingredients, and packaging materials received from non-approved suppliers shall be acceptable only in an emergency situation, and provided they are inspected or analyzed before use.

RESPONSE: COMPLIANT

2.4.4.3 The responsibility and procedure for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.4.4 The site's food defense plan (refer to 2.7.1.1) shall include measures to secure incoming materials and ingredients and protect them from deliberate act of sabotage or terrorist-like incidents.

RESPONSE: COMPLIANT

2.4.4.5 The site's food fraud vulnerability assessment (refer to 2.7.2.1) shall include the site's susceptibility to raw material or ingredient substitution, mislabeling, dilution and counterfeiting which may adversely impact food safety.

RESPONSE: COMPLIANT

2.4.4.6 The food fraud mitigation plan (refer to 2.7.2.2) shall include methods by which the identified food safety vulnerabilities from ingredients and materials shall be controlled.

RESPONSE: COMPLIANT

2.4.4.7 Raw materials, ingredients, and packaging materials received from other facilities under the same corporate ownership, shall be subject to the same specification requirements (refer to 2.3.2) and approved supplier requirements as all other material providers.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.4.9 Supplier audits shall be based on risk and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

RESPONSE: COMPLIANT

2.4.4.10 A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Product or Equipment

The facility has a written procedure, "31 - FSQA Product Retention Policy" Doc No. 1409 dated 3/5/19 that ensures all products, equipment, tools, and facilities that do not meet Smithfield requirements, customer requirements, government regulations or that need to be held for food safety or quality violations are retained and controlled until the non-conformance or the reason for holding as been corrected or alleviated. All employees have the responsibility for identifying any nonconforming incoming materials, ingredients, supplies, in process product, finished product, equipment, tools, or areas throughout the entire process. All employees are responsible for notifying FSQA or a member of management or nonconforming products or equipment. All nonconforming materials, product or equipment is identified by the application of hold tags and/or tape. The nonconforming product should be segregated from conforming product when possible. Non-conforming product is placed on hold electronically. Nonconforming materials, product, areas and equipment can only be released by the FSQA Department or their designee after all inspections and analyses are completed, documented and meet established requirements. Records of all released products and equipment must be maintained. The auditor reviewed the hold log for July - August 2019. Records reviewed showed the product that was held, defect, quantity, and disposition. No products were on hold at the time of the audit.

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

RESPONSE: COMPLIANT

2.4.5.2 Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.

RESPONSE: COMPLIANT

2.4.6 Product Rework

The facility follows the written "Repackaging of Packaged Meats" policy Doc No. 1629 dated 7/13/17 that's purpose is to define the parameters to control rework. Traditional "rework" is not done at this facility. Rework at this facility would be repackaging finished product or something similar. The plant must keep records clearly documenting the lot numbers and amount of rework used. Records for rework are included with the hold log and maintained electronically. The auditor reviewed the finished product rework records for July - August 2019. Records were complete showing the disposition of the rework.

2.4.6.1 The responsibility and methods outlining how ingredients, packaging materials, or products are reworked shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are supervised by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Each batch of reworked product is inspected or analyzed as required before release; iv. Inspections and analyses shall conform to the requirements outlined in element 2.5.6; and v. Release of reworked product shall conform to element 2.4.7

RESPONSE: COMPLIANT

2.4.6.2 Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

2.4.7 Product Release

The facility follows the written "31 - FSQA Product Retention Policy" Doc No. R-39185 dated 3/5/19 that ensures all nonconforming products, equipment, tools, and facilities that do not meet Smithfield requirements, customer requirements, government regulations or that need to be held for various reasons are retained and controlled until the nonconformance or the reason for the hold has been corrected or alleviated. The facility is required to complete a pre-shipment review for finished products before the product is shipped. The pre-shipment review is completed by a designated individual that has received specialized training. The pre-shipment review ensures that the product complies with regulatory, company, and customer requirements. The company policy ensures product shall only be released by authorized personnel after all required food safety and / or quality inspections and analysis are successfully completed and documented to validate that regulatory, company, and customer specifications have been achieved and passed. Product that is found non-compliant will be retained back to the last acceptable inspection and disposition appropriate with the deficiencies will be assigned and completed prior to additional inspection or release for sale. Records of pre-shipment review and release of hold will be maintained at the facility for 2 years plus the current year. The auditor reviewed the pre-shipment review records for November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. Records were complete and signed by the person making the review.

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released: i. By authorized personnel; and ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release shall be maintained.

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

The Food Safety and Quality systems use the CODEX HACCP methodology to assess if a hazard is reasonably likely to occur or not. Part of the assessment is to evaluate biological hazards. Environmental Monitoring programs are developed and implemented based on risk of hazards. The facility follows the written "14-Environmental Monitoring RTE Lines & Areas) program Doc No. 24244 dated 12/5/18 that is designed to be utilized by the facility to aggressively seek out and eliminate Listeria monocytogenes from the environment before it has a chance to contaminate product. All RTE lines where product is post-lethality exposed will be swabbed for the presence of Listeria spp. as prescribed in the policy. Swabbing will be done weekly if production in run on that line. The sampling day and shift will be randomly generated. Swabbing will be done no sooner than 2 hours after start of production. Pre-moistened swabs or sponges will be used and an area 12" x 12" will be swabbed when possible. A separate swab or sponge will be used for each site. Samples may be composited up to three per bag. Product contact sites are sampled as follows: three pre-determined sites; two operator's gloves, one exploratory contact site. Non-contact sites are sampled as follows: three exploratory, non-contact, sites are swabbed on each line; twenty percent of all drains in the post-lethality RTE area are sampled. The program lists proper corrective actions to take is a suspect positive is found. Deep cleaning and retesting is required. If the retest is negative, the line returns to normal testing. If the retest result is suspect positive, more extensive cleaning and testing is required. The auditor reviewed environmental results for January - August 2019. The facility has had one suspect positive food contact swab out of 2,987 and 1 non-food contact suspect positive out of 1,124 swabs. Swabbing of drains resulted in 8 suspect positive out of 722 swabs. Proper corrective action was noted. The facility followed the written program when the positives occurred.

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food and pet food manufacturing processes.

RESPONSE: COMPLIANT

2.4.8.2 The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.8.3 An environmental sampling and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.

RESPONSE: COMPLIANT

2.4.8.4 Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness

The facility follows the requirements of the "Verification and Validation" policy Doc No. 35128 dated 8/30/19 that explains that the SQF Practitioner is responsible for documenting and implementing the methods, responsibility and criteria for the verification and validation of GMPs, CCPs, and CQPs. All policies are reviewed at a minimum of annually to ensure that they are accurate. The company's Pre-requisite Programs, Food Safety Plan, and Food Quality Plan have identified Critical Limits for insuring food safety and quality. The facility conducts documented validation of key pre-requisite programs and critical limits for food safety (Critical Control Point limits) and food quality (Critical Quality Point limits) to ensure they achieve their intended purpose and are still effective. The SQF Practitioner is responsible for documenting and implementing the methods, responsibility and criteria for the verification and validation of SQF Pre-requisite Programs, Critical Control Points, and Critical Quality Points. CCP 1B (Cooking) was validated on 8/14/19. CQPs were validated on 9/4/19. Records of validation are maintained by the SQF Practitioner.

2.5.1.1 The methods, responsibility and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall ensure that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required result; ii. Critical food safety limits are validated, and re-validated annually; iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and iv. All applicable elements of the SQF Program are implemented and effective.

RESPONSE: COMPLIANT

2.5.1.2 Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities

The facility has established a verification schedule that describes the activities, frequency, and responsible people to maintain the given schedule. The company documents and verifies the effectiveness of the Pre-requisite Programs, GMPs, Food Safety CCPs and Food Quality CQPs. This is done according to the verification and validation documentation schedule. The SQF Practitioner reviews inspection records to ensure all monitoring tasks are completed at the assigned frequency. The auditor reviewed the verification activities for pre-requisite programs and for the pre-shipment reviews for the following dates: November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. The verification of the records was supported by the initials or signature of the individual doing the verification check.

2.5.2.1 A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity shall be prepared and implemented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.5.2.3 Records of the verification of monitoring activities shall be maintained.

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action

The facility follows the written "07 - FSQA Deviation and Reporting Requirements" Doc No. 24238 dated 6/4/19 that details the responsibility and methods outlining how corrections and corrective actions were determined, implemented and verified, including the identification of the root cause and resolution of noncompliance of critical food safety limits, and deviations from food safety requirements. The facility completes a "Food Safety Action Report" if HACCP deviations occur and completes the "CQP / Quality Failure Corrective Action Report" for CQP failures. The facility has not had a HACCP CCP deviation or a CQP deviation since the last SQF audit. The auditor reviewed the corrective and preventive action taken for three NRs; 10/3/18 – Damaged wall coating at the exit of blast cooler #5; 10/23/18 – Netted product contacting the floor; 3/7/19 – Pre-op inspection failure. Proper corrective and preventive actions were taken for all three non-compliance records. HACCP deviations, Quality deviations, and USDA NR records are all maintained for an indefinite period of time.

2.5.3.1 The responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits, and deviations from food safety requirements, shall be documented and implemented.

RESPONSE: COMPLIANT

2.5.3.2 Records of all investigation and resolution of non-conformities including their corrections and corrective action shall be maintained.

RESPONSE: COMPLIANT

2.5.4 Product Sampling, Inspection and Analysis

The company employs a trained staff to inspect and analyze finished product and work in progress at designated process steps to ensure it conforms to specification. The receiving and quality departments have the responsibility for proper inspection of raw materials and dry supply. The operations and quality departments have the responsibility for proper inspection of WIP and finished products. The frequencies and methods of sampling, inspection and analysis will be sufficient to maintain all regulatory, Customer, and Specification commitments. Product samples submitted to the laboratory are analyzed by trained staff utilizing recognized methodologies. Records of all inspection and analysis are maintained and accessible to the applicable personnel either electronically or on paper. The facility follows the written "13-Product Pathogen Testing" procedure Doc No. 24243 dated 7/11/19 that has a purpose to verify existing Food Safety Policies and Practices within the plant. The policy defines the responsibilities and action required when USDA selects finished product samples, a customer requests a certificate of analysis (COA) of finished products, or the company requires test samples for pathogenic bacteria. (Listeria monocytogenes, Salmonella spp., Staphylococcal enterotoxin, Escherichia coli o157:H7 Clostridium perfringens). Pathogen testing results were reviewed for January – July 2019. All test results were negative. The auditor reviewed environmental results for January – August 2019. It was noted that positive results had proper corrective actions. The facility followed the written program when the positive occurred. The facility receives test samples from a certified laboratory to run in house to accommodate the proficiency testing. The outside labs are both accredited to ISO 17025 standards. Proficiency testing was last completed on July 19, 2019.

2.5.4.1	The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress shall be documented and implemented. The methods applied shall ensure: i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements; ii. Inspections are conducted to ensure raw materials, work in process and finished products comply with the relevant specification, regulatory requirements and are true to label; and iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods. **RESPONSE:** COMPLIANT
2.5.4.2	On-site personnel that conduct environmental or product testing shall participate in an applicable proficiency testing program at least annually to ensure accuracy of results. **RESPONSE:** COMPLIANT
2.5.4.3	Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard, and shall be included on the site's contract service specifications register (refer to 2.3.3.1). **RESPONSE:** COMPLIANT
2.5.4.4	Records of all inspections and analyses shall be maintained. **RESPONSE:** COMPLIANT
2.5.5	**Internal Audits and Inspections** Internal audits that measure the effectiveness of the SQF system are conducted per the written auditing schedule. Internal audits following SQF standards are done on an annual basis. Internal audit methodology is patterned after the official certification audits, to include facility observations, employee interviews, review of records, desk audits and corrective actions. Internal audits to the SQF standard are completed by the Internal Audit team that is lead by the FSQA Manager. The FSQA Manager, along with the entire Internal Audit Team, received formal internal auditor training on 8/1/19. A monthly facility audit is completed and documents the examination of products, processes, facilities, equipment, environment and systems to determine the effectiveness of the overall Food Safety and Quality system requirements including pre-requisite programs, food safety plans, quality plans, GMPs, internal and external physical plant, production equipment and legislative controls. The audit's focus is on production of safe and wholesome product while verifying compliance to Food Safety and Quality requirements. The audits are performed by a cross-functional team to identify physical, structural, and general improvements to the plant environment. Deficiencies are identified and addressed in a timely manner. Corrective actions must be documented on a report so that the ongoing status of each corrective action can be effectively tracked. Facility management reviews the findings and corrective actions during their monthly meeting. The auditor reviewed the monthly internal audits for January – August 2019. They contained proper corrective actions and dates that the action was completed.
2.5.5.1	The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code for Manufacturing are audited as per the SQF audit checklist or similar tool; ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken; iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions. **RESPONSE:** COMPLIANT
2.5.5.2	Staff conducting internal audits shall be trained and competent in internal audit procedures. **RESPONSE:** COMPLIANT
2.5.5.3	Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and building /equipment maintenance is compliant to the SQF Food Safety Code for Manufacturing. The site shall: i. Take corrections or corrective and preventative action; and ii. Maintain records of inspections and any corrective action taken. **RESPONSE:** COMPLIANT
2.5.5.4	Where practical staff conducting internal audits shall be independent of the function being audited. **RESPONSE:** COMPLIANT
2.5.5.5	Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained. **RESPONSE:** COMPLIANT

2.6.1 Product Identification

Source material, work in progress, finished product, rework, and all forms of product will have clearly labeled physical identification codes, descriptions or markings which meet all company, regulatory, and customer requirements throughout the manufacturing and shipping process. The facility uses the suppliers lot code for all incoming raw materials, ingredients, and packaging material. The lot code is used to track the material throughout the production process. Finished products are assigned a code that contains all the information about ingredients and packaging used. All products are traced through the system using SAP, an electronic system. The finished products produced at this facility contain a "use or freeze by date" that can also be used as a trace code. Product start up and changeovers are organized and monitored by production supervisors. QA monitors the first product run after a changeover, including the labeling and finished product parameters.

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

RESPONSE: COMPLIANT

2.6.1.2 Product identification records shall be maintained.

RESPONSE: COMPLIANT

2.6.1.3 Product start up and changeover procedures during packing shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label, and that the changeover is inspected and approved by an authorized person.

RESPONSE: COMPLIANT

2.6.2 Product Trace

The facility has a tracing system that ensures accurate tracking of raw inputs as well as finished product to the customer's location (one up and one back). The product tracking system will be tested annually as part of the mock product recall exercise. The facility does a traceability exercise at least annually. The last was dated 7/18/19 for a cleaning chemical used in the facility that was not approved for a food production facility. The contract cleaning service used the chemical from July 8 through July 17. The chemical in question was a quaternary ammonia. The facility produced 3.2 million lbs of product during that time period. Three million pounds had been shipped and 200,000 lbs was still in storage. 100% of the product was accounted for in 1 hour 47 minutes. Prior to 7/18/19, the facility did a traceability exercise on 3/7/18 for an ingredient (Glaze packet). All records were available for review for both exercises. The auditor reviewed the records for incoming ingredients and packaging material as well as records for the shipment of finished product for the following days: November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. Records were complete and signed or initialed by the person making the check.

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable to the customer (one up) and provides traceability through the process to the manufacturing supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back); ii. Traceability is maintained where product is reworked; and iii. The effectiveness of the product trace system shall be reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.3)

RESPONSE: COMPLIANT

2.6.2.2 Records of raw and packaging material receipt and use, and finished product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall

The facility follows the written "32-Crisis Management & Continuity Planning" Doc No. 24256 dated 3/20/18 that includes guidelines for product recall. The manual includes responsibilities and specifics for any crisis involving product that could result in market withdrawals, stock recoveries, or recalls throughout the production and distribution system. The Corporate FSQA Manager is responsible for initiating, managing, and investigating a product withdrawal or recall. The Plant Manager has been designated as the team leader at the facility. Sources of legal, regulatory, and expert advice is available through the corporate office. The written plan requires that SQFI and the certification body be notified within 24 hours in instances of a food safety incident or product recall. The contact information is listed on the crisis contact list. The written plan requires that an investigation be completed to determine the root cause of a withdrawal or recall. The facility tests the recall system at least one time annually. The last test was completed on 7/18/19. See 2.6.2.1 for details. Auditor Requested Trace Exercise: The auditor requested that a traceability exercise be completed during the audit. The auditor chose to trace a finished product Item #90070800020754 Costco Spiral Sliced Ham produced on June 3, 2019. The facility produced 5,572 cases of product and shipped 100% of the product to two storage freezers. The facility traced back and identified the lot numbers of the meat, ingredients, and food contact packaging material that was used in the process. The exercise was completed in 43 minutes. All records and paperwork was available for review.

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

RESPONSE: COMPLIANT

2.6.3.2 Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.

RESPONSE: COMPLIANT

2.6.3.3 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually. Testing shall include incoming materials (one back) and finished product (one up).

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.6.3.5 Records of all product withdrawals, recalls and mock recalls shall be maintained.

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan

The facility follows the written "38 – Food Security" policy Doc No. 24260 dated 6/5/19 that defines the requirements to implement and document an ongoing and effective food defense plan. The plan defines the methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident. The plan addresses personnel access control, perimeter fence, external and internal lighting, locks (no direct access into sensitive areas), and hazard material control that are documented, implemented and maintained. The Plant Manager is the senior site person responsible for food defense at the facility. The facility's exterior perimeter is completely fenced and all employees and visitors must pass by security to enter the facility. Facility employees must swipe their employee ID card for entrance. All areas of the facility that have restricted access are marked with "Authorized Employees Only" signs. Access to product storage area is restricted to designated employees. Access to non-meat ingredient storage areas is also restricted. Chemicals are stored in areas locked with restricted access. Finished product storage areas are restricted to designated employees. All outgoing products are shipped on locked or sealed trailers. The facility conducted a challenge of the system on 9/6/19 when the QA Supervisor passed by the security entrance without showing credentials. The facility also completed the USDA/FSIS Food Defense Plan Securities Measures for Food Defense. This is a risk assessment of the facility and the food defense plan. The self assessment was completed on 8/30/19.

2.7.1.1 The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained.

RESPONSE: COMPLIANT

2.7.1.2 A food defense plan shall include: i. The name of the senior site management person responsible for food defense; ii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing and storage areas through designated access points; iii. The methods implemented to protect sensitive processing points from intentional adulteration; iv. The measures taken to ensure the secure receipt and storage of raw materials, packaging, equipment and hazardous chemicals; v. The measures implemented to ensure raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are held under secure storage and transportation conditions; and vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.

RESPONSE: COMPLIANT

2.7.1.3 The food defense plan shall be reviewed and challenged at least annually.

RESPONSE: COMPLIANT

2.7.1.4 Records of reviews of the food defense plan shall be maintained.

RESPONSE: COMPLIANT

2.7.2 Food Fraud

Smithfield Foods corporate completed a Self Assessment on Food Fraud Vulnerability on 11/20/18. The assessment included all ingredients, packaging, labels, and protein suppliers for fresh meat. The results of the self assessment are located on Qualtrax and available to all Smithfield facilities. Smithfield has a robust vendor approval program that approves only suppliers that will meet their criteria. The Vendor Approval policy defines the requirements for approval of vendors intending to supply products for Smithfield. A primary objective of Smithfield is to market safe products of consistent quality that meet or exceed their customer and consumer expectations and comply with the HACCP and GFSI requirements. To accomplish this, Smithfield suppliers must have the same objectives. All vendors are required to review the Smithfield Foods Vendor Packet and sign the acknowledgement form prior to suppliers being approved. All meat, ingredients, and packaging materials are inspected upon receipt into the facility to insure compliance. The facility cannot purchase materials from unapproved suppliers. The materials and packaging used for all meat products are under the jurisdiction of USDA / FDA regulations and must comply with all company specifications. Once approved all suppliers are evaluated on an on-going basis for performance. If a supplier cannot maintain that performance then they would be removed. The facility inspects products upon receipt. QA will verify the products are made to specifications. Smithfield has strong control programs in place to reduce the risk of food fraud. The programs are evaluated on an ongoing basis and adjusted as needed to control the risks. Protein suppliers are inspected by FSIS. Changes in FDA and FSMA are helping the ingredient and packaging suppliers improve their programs to reduce risks.

2.7.2.1 The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.

RESPONSE: COMPLIANT

2.7.2.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.

RESPONSE: COMPLIANT

2.7.2.3 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.

RESPONSE: COMPLIANT

2.7.2.4 Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.

RESPONSE: COMPLIANT

2.8.1 Allergen Management for Food Manufacturing

The facility has a written "34 - Allergen Control" policy Doc No. 24257 dated 6/20/18 that outlines the appropriate procedures for handling allergens in the facility. A HACCP based risk assessment has been completed for raw materials. No allergen containing ingredients or materials are used at the facility. The plant must conduct an assessment of each new ingredient or change to ingredients to determine if the allergen program is needed or requires reassessment. The facility does not allow loose nuts in the vending machines. Allergen awareness is covered during employee training. N/A - The facility does not produce allergen containing products.

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

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not produce allergen containing products.

2.8.1.3 Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not produce allergen containing products.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not produce allergen containing products.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not produce allergen containing products.

2.8.1.6	Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A - The facility does not produce allergen containing products.
2.8.1.7	The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A - The facility does not produce allergen containing products.
2.8.1.8	The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work in progress and finished product is true to label with regard to allergens. Such measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels and verification of labels on finished product as appropriate and product change over procedures. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A - The facility does not produce allergen containing products.
2.8.1.9	The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A - The facility does not produce allergen containing products.
2.8.1.10	Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A - The facility does not produce allergen containing products.
2.8.1.11	Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introducing unintended allergens through supplier, contract manufacturer, employee and visitor activities. **RESPONSE:** COMPLIANT
2.8.2	**Allergen Management for Pet Food Manufacturing** N/A – the facility does not produce any pet food products.
2.8.2.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those inputs and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch rooms, visitors; iii. A list of allergens which is accessible by relevant staff. iv. The hazards associated with allergens and their control incorporated into the food safety plan. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A – the facility does not produce any pet food products.
2.8.2.2	Product labeling, in accordance with regulatory requirements, shall include allergens where risks from cross contact have been identified. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A – the facility does not produce any pet food products.
2.8.3	**Allergen Management for Manufacturers of Animal Feed** N/A – The facility does not manufacturer Animal Feed.

2.8.3.1 Sites that exclusively manufacture animal feed and do not manufacture, handle or store food or pet food products are not required to implement an allergen management plan unless required by regulation or customer requirement.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A – The facility does not manufacturer Animal Feed.

2.8.3.2 Where an allergen management plan is required by regulation or customer specification, the requirements of 2.8.2 shall apply.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A – The facility does not manufacturer Animal Feed.

2.9.1 Training Requirements

The facility follows the written "37 – Food Safety and Quality Employee Training" policy Doc No. R - 24259 dated 6/4/19 that requires the facility to have a training program in place for both new and existing employees. There are written programs addressing the training requirements for personnel practices, food safety & quality requirements, pre-requisite programs and specifications. Training is completed using Qualtrax (electronic), formal class room training, video or power point presentation training, and one on one /on-the-job training. Jacob Davenport, FSQA Manager, has been formally trained in HACCP & SQF (2017). Jacob is responsible for the implementation and maintenance SQF Food Safety and Quality System at the facility.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.9.2 Training Program

The facility training program requires all employees to receive the appropriate job specific training prior to performing the job independently. They also receive on-the-job training that reviews the food safety and quality aspects of that job including how to properly fill associated paperwork. Employees responsible for monitoring and verifying GMPs shall receive job specific training for all programs relating to the GMPs. Employees responsible for monitoring and verifying HACCP activities shall receive job specific HACCP Quality Plan training. Employees responsible for monitoring and verifying tasks associated with the SQF system will receive job specific SQF training. Employee training is done at time of hire and on an annual basis thereafter.

2.9.2.1 An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Developing and applying Good Manufacturing Practices; ii. Applying food regulatory requirements; iii. Steps identified by the hazard analysis and/or other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety; and iv. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.9.3 Instructions

The plan requires new and current employees receive training to ensure they understand and execute the requirements and objectives of the Quality Assurance Policies, Programs, and Work Instructions. The training ensures that each employee is able to perform their responsibilities. Quality Policies, Programs and Work Instructions are available to all QA and FS employees. Corporate programs are available on Qualtrax. Local policies and procedures are available on the company share drive.

2.9.3.1 Instructions shall be available in the languages relevant to the staff, explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety and process efficiency are to be performed.

RESPONSE: COMPLIANT

2.9.4 HACCP Training Requirements

The Quality Assurance Manager has been formally trained in HACCP. He is responsible for the development and maintenance of the Food Safety Plan at the facility.

2.9.4.1 HACCP training shall be provided for staff involved in developing and maintaining food safety plans.

RESPONSE: COMPLIANT

2.9.5 Language

Training is provided in English and Spanish to facility employees. A French and Burmese translator is available if needed.

2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.

RESPONSE: COMPLIANT

2.9.6 Refresher Training

The facility training programs requires that all employees receive training at time of hire and on an annual basis thereafter. Refresher training would required when significant changes to the Food Safety program, the Food Quality Program, or changes in process or procedures occur.

2.9.6.1 The training program shall include provision for identifying and implementing the refresher training needs of the organization.

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

The facility maintains a training skills register and all training activities are documented. The training register includes the participant name, description of the skills and training provided, date of training, and the name of the qualified trainer. Supervisors verify that the training was completed and that the trainee is competent to complete the required tasks. The training skills register is electronic and maintained by the FS / QA Department.

2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Supervisor's verification that the training was completed and that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

No operations in the vicinity of the site interfere with the safe and hygienic operation of the premises. The facility has a grant of inspection from the U.S. Department of Agriculture. (Est. # 509K). The grant of inspection was dated 3/7/19.

11.1.1.1 The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations.

RESPONSE: COMPLIANT

11.1.1.2 The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

11.2.1 Materials and Surfaces

All product contact surfaces were constructed properly using appropriate materials. All non-food surfaces were properly constructed using appropriate materials.

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

RESPONSE: COMPLIANT

11.2.2 Floors, Drains, and Waste Traps

Floors were properly graded and made of appropriate materials. Floor drains were properly constructed and maintained. Drain covers were used. No excessive water was observed on the floors. Drains are easily accessible and located so they can be properly cleaned. The facility uses sanitizing quat blocks in the RAW and RTE production drains and cooler drains. Drains were directed to the facility waste water system then directed to the City Sewer System. No waste collection is in the processing areas. There are no waste trap systems at the facility. Waste water flows directly to the waste water plant.

11.2.2.1 Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

RESPONSE: COMPLIANT

11.2.2.2 Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or waste water under normal working conditions.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.2.4 Waste trap system shall be located away from any food handling area or entrance to the premises.

RESPONSE: COMPLIANT

11.2.3 Walls, Partitions, Floors and Ceilings

Walls, ceilings, and doors were observed to be of durable construction and the internal surfaces were smooth and impervious. Wall to wall and wall to floor junctions were designed properly to be easily cleaned and were sealed to prevent the accumulation of food debris. Overhead piping was properly designed and maintained. Conduits and pipes were properly constructed to allow for ease of cleaning. The facility does not have pipes carrying sanitary waste or waste water that are located directly over product lines. Doors, windows, and their frames located in the processing areas are properly constructed and easily cleaned. The facility does not have windows in the processing areas. The facility's ceilings are constructed and maintained to prevent contamination to products. The facility does not have drop ceilings in the production or storage areas of the facility. Drop ceilings are in the office areas and employee amenities area.

11.2.3.1 Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light-colored finish, and shall be kept clean (refer to 11.2.13.1).

RESPONSE: COMPLIANT

11.2.3.2 Wall to wall and wall to floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: COMPLIANT

11.2.3.3 Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed to prevent the contamination of food, ingredients and food contact surfaces and allow ease of cleaning.

RESPONSE: COMPLIANT

11.2.3.4 Pipes carrying sanitary waste or waste water that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients and food contact surfaces, and shall allow ease of cleaning.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.3.6 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products.

RESPONSE: COMPLIANT

11.2.3.7 Drop ceilings shall be constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.

RESPONSE: COMPLIANT

11.2.4 Stairs, Catwalks and Platforms

Stairs, platforms, and catwalks were properly constructed and maintained in good condition.

11.2.4.1 Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1).

RESPONSE: COMPLIANT

11.2.5 Lightings and Light Fittings

Lighting was adequate in the food processing area and at inspection stations and staff is able to carry out tasks efficiently and effectively. All light fittings were observed to be shielded or shatterproof in the facility, including the warehouses and other areas where the product is protected. Light fixtures that are not flush mounted to the ceiling are made of cleanable materials and are included in the master sanitation schedule.

11.2.5.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.5.3 Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination.

RESPONSE: COMPLIANT

11.2.6 Inspection / Quality Control Area

Inspection belts and tables are provided in the process area(s) for inspection of materials during manufacturing. Inspection areas are provided with adequate lighting. Hand wash facilities are within easy access of the inspection area. Waste is removed from inspection / quality control areas on a routine basis. The inspection / quality control areas were noted to be clean with no build-up of trash or product.

11.2.6.1 A suitable area shall be provided for the inspection of the product if required.

RESPONSE: COMPLIANT

11.2.6.2 The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to hand washing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

RESPONSE: COMPLIANT

11.2.7 Dust, Insect, and Pest Proofing

All external windows, doors, and other openings were effectively sealed when closed and provided protection against dust, vermin, and flies. Personnel doors are fitted with self-closing devices and were properly sealed. External doors are insect proofed by a self closing device. Dock doors include bumpers and shelters to seal around truck/trailer. Insect light traps are properly located and do not present a contamination risk.

11.2.7.1 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin and other pests.

RESPONSE: COMPLIANT

11.2.7.2 External personnel access doors shall be provided. They shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against ingress of dust, vermin and other pests.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.7.4 Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison rodenticide bait shall not be used inside ingredient or product storage areas or processing areas.

RESPONSE: COMPLIANT

11.2.8 Ventilation

Adequate ventilation was provided in all areas. No overhead condensation was observed at any time during the audit including the area housing the cooking systems. The RTE areas of the facility, including the cook areas, have positive air pressure.

11.2.8.1 Adequate ventilation shall be provided in enclosed processing and food handling areas.

RESPONSE: COMPLIANT

11.2.8.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.12, to prevent unsanitary conditions.

RESPONSE: COMPLIANT

11.2.8.3 Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features: i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over the cooker(s); ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk; and iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.

RESPONSE: COMPLIANT

11.2.9 Equipment, Utensils, and Protective Clothing

Smithfield Corporate requires the facility to have a specification for equipment and utensils prior to purchasing. For larger items, a capital improvement request is required. The facility's equipment and utensils are designed, constructed, installed, operated and maintained so as to not pose a contamination threat. Tables, conveyors, injectors, stuffers and other mechanical processing equipment are hygienically and properly designed and easily cleaned. Equipment surfaces were smooth, impervious and free from cracks or crevices. Product containers for edible and inedible material were all constructed of materials that are non-toxic, smooth, and easily cleaned. Inedible product is placed in yellow containers on the RTE side and in red containers on the RAW side of the facility. Waste water is directly discharged into the floor drainage system. Facility employees wear cloth smocks (in RAW area) and use plastic aprons with sleeves, and powder free latex gloves that will not contaminate food products. Plastic aprons with sleeves and gloves are single use. Smocks are laundered by a contract service. All protective wear, including smocks, are removed when exiting the production area. The employee will use a clean smock and new gloves, and apron with sleeves when returning to production. Equipment and utensils are cleaned daily by the sanitation crew. Protective clothing (smocks) are cleaned daily by a contracted company.

11.2.9.1 Specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.9.4 Product containers, tubs, bins for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned as per 11.2.13. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

11.2.9.5 Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system, and to meet local regulatory requirements.

RESPONSE: COMPLIANT

11.2.9.6 Protective clothing shall be manufactured from material that will not contaminate food and is easily cleaned.

RESPONSE: COMPLIANT

11.2.9.7 Racks shall be provided for the temporary storage of protective clothing when staff leaves the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.

RESPONSE: COMPLIANT

11.2.9.8 All equipment, utensils and protective clothing shall be cleaned after use or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

11.2.10 Premises and Equipment Maintenance

The facility has a planned maintenance schedule and a SOP for Preventive Maintenance and Repairs. The preventative maintenance program is computerized (SAP) and generates preventive maintenance work orders. Planned maintenance activities are completed during non-production hours when possible. Maintenance technicians follow the outline listed on the PM worksheet that is generated by the computerized maintenance system. The maintenance schedule includes buildings, equipment, and other areas of the premises. Maintenance technicians are aware of product safety and quality requirements when doing maintenance activities. Any failures of the plant in general, including the warehouse areas, or processing equipment will be documented by the maintenance department. These failures will be considered and the maintenance schedule may be adjusted. The maintenance staff and contractors are required to follow the facility GMPs. Maintenance and engineering contractors must be trained on the facility food safety and personal hygiene requirements before starting work. If maintenance activities occur during production hours, the area supervisor must be informed of any work being performed by maintenance. General maintenance activities are planned for 3rd shift during sanitation or on weekends when production is not in operation. If temporary repairs must be done, they shall not pose a threat to product safety or quality and should be included in the cleaning program. No temporary repairs were noted during the observation portions of the audit. The written maintenance program requires that all tools and extra parts be removed from the work area after maintenance is complete and inform the area supervisor so the area can be cleaned. Pre-op inspection must be completed before the area is released for production. The facility only uses food grade lubricants on equipment and their use is controlled to prevent product contamination. There was no paint observed on product contact surfaces.

11.2.10.1	The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and implemented in a manner that minimizes the risk of product, packaging or equipment contamination. **RESPONSE:** COMPLIANT
11.2.10.2	Routine maintenance of plant and equipment in any food processing, handling or storage area shall be performed according to a maintenance-control schedule and recorded. The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality. **RESPONSE:** COMPLIANT
11.2.10.3	Failures of plant and equipment in any food processing, handling or storage area shall be documented, reviewed and their repair incorporated into the maintenance control schedule. **RESPONSE:** COMPLIANT
11.2.10.4	Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3.1, 11.3.2, 11.3.3, 11.3.4). **RESPONSE:** COMPLIANT
11.2.10.5	All maintenance and other engineering contractors required to work on site shall be trained in the site's food safety and hygiene procedures, or shall be escorted at all times, until their work is completed. **RESPONSE:** COMPLIANT
11.2.10.6	Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling or storage area. **RESPONSE:** COMPLIANT
11.2.10.7	The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times. **RESPONSE:** COMPLIANT
11.2.10.8	Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions. **RESPONSE:** COMPLIANT
11.2.10.9	Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed and a pre-operational inspection conducted prior to the commencement of site operations. **RESPONSE:** COMPLIANT
11.2.10.10	Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product. **RESPONSE:** COMPLIANT
11.2.10.11	Paint used in a food handling or contact zone shall be suitable for use and in good condition and shall not be used on any product contact surface. **RESPONSE:** COMPLIANT

11.2.11 Calibration

The facility follows the written "Thermometer Calibration and Accuracy Verification" procedure Doc No. 10532 dated 10/9/15 that establishes the criteria to be followed for the calibration of thermometers. For scale calibration, the facility follows the written "Scale Verification" procedure Doc No. 1935 dated 4/18/18. If testing and measuring equipment is found to be out of calibration, product will be placed on hold back to the last verifiable good check and reworked. Calibrated equipment is stored in a secure area when not in use to prevent damage and unauthorized adjustment. Equipment is calibrated to national reference standards and methods. Thermometer calibration is verified using a NIST certified calibration block - CheckTemp II by Tel-Tru. The facility has three CheckTemp machines. The dates of certification are 5/9/19, 4/15/19, and 7/30/19 for the three machines. The facility uses an outside contractor to certify the scales used in the facility. Scales are certified annually. Scales were last certified on 7/27/19 by Accurate Superior Scales, Kansas City, MO. Metal detector calibration is verified daily before production starts, hourly during production, and at the end of the production day. Metal detector calibration is verified using a seeded sample for Fe, Non-Fe, and Stainless Steel. The auditor reviewed calibration verification records for the following days: November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. Records were found to be complete and were initialed or signed by the person doing the check.

11.2.11.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite program, food safety plans and food quality plans and other process controls, or to demonstrate compliance with customer specifications shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

11.2.11.2 Procedures shall be documented and implemented to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state.

RESPONSE: COMPLIANT

11.2.11.3 Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.11.5 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.

RESPONSE: COMPLIANT

11.2.11.6 Calibration records shall be maintained.

RESPONSE: COMPLIANT

11.2.12 Pest Prevention

The facility contracts the pest control service to Schendel Pest Control, Lenexa, KS. The premises and its surrounding areas are kept free of waste and accumulated debris. The inspection of the exterior of the facility did not reveal any rodent or pest problems. If pest activity is identified, the surrounding area will be inspected to determine if any food products, raw materials or packaging have been contaminated. The pest control service technician would be contacted to do an emergency service of the area where the activity was identified. If any food products, raw materials or packaging has been contaminated, the products would be disposed of. The emergency service report would be generated and placed in the pest control book. The integrated pest management system describes the methods and responsibility of the pest control program. The PCO will record any pest sightings and provide trend reports of pest activity. The program will outline the methods used to prevent pest problems, the method of elimination, the frequency of service, prepare a map of all pest control devices with location and number, list the approved chemicals for the facility, and provide sample labels and SDS for approved chemicals. The PCO will service the facility on a regular basis as described in the integrated pest control program. The PCO will meet with a company official after each service and leave a record of the service. The Pest Control Companies IPM program was dated July 25, 2019. There are 43 live catch devices on the interior of the facility that are serviced by the PCO weekly. Any activity is noted on the service report left by the PCO after each visit. There are 25 exterior bait stations that are serviced 2x month by the PCO. Any activity is noted on the service report. The exterior stations were all locked and secured. Live catch devices are located on each side of doors that open to the exterior. This includes dock doors. ILT bulbs are replaced annually. 11.2.12.7 N/A - The facility does not store pesticides on site. Comment: The written pest control program includes a current PCO Applicator's license (expires 5/31/20) and a letter of indemnity insurance (expires 12/19/19). The company business license from the Department of Agriculture State of Kansas expires on 12/31/19. The facilities pest control maps, dated 7/25/19, is included in the pest control program and are reviewed regularly by the person responsible for the program. SDS sheets and labels were available online to review for chemicals used in the plant. These documents are available on-line at schendelpest.pestconnect.com. SDS sheets and sample labels were reviewed for First Strike Soft Bait (EPA #7173-258, Advion Ant Gel (EPA #100-1498), and Gentrol (EPA #2724-351). The SDS and sample labels were available for review and were located on-line. The site maintains pest control inspection records in the pest control binder. The PCO checks the interior pest control devices every week and exterior bait stations 2x month. The pest control company does a quarterly pest control audit with the facility and the records are located on line. All pest control services are completed by the PCO. 11.2.12.9 N/A - The facility does not dispose of unused pest control chemicals. The PCO controls all pesticides and rodenticides.

11.2.12.1 The methods and responsibility for pest prevention shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.

RESPONSE: COMPLIANT

11.2.12.2	Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging. **RESPONSE:** COMPLIANT
11.2.12.3	Food products, raw materials or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation investigated and resolved. Records shall be kept of the disposal, investigation, and resolution. **RESPONSE:** COMPLIANT
11.2.12.4	The pest prevention program shall: i. Describe the methods and responsibility for the development, implementation and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods; v. Outline the frequency with which pest status is to be checked; vi. Include on a site map the identification, location, number and type of bait stations set; vii. List the chemicals used (they are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available); viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests. **RESPONSE:** COMPLIANT
11.2.12.5	Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present. **RESPONSE:** COMPLIANT
11.2.12.6	Records of all pest control applications shall be maintained. **RESPONSE:** COMPLIANT
11.2.12.7	Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.5 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A - The facility does not store pesticides on site.
11.2.12.8	Pest contractors shall be: i. Licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.3) which will include and maintain a site map indicating the location of bait stations traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and vi. Provide a written report of their findings and the inspections and treatments applied. **RESPONSE:** COMPLIANT
11.2.12.9	The site shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that: i. Empty chemical containers are not reused; ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor. **RESPONSE:** NOT APPLICABLE **EVIDENCE:** N/A - The facility does not dispose of unused pest control chemicals. The PCO controls all pesticides and rodenticides.

11.2.13 Cleaning and Sanitation

The facility has an effective Sanitation SOP program that has been properly implemented. The master sanitation schedule lists the areas and equipment to be cleaned. There are written procedures on how to clean all equipment. The cleaning guidelines were written in English. The site manager would translate for any Spanish speaking employees. N/A - The facility does not have a Clean in Place (CIP) system. Comment: Production and Quality employees do a pre-op inspection to verify the effectiveness of cleaning prior to the start of production. The facility completes a weekly TPC check on product contact and non-product contact sites to verify the effectiveness of Sanitation. Twenty four (24) 3M Petri Film (TPC) plate samples are done weekly. The pass/fail limit for TPC is 24 cfu. Fourteen (14) of the plates are used in the RTE area and ten (10) are used in the Raw area. The facility has an in house laboratory that completes the test and records are maintained electronically. The auditor reviewed the swabbing results for the past 12 months. Proper corrective actions were taken for any swabs that results are > 24 colony forming units (cfu). The auditor reviewed the master sanitation schedule for January - July 2019 and the pre-op records for November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. Proper corrective actions were noted for any deficiencies found during pre-op. The auditor returned to the facility at 5:00 AM on the second morning of the audit to observe the end of sanitation and the pre-operational inspection in the RTE processing area. During the pre-op inspection, the auditor requested that a titration test be completed for the sanitizer used in the production area (K Quat 4 Quaternary Ammonium based sanitizer). The Sanitation Site Manager did the titration test and the results were 380 ppm. The ppm range for that chemical is 200 - 400 ppm. No issues were observed and all areas were clean. No high pressure hoses are left in the production room after the end of sanitation. Sanitizer was used on all equipment after the inspection was completed. Mid-shift cleaning is NOT done in the RTE area. Racks and areas for storing cleaned utensils are provided. The sanitation chemicals used in the facility are approved for use in a food production facility. Each chemical has an approval letter that is stored in the Chemical Information Book. The facility follows the written "14-Environmental Monitoring RTE Lines & Areas) program Doc No. 24244 dated 12/5/18 that is designed to be utilized by the facility to aggressively seek out and eliminate Listeria monocytogenes from the environment before it has a chance to contaminate product. All RTE lines where product is post-lethality exposed will be swabbed for the presence of Listeria spp. as prescribed in the policy. Swabbing will be done weekly if production in run on that line. The sampling day and shift will be randomly generated. Swabbing will be done no sooner than 2 hours after start of production. Pre-moistened swabs or sponges will be used and an area 12" x 12" will be swabbed when possible. A separate swab or sponge will be used for each site. Samples may be composited up to three per bag. Product contact sites are sampled as follows: three pre-determined sites; two operator's gloves, one exploratory contact site. Non-contact sites are sampled as follows: three exploratory, non-contact, sites are swabbed on each line; twenty percent of all drains in the post-lethality RTE area are sampled. The program lists proper corrective actions to take is a suspect positive is found. Deep cleaning and retesting is required. If the retest is negative, the line returns to normal testing. If the retest result is suspect positive, more extensive cleaning and testing is required. The auditor reviewed environmental results for January - August 2019. The facility has had one suspect positive food contact swab out of 2,987 and 1 non-food contact suspect positive out of 1,124 swabs. Swabbing of drains resulted in 8 suspect positive out of 722 swabs. Proper corrective action was noted. The facility followed the written program when the positives occurred. The facilities detergents and sanitizers are approved for use in a food production facility. A chemical inventory log is available for review. The chemical inventory is done weekly by the sanitation site manager. Cleaning chemicals are properly stored in a locked room. SDS sheets are available for all chemicals used in the facility. The facility does annual sanitation training. Regular sanitation training was last completed in August 2019. Chemical handling training was last completed on 8/19/19. The auditor reviewed the sample label and SDS for K Quat 4 Quaternary Ammonium Sanitizer and K Foam SF Plus Chlorinated Caustic High Foaming Cleaner. The sample labels and SDS are stored in the chemical room and the sanitation office. The facility would dispose of unused detergents and sanitizers by sending them back to the supplier. The facility receives chemicals mainly in bulk containers. When empty, the containers are rinsed and recycled. The facility maintains daily pre-operational records on site for 2 years.

11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Methods used to confirm the correct concentrations of detergents and sanitizers, and vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.2.13.2 Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing.

RESPONSE: COMPLIANT

11.2.13.3 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils shall be provided as required.

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not have a Clean in Place (CIP) system.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.13.7	The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared. **RESPONSE:** COMPLIANT
11.2.13.8	Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labelled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use; ii. An inventory of all chemicals purchased and used shall be maintained; iii. Detergents and sanitizers are stored as outlined in element 11.6.4; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v. Only trained staff handles sanitizers and detergents. **RESPONSE:** COMPLIANT
11.2.13.9	Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained. **RESPONSE:** COMPLIANT
11.2.13.10	The site shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor. **RESPONSE:** COMPLIANT
11.2.13.11	A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained. **RESPONSE:** COMPLIANT

11.3.1 Personnel

The facility's GMP's covers disease control. Individuals with open wounds, coughing, sneezing, spitting, or any other means of contacting materials, ingredients, food packaging, food, or food contact surfaces will not be allowed to work in the production or warehouse areas. The facility has trained employees who are emergency responders to react to emergencies that result in injury and the spillage of bodily fluids. After the incident is under control, they will ensure that the affected areas are adequately cleaned and contaminated materials are properly disposed of. The facilities GMP's includes requirements for sores and cuts. The facility requires band-aids that are blue and metal detectable. The facilities GMP's prohibits smoking, eating, and drinking in production areas.

11.3.1.1	Personnel who are known to have been known to be carriers, or are carriers, of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food, or enter storage areas where food is exposed. **RESPONSE:** COMPLIANT
11.3.1.2	The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids from open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury which causes spillage of bodily fluid, properly trained employee shall ensure that all affected areas including handling and processing areas have been adequately cleaned and that all materials and products have been quarantined and disposed of. **RESPONSE:** COMPLIANT
11.3.1.3	Personnel with exposed cuts, sores or lesions shall not be engaged in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing. **RESPONSE:** COMPLIANT
11.3.1.4	Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging or equipment. **RESPONSE:** COMPLIANT

11.3.2 Hand Washing

Hand washing stations are provided at the entrance point to the processing area and at accessible locations in the production areas. Hand wash basins are constructed of appropriate material and have available hot / warm water. Hand soap and paper towels are provided at each hand wash station. The facility produces processed RTE meats and has well equipped hands-free wash sinks and sanitizer available in appropriate places. Hand wash signs were posted at all other hand wash sinks. The auditor observed company personnel properly washing hands when entering food processing / handling areas and after handling hoses or contaminated material. These requirements are all included in the facility's written GMP's. The facility's GMP's require employees to wash hands when entering the production area.

11.3.2.1 Hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.2.4 A sign instructing people to wash their hands, and in appropriate languages, shall be provided in a prominent position.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.2.6 When gloves are used, personnel shall maintain the hand washing practices outlined above.

RESPONSE: COMPLIANT

11.3.3 Clothing

The facility uses consumer complaints and product micro analysis as a risk analysis to ensure that the clothing and hair policy protects materials, food and food contact surfaces from microbiological and physical contamination. The facility provides smocks (clean outer garments) and footwear stipend for employees. Employees are required to wear steel toed boots. The auditor observed staff in high risk areas (RTE) wearing clean correct clothing. If smocks or aprons become excessively soiled, the employee will dispose of the apron and change into a clean smock. Gloves and aprons with sleeves were observed to be intact and in a sanitary condition. Gloves and aprons with sleeves are disposable and changed after each break, upon re-entry into the processing area and when damaged. Gloves and aprons with sleeves are single use and replaced as needed.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.4 Jewelry and Personal Effects

The facility does not allow jewelry in the processing areas with the exception of a medical alert bracelet. Wearing the medical alert bracelet must be cleared through personnel.

11.3.4.1 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and prescribed medical alert bracelets can be permitted, however the site will need to consider their customer requirements and the applicable food legislation.

RESPONSE: COMPLIANT

11.3.5 Visitors

Visitors were observed wearing suitable footwear and clothing in the processing areas. All plant employees, including management and maintenance, were observed properly following the company protocol. Visitors are required to remove jewelry and other loose objects before entering the production area. Visitors are required to follow the facility's GMP's which states "Visitors exhibiting visible signs of illness may be prevented from entering food processing areas". All visitors were observed entering and exiting the processing areas through the proper staff entrance points and complying with the required hand washing / sanitizing. Visitors must receive GMP training before entering the facility. When in the production areas, visitors must be accompanied by a plant employee.

11.3.5.1 All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area.

RESPONSE: COMPLIANT

11.3.5.2 All visitors shall be required to remove jewelry and other loose objects.

RESPONSE: COMPLIANT

11.3.5.3 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed.

RESPONSE: COMPLIANT

11.3.5.4 Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all hand washing and personnel practice requirements.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.6 Staff Amenities

Staff amenities have adequate lighting and ventilation and are made available to all employees.

11.3.6.1 Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and processing of product.

RESPONSE: COMPLIANT

11.3.7 Change Rooms

Smocks and/or aprons with sleeves are provided for staff and visitors. Areas are provided to change into and out of smocks and the protective clothing. The facility provides locker rooms for employees to store street clothing and personal items. N/A - Showers are not required at this facility.

11.3.7.1 Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required.

RESPONSE: COMPLIANT

11.3.7.2 Change rooms shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled.

RESPONSE: COMPLIANT

11.3.7.3 Provision shall be made for staff to store their street clothing and personal items separate from food contact zones and food and packaging storage areas.

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - Showers are not required at this facility.

11.3.8 Laundry

The facility provides clean smocks and/or aprons with sleeves for employees working in the high risk area. Smocks are laundered by a contracted company. White cloth gloves provided by the company are laundered in house.

11.3.8.1 Provision shall be made for the laundering and storage of clothing worn by staff engaged in high risk processes and for staff engaged in processing operations in which clothing can be heavily soiled.

RESPONSE: COMPLIANT

11.3.9 Sanitary Facilities

Rest rooms are located away from processing rooms. Rest rooms are properly designed and maintained. Sanitary drainage is connected to the City Sewer System. All rest rooms are equipped with hand wash sinks (basins).

11.3.9.1 Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and vi. Kept clean and tidy.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.9.3 Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.2.

RESPONSE: COMPLIANT

11.3.10 Lunch Rooms

The lunch room area is separate from food processing areas. The lunch room is properly ventilated, well lit, and have an adequate number of tables and chairs for employees. A sink with hot and cold water, refrigerated storage, and microwave ovens are provided. The lunch room is adequately heated and cooled. The outside eating areas were clean and free of waste materials. Hand wash signs are posted at the entrance to the processing area. The signs are in English and Spanish and have hand wash graphics.

11.3.10.1 Separate lunch room facilities shall be provided away from a food contact/handling zone.

RESPONSE: COMPLIANT

11.3.10.2 Lunch room facilities shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities enabling them to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.10.4 Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in lunch rooms and at lunch room exits, and in outside eating areas, if applicable.

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

The auditor observed all personnel entering the processing area only through personnel access doors. Doors were observed kept closed. The auditor observed packaging material, food products, and ingredients were in appropriate containers as required and off the floor. The facilities waste containers are all color coded and emptied as needed. Employees are not allowed to eat or taste product in the processing areas. The facility does not allow the wearing of false fingernails, extended eyelashes, or the use of nail polish. All employees are required to wear the provided hair net and beard for employees with facial hair. N/A - The facility staff does not undertake sensory evaluations in the food handling /contact zone area(s). Comment: Wash down hoses were observed properly stored when not in use.

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2; vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food; vii. Hair restraints are used where product is exposed.

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility staff does not undertake sensory evaluations in the food handling / contact zone area(s).

11.4.1.3 All wash down hoses shall be stored on hose racks after use and not left on the floor.

RESPONSE: COMPLIANT

11.5.1 Water Supply

The facility has an adequate supply of potable water, provided by the Kansas City Municipal Water District, that is used during processing operations, as an ingredient, and for cleaning. Hot and cold water is available in adequate supply to clean equipment and the facility. The facility has two backflow devices on the main waterlines entering the building. The backflow devices are checked and certified on an annual basis. They were last certified on 4/28/19 by the KC Water Services, Kansas City, MO. N/A - The facility does not have non-potable water in the facility. N/A - The facility does not have on-site water storage facilities.

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment.

RESPONSE: COMPLIANT

11.5.1.2 Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

11.5.1.3 The delivery of water within the premises shall ensure potable water is not contaminated.

RESPONSE: COMPLIANT

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not have non-potable water in the facility.

11.5.1.5 Where water is stored on site, storage facilities shall be adequately designed, constructed and maintained to prevent contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not have on-site water storage facilities.

11.5.2 Water Treatment

Water is not treated before being used in the facility. The facility receives potable chlorinated water from the Kansas City Municipal Water District. The facility has a waste water treatment area where solids are removed from the waste water and the pH is stabilized. Engineering is responsible for the waste water treatment area. The waste water treatment area is staffed 24 / 7. The facility monitors the pH level of the waste water on a regular basis. Water at the facility is used as an ingredient in processing and in cleaning and sanitizing equipment. The facility has the 2019 Water Quality Report from the supplier. The facility does water potability testing on a monthly basis using the in house Smithfield Lab at the facility. On an annual basis, a water sample is sent to the University of Iowa Lab, Iowa City, IA. The Iowa Lab is a certified water testing laboratory. Three sites from the interior of the facility are sampled each month. Three samples are also sent to Iowa for the annual test. Test results were reviewed for 8/28/19 and 7/8/19. Sample results were "non-detectable" for Coliform. The facilities annual water potability test was completed on 7/10/19 by Iowa University. The results were "non-detectable" for Coliform.

11.5.2.1 Water treatment methods, equipment and materials, if required, shall be designed, installed and operated to ensure water receives an effective treatment.

RESPONSE: COMPLIANT

11.5.2.2 Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

RESPONSE: COMPLIANT

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the indicators specified.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.3 Ice Supply

N/A - The facility does not make or use ice.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not make or use ice.

11.5.3.2 Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not make or use ice.

11.5.4 Monitoring Water Microbiology and Quality

The facility receives potable water from the Kansas City Municipal Water District. The facility uses the potable water for hand washing, as an ingredient, and for cleaning food contact surfaces and equipment. The facility has the 2019 Water Quality Report from the supplier. The facility does water potability testing on a monthly basis using the in house Smithfield Lab that is on site. The facility uses the Iowa University Lab, Iowa City, Iowa for the annual certified water potability report. Three sites from the interior of the facility are sampled each month in house and three sites are sampled and sent to Iowa for testing on an annual basis. Test results were reviewed for in house testing for 8/28/19 and 7/8/19 and 7/10/19 for the Iowa test. Sample results were "Negative" for Coliform for all tests. The facility does not make or use ice in any process.

11.5.4.1 Water shall comply with local, national or internationally recognized potable water microbiological and quality standards as required when used for i. washing, thawing and treating food; ii. handwashing iii. to convey food; iv. as an ingredient or food processing aid; v. cleaning food contact surfaces and equipment; vi. the manufacture of ice; or vii. the manufacture of steam that will come into contact with food or used to heat water that will come in contact with food.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.4.3 Water and ice shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

11.5.5 The Quality of Air and Other Gasses

The facility uses compressed air to open product contact bags in the RTE area. The compressed air is filtered using a 0.2 micron filter at the point of use. The facility does micro testing of compressed air monthly from eight sites where compressed air contacts the bags. Test results were reviewed for January - July 2019. APC and Yeast / Mold test results were all acceptable. No other gasses such as CO2 or Nitrogen are used in the process.

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

RESPONSE: COMPLIANT

11.5.5.2 Compressed air systems, and systems used to store or dispense other gasses used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

RESPONSE: COMPLIANT

11.6.1 Storage and Handling of Goods

The facility follows the documented procedure for the safe hygienic storage of raw materials, ingredients, packaging materials, equipment, and chemicals. Refrigerated materials are stored in coolers that are electronically controlled for the proper storage temperature. Ingredients and packaging materials are stored in designated dry areas away from any wet processing. Sanitation chemicals are stored away from the processing areas. The chemicals are in a separate locked area that is only accessible by sanitation employees. Stock rotation is on a FIFO basis. The facility uses a computerized warehouse management system (SAP) for inventory control. The inventory management system is used to ensure that all ingredients, materials, WIP, rework, and finished products are used within their designated shelf life. Rooms used for equipment storage are properly designed and constructed and easily cleaned. N/A - The facility does not hold product in temporary or overflow areas that are not designed for the safe storage of goods. N/A - The facility does not have alternate or temporary storage areas.

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

RESPONSE: COMPLIANT

11.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.1.4 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers.

RESPONSE: COMPLIANT

11.6.1.5 Where goods described in 11.6.2 to 11.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not hold product in temporary or overflow areas that are not designed for the safe storage of goods.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not have alternate or temporary storage areas.

11.6.2 Cold Storage, Freezing and Chilling of Foods

The facility's coolers are designed and constructed to allow efficient refrigeration. The rooms are easily accessible for cleaning and inspection. All products produced at the facility are refrigerated. The facility does not have a storage freezer. The facility has sufficient refrigeration capacity to chill and store refrigerated product. The defrost discharge lines from the refrigeration units in the coolers are directed to drains. The coolers are fitted with a wall mounted thermometer. The thermometers are located in the warmest part of the coolers. Refrigeration employees manually monitor the refrigerated room temperatures 2x each shift. Refrigeration employees work 24/7. Loading and unloading docks are refrigerated and designed to protect product being loaded and unloaded. Dock doors are fitted with shelters to seal around the trailer and dock door during the loading / unloading process.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.2.3 Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.

RESPONSE: COMPLIANT

11.6.2.4 Freezing, chilling and cold storage rooms shall be fitted with temperature monitoring equipment and located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible.

RESPONSE: COMPLIANT

11.6.2.5 Loading and unloading docks shall be designed to protect the product during loading and unloading.

RESPONSE: COMPLIANT

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

Dry ingredient and packaging storage rooms are separate from wet processing to protect from potential water contamination. The dry storage area has racks for the storage of packaging material that are made of impervious materials and place away from the walls for easy cleaning. The facility's fork-lifts are battery powered. No hydrocarbons are emitted.

11.6.3.1 Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration.

RESPONSE: COMPLIANT

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Sanitation chemicals are stored separately in a locked area away from product and packaging materials. Packaging material and processing utensils are stored separate from hazardous chemicals. All chemicals are stored in the secure chemical storage area. Personnel requiring chemicals for emergency cleaning or sanitizing must gain access to the locked chemical area from an area supervisor. The facility does not store pesticides, rodenticides, fumigants, or insecticides. Secondary containers for sanitation chemicals were clearly labeled. The sanitation chemical storage area is adequately ventilated with no cross contamination between chemicals. The room is properly identified as a "chemical storage area". Access is restricted to personnel trained to handle chemicals. Sample labels and SDS are available in a binder in the chemical storage area and in the sanitation office. Chemical inventory is done by the sanitation site manager. Spill kits are available for use if needed.

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to staff, product, packaging, product handling equipment or areas in which the product is handled, stored or transported.

RESPONSE: COMPLIANT

11.6.4.2 Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4.4 Pesticides, rodenticides, fumigants and insecticides shall be stored separate from sanitizers and detergents. All chemicals shall be stored in their original containers, or in clearly labelled and suitable secondary containers if allowed by applicable legislation.

RESPONSE: COMPLIANT

11.6.4.5 Hazardous chemical and toxic substance storage facilities shall: i. Be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals; ii. Be adequately ventilated; iii. Be provided with appropriate signage indicating the area is a hazardous storage area; iv. Be secure and lockable to restrict access only to those personnel with formal training in the handling and use of hazardous chemicals and toxic substances; v. Have instructions on the safe handling of hazardous chemicals and toxic substances readily accessible to staff; vi. Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility; vii. Have suitable first aid equipment and protective clothing available close to the storage area; viii. In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and ix. Be equipped with spillage kits and cleaning equipment.

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

Loading and unloading is conducted in a covered refrigerated shipping dock with proper shelters. The facility has documented instructions for loading and unloading of product onto trucks / trailers. Loading and unloading methods were being followed as written. No product contamination was observed during the loading or unloading process.

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

RESPONSE: COMPLIANT

11.6.6 Loading

The facility inspects outbound vehicles before loading product. The auditor reviewed shipping records, including vehicle inspection, for the following days: November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. Records were found to be complete with a signature or initials of the individual completing the task. Loading is done in a covered refrigerated shipping dock with proper shelters. Finished product is all refrigerated. Loaded trailers are sealed or locked when leaving the shipping area.

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

RESPONSE: COMPLIANT

11.6.6.2 Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity during loading and transport.

RESPONSE: COMPLIANT

11.6.6.3 Vehicles (e.g. trucks/vans/containers) shall be secured from tampering using a seal or other agreed upon, acceptable device or system.

RESPONSE: COMPLIANT

11.6.7 Transport

Trailers are pre-cooled to a set temperature before the loading process begins. This information is recorded on the shipping records. While loading a carrier, plant employees will follow all requirements set forth in the Smithfield Transportation Policy which includes documenting product and trailer temperatures prior to loading. Units will be pre-chilled prior to loading. Product temperature checks will be checked prior to loading. All carriers for transport used by this facility have alarms built into their refrigeration units to detect high temperatures in the transport vehicle. Product temperatures are monitored during the loading process. The trucking company becomes responsible for maintaining proper temperatures during transport. Transportation and delivery was not included in the scope of the audit.

11.6.7.1 Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and product temperatures recorded at regular intervals during loading as appropriate.

RESPONSE: COMPLIANT

11.6.7.2 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature checked at regular intervals during transit.

RESPONSE: COMPLIANT

11.6.8 Unloading

The facility checks perishable product temperatures during the unloading process. Refrigeration unit temperatures are checked prior to unloading and recorded on the incoming paperwork. The facility has written guidelines for unloading product from trucks / trailers. Unloading practices are not potentially detrimental to product.

11.6.8.1 Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.1 Process Flow

Process flow is designed to prevent cross contamination and is very organized. The facility processes raw materials in one section of the building. Products then go through the cooking cycle. The cooking area is located in the center of the facility. Fully cooked product is transferred to the RTE areas where it is further processed and packaged. The finished product is stored in designated cooler until shipped to customers or storage facilities. The flow of personnel is well managed to prevent cross contamination.

11.7.1.1 The process flow shall be designed to prevent cross contamination and organized so there is a continuous flow of product through the process. The flow of personnel shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

Dry ingredients and packaging materials are received and stored separately from raw materials. Unprocessed raw materials are received and kept separate from finished goods.

11.7.2.1 Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross contamination.

RESPONSE: COMPLIANT

11.7.3 Thawing of Food

N/A - The facility does not thaw frozen product.

11.7.3.1 Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not thaw frozen product.

11.7.3.2 Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature does not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not thaw frozen product.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not thaw frozen product.

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

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A - The facility does not thaw frozen product.

11.7.4 High Risk Processes

The facility produces RTE meats under controlled conditions. The facilities HACCP plan requires a Cook Step ("kill" step) with a 7 log reduction. The facility is segregated into raw and fully cooked areas. The facility has an environmental monitoring program in place for the high risk areas and has a written procedure detailing the applicable pathogen (Listeria) to test for. The program includes routine sampling of food contact sites, routine sampling on non-contact sites, corrective action, and scientific / technical support. High risk processes are conducted in separate areas with designated staff that are dedicated to that area. The staff access point to the high risk areas are through a clean room. Staff are required to wear plastic aprons with sleeves and gloves in the high risk area. The access points have boot sanitizer baths, hands free hand wash, paper towel dispenser, and hands free hand sanitizers. Product transfer points are designed to not compromise the high risk area and to minimize the risk of cross contamination.

11.7.4.1 The processing of high risk food shall be conducted under controlled conditions such that sensitive areas in which high risk food has undergone a "kill" step, a "food safety intervention" or is subject to post process handling, are protected/segregated from other processes, raw materials or staff who handle raw materials to ensure cross contamination is minimized.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.4.3 Staff access points shall be located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.

RESPONSE: COMPLIANT

11.7.4.4 Staff engaged in high risk areas shall change into clean clothing or temporary protective outerwear when entering high risk areas.

RESPONSE: COMPLIANT

11.7.4.5 Product transfer points shall be located and designed so as not to compromise high risk segregation and to minimize the risk of cross contamination.

RESPONSE: COMPLIANT

11.7.5 Control of Foreign Matter Contamination

The facility follows the written "09-Foreign Material Control" policy to establish methods to prevent foreign material contamination. The policy also establishes the requirements for foreign material identification and detection programs. Foreign material prevention methods are established and communicated to employees during GMP training. All employees are encouraged to report any sources of foreign material or contamination. Foreign material includes insects, rust, insulation, flaking paint, wood, metal, and glass. Minor: The auditor observed several spiral slicers in the RTE area that had peeling safety stickers. The peeling material could be a source for foreign material contamination. Comment: Methods to control include the glass control policy and foreign material control policies. Pre-operational inspections are performed daily. Area SSOP checks are also done daily. Equipment and areas are checked to make sure they are in good condition and free from contaminants. Facility pre-op inspection records were reviewed for November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. Records were found to be complete and initialed or signed by the person responsible for making the check. Proper corrective actions were noted for any deficiencies found during the pre-op process. The "Foreign Material Control" policy establishes methods to prevent foreign material contamination. Included in the Foreign Material Control policy are requirements for glass and brittle plastic. Glass and brittle plastic inspections are done bi-annually and recorded on the facility glass and light audit report. The last was completed on 6/28/19. The facility has a list identifying the location of all the glass and brittle plastic. The facility uses wooden pallets in the palletizing area. Wooden pallets were observed to be well maintained and in good condition. No loose metal objects were observed above the processing equipment. Knives and cutting instruments were clean and controlled. No snap-off blades are used in the facility.

11.7.5.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff.

RESPONSE: COMPLIANT

11.7.5.2 Inspections shall be performed to ensure plant and equipment remains in good condition, equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: MINOR

EVIDENCE: Minor: The auditor observed several spiral slicers in the RTE area that had peeling safety stickers. The peeling material could be a source for foreign material contamination.

ROOT CAUSE: Stickers begin to peel after heavy chemical use

CORRECTIVE ACTION: Maintenance has added sticker checks to their routine maintenance program and we will maintain these in stock. We have also met with sanitation to cut/remove loose stickers. We have also added this to our slicer tracking sheet

VERIFICATION OF CLOSEOUT: The auditor reviewed the program for maintenance to monitor the stickers on equipment and deemed this acceptable. CB

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11.7.5.3 All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location.

RESPONSE: COMPLIANT

11.7.5.4 Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing /contact zones.

RESPONSE: COMPLIANT

11.7.5.5 Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.5.7 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.6 Detection of Foreign Objects

The facility does not use screens, sieves or filters. The facility does use metal detectors to detect foreign material on each packaging line. Metal detectors are checked at start-up, every hour during production, and at the end of the production shift. The facility uses in-line metal detectors post packaging. The metal detectors have automatic product diversion if metal is detected. Daily metal detector records were reviewed for November 5 – 7, 2018, February 5 – 7, 2019, May 6 – 8, 2019, and August 5 – 7, 2019. All records were legible and signed (or initialed) by the person making the checks. The seeded samples used to test the accuracy of the metal detectors are as follows: Fe 4.0 mm, Non-Fe 5.0 mm, Stainless Steel 6.0 mm. The facility follows the written "Metal Detector Procedure" that provides direction for handling product if a metal detector stops performing correctly or if product is rejected. The facility maintains all production and quality records for 2 years.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.6.3 Records shall be maintained of the inspection of foreign object detection devices and of any products rejected or removed by them. Records shall include any corrective actions resulting from the inspections.

RESPONSE: COMPLIANT

11.7.7 Managing Foreign Matter Contamination Incidents

If foreign material is detected, the product will be isolated, inspected and reworked. Glass policy describes the method for cleaning an area affected by glass breakage. There have been no instances of glass or hard plastic breakage in the facility in the past 12 months.

11.7.7.1 In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed of.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.8.1 Location

The facility has an on-site laboratory for bac-t testing. Petri Film is incubated and then read in the lab. Pathogen and chemical testing is also done in house. The lab is separated from the food processing area and is located in another building on the property. Access to the lab is restricted. Lab waste is well managed and kept separate from food waste. Lab waste water outlets are directed to the City Sewer system. Food processing drains are directed to the facility waste water plant. There is adequate signage identifying the Laboratory as a restricted area. The lab is identified as a "restricted area". Authorized personnel only allowed in the lab.

11.8.1.1 On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.

RESPONSE: COMPLIANT

11.8.1.2 Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory waste water outlet shall as a minimum be down stream of drains that service food processing and handling areas.

RESPONSE: COMPLIANT

11.8.1.3 Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel.

RESPONSE: COMPLIANT

11.9.1 Dry and Liquid Waste Disposal

Waste is removed from the production areas each shift. Waste is contained in color coded containers before disposal. The facility does not use any trolleys or vehicles to move waste. Waste containers are cleaned on a daily basis. Waste containers on site are properly segregated and contained and fly proofed with a lid or enclosed top. Inedible waste is denatured and is sent to a rendering plant. Liquid waste is directed to the floor drains and then to the waste water treatment area. Daily pre-op and operational inspections review waste removal conditions.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.9.1.3 Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition and cleaned and sanitized regularly so as not to attract pests and other vermin.

RESPONSE: COMPLIANT

11.9.1.4 Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging.

RESPONSE: COMPLIANT

11.9.1.5 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

RESPONSE: COMPLIANT

11.9.1.6 Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing.

RESPONSE: COMPLIANT

11.9.1.7 Waste held on site prior to disposal shall be stored in a separate storage facility and suitably insect proofed and contained so as not to present a hazard.

RESPONSE: COMPLIANT

11.9.1.8 Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard.

RESPONSE: COMPLIANT

11.9.1.9 Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.

RESPONSE: COMPLIANT

11.10.1 Grounds and Roadways

The exterior of the facility is included in the monthly GMP audit. All areas of the facility grounds were well maintained to minimize dust and are kept free of trash and debris. Minor: The auditor observed several areas of standing water in the truck parking zone and in front of the shipping /receiving areas. The facility had brought gravel in to fill the low spots, but wet ground and truck traffic has caused the gravel to sink down and pot holes formed again. Comment: The facility grass and green areas were well maintained. Equipment stored outside the facility was well organized and did not present a hazard. The facility has concrete and hard surface walkways leading to the facility entrance.

11.10.1.1 Measures shall be established to maintain a suitable external environment, and the effectiveness of the established measures shall be monitored and periodically reviewed.

RESPONSE: COMPLIANT

11.10.1.2 The grounds and area surrounding the premises shall be maintained to minimize dust and kept free of waste, accumulated debris or standing water so as not to attract pests and vermin.

RESPONSE: MINOR

EVIDENCE: Minor: The auditor observed several areas of standing water in the truck parking zone and in front of the shipping /receiving areas. The facility had brought gravel in to fill the low spots, but wet ground and truck traffic has caused the gravel to sink down and pot holes formed again.

ROOT CAUSE: Heavy truck traffic has caused the parking lot to be in disrepair

CORRECTIVE ACTION: The plant has dedicated a value per month for parking lot repairs. During repair times, standing water will be vacuumed out of low areas as needed

VERIFICATION OF CLOSEOUT: The auditor accepts the corrective action of vacuuming out the water until the allocated monies are available for complete repair. CB

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11.10.1.3 Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises.

RESPONSE: COMPLIANT

11.10.1.4 Paths, roadways, loading and unloading areas shall be adequately drained to prevent ponding of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

RESPONSE: COMPLIANT

11.10.1.5 Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises.

RESPONSE: COMPLIANT

11.10.1.6 Paths from amenities leading to site entrances are required to be effectively sealed.

RESPONSE: COMPLIANT