Audit Information

Audit Type: SQF Food Safety Audit Edition 8.0
Audit Number: 83925
Supplier: Smithfield Packaged Meats Corp.(45735)
Company Name: Smithfield Packaged Meats Corp. - Arnold
Company Number: 10138
Company Address:
2200 Rivers Edge Drive
Arnold, PA 15068
United States
Certification Body: Mérieux NutriSciences Certification
Certification Body Address:
111 East Wacker Dr
Suite 2300
Chicago, IL 60601
United States
CB#: CB-1-Mérieux
Accreditation Body: JAS-ANZ
Accreditation Number: Z3720906AB

Audit Duration: 04/03/2019 - 04/05/2019
Time Spent Auditing: 23 hours
Time Spent Writing Report: 7 hours
Certification Issue Date: 05/29/2019
Certification #: 107139
Certification Type: Recertification
Audit Rating/Score: Good / 95
Certification Decision Date: 05/29/2019
Certification Expiration Date: 06/05/2020
Certification Decision: Certified
Food Sector Categories:
8. Processing of Manufactured Meats and Poultry
Products: Beef, Chicken, Meat Balls, Pork, Sausage, Turkey
Scope of Certification: Beef, Chicken, Meat Balls, Pork, Sausage, Turkey

Audit Team

FIRST NAME	LAST NAME	PERSON #	ROLE
Jaime	Lastra	10049	Lead Auditor
Sandra	Luttrell	132944	Technical Reviewer

Non-Conformities

ELEMENT	PRIMARY RESPONSE	EVIDENCE
11.2.5.2	Minor	Minor - A light cover was observed with a crack above packaging area (RTE).
11.2.9.2	Minor	Minor – Two blue plastic containers used for allergen ingredients were used for not the indent purpose.
11.2.10.1	Minor	Minor – A plastic-glass cover was observed broken in one of the fillers at the RTE area.
11.2.13.9	Minor	Minor – A non-labeled plastic spray bottle was used at the women's bathroom.
11.3.1.4	Minor	Minor – A disposable coffee cup was observed inside the uniform room.

Root Cause Analysis

ELEMENT	PRIMARY RESPONSE	ROOT CAUSE
11.2.5.2	Minor	Crack was not observed during last glass and brittle plastic audit.
11.2.9.2	Minor	The blue containers being used for both raw edible product and allergens was an oversight of our color coding policy.
11.2.10.1	Minor	Door was written up on glass and brittle plastic audit, however a replacement was never ordered by maintenance.
11.2.13.9	Minor	The bottle was sitting on top of a cabinet and was not seen by FSQA when we audit the locker rooms
11.3.1.4	Minor	Area is not highly used so it was not checked frequently for clutter

Corrective Actions

CLAUSE	PRIMARY RESPONSE	CORRECTIVE ACTION	VERIFICATION OF CLOSEOUT	COMPLETION DATE	CLOSE OUT
11.2.5.2	Minor	Light fixture was replaced	JL: Based on the information sent regarding the replacement of the light fixture, the NC is closed.	04/08/2019	04/22/2019
11.2.9.2	Minor	Color coding policy has been changed so that blue totes are only for edible raw product. Purple, red, green, and gray buckets color coded for each allergen have been purchased and will be used in place of the blue totes. See attached SOP	JL: Based on the information sent about the revision for the container color code and employee training, the NC is closed.	04/18/2019	04/22/2019
11.2.10.1	Minor	New door was ordered. See attached purchase order	JL: Based on the information regrinding the replacement of the plexi-glass door, the NC is closed.	04/18/2019	04/22/2019
11.2.13.9	Minor	Bottle was thrown away and replaced with a labeled Lysol spray bottle. See attached photo	JL: Based on the employee training conducted regarding the chemical cleaning container labeling procedure, the NC is closed.	04/08/2019	04/22/2019
11.3.1.4	Minor	Debris and coffee cup in uniform room were thrown away and area was cleaned up. See attached photo	JL: Based on the employee training conducted during the audit regarding the GMP's and by the information sent about the addition of the area to the FSQA "Auxiliary area" audit, the NC is closed.	04/08/2019	04/22/2019

Statements

SECTION	ELEMENT	EVIDENCE
Audit Statement Audit	SQF Practitioner Name	Renae Wagner
	SQF Practitioner Email	rnwagner@smithfield.com
	Opening Meeting	Renae Wagner: Quality Assurance/Food Safety Manager (SQF Practitioner), Jason Flosa: HACCP Supervisor, Melanie Hayes: Corporate Food Safety Manager, Chris Materrese: Plant Manager, Jaime Lastra: SQF Auditor.
	Auditor Recommendation	It is the auditor's recommendation that the facility would maintain the certification after all NCR's have been completed.
	Closing Meeting	Renae Wagner: Quality Assurance/Food Safety Manager (SQF Practitioner), Jason Flosa: HACCP Supervisor, Anthony White: Co-Packer Auditor, Melanie Hayes: Corporate Food Safety Manager, Chris Materrese: Plant Manager, Jaime Lastra: SQF Auditor.
	Facility Description	Smithfield Foods, Inc. (Arnold, PA) is a subsidiary of Smithfield Foods. The plant was built in 1989 and is approximately 93,000 total square feet consisting of a production, packaging, warehouse, storage, and offices. The plant is constructed of concrete block, insulated steel panels, and pre-cast concrete panels with steel supports and concrete floors. The plant has three storage coolers and one freezer for storage. The plant employs approximately 200 people working three shifts (two production and one sanitation) five to seven days per week. The plant has USDA approval for extended run operations. Sanitation is performed on third shift by a contracted sanitation company. The plant produces (8) processed meat and poultry products (fully cooked and IQF pork, beef, turkey, and chicken sausage patties, links, crumbles, and meatballs. The plant has a Grant of Inspection by the USDA (Est. No. 2121 / P-2121).

Result List

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
2.1.1 Food Safety Policy	2.1.1.1	Compliant	
	2.1.1.2	Compliant	
Section Summary: The Corporate Quality Policy (12/5/18) dated signed by plant manager and QA manager was available in English and communicated to all employees through the New Employee Orientation Training and through the Annual Training process. The Quality Policy was posted at the plant main entrance, break rooms and management offices.			
2.1.2 Management Responsibility	2.1.2.1	Compliant	
	2.1.2.2	Compliant	
	2.1.2.3	Compliant	
	2.1.2.4	Compliant	
	2.1.2.5	Compliant	
	2.1.2.6	Compliant	
	2.1.2.7	Compliant	
	2.1.2.8	Compliant	
	2.1.2.9	Compliant	
	2.1.2.10	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	2.1.2.11	Compliant	

Section Summary: Management Responsibilities are documented under the Management Responsibility Document. The Management Responsibilities include a plant specific organizational chart (3/6/2019) including employees with food safety and product quality responsibilities reviewed and approved by the plant management, the designation of a full-time (QA Manager) employees as the SQF Practitioners, Advance HACCP training certification issued 6/3-4/2008, SQF Practitioner responsibilities related to the SQF certification for food safety, product quality, regulatory requirements, customer food safety and quality specification requirement the implementation of a training program (Food Safety and Quality Employee Training) Training Program). Under the Training Plan, management is responsible for employee training based on employee job position training needs, food safety and food quality requirements, the responsibility to report food safety and quality problems to personnel with authority to initiate action (verified by documentation reviews and employee interviews). Corporate management and the plant senior management have ensured adequate resources are available to achieve food safety and quality objectives and to support the development, implementation, maintenance and ongoing improvement of the SQF System for food safety and product quality. SQF System Improvement key elements includes results from internal and external audits, results from company meetings, employee feedback, data collection, customer feedback. Management and plan staff commitment to food safety and product quality was demonstrated through the entire audit. Job description of employees with food safety and product quality responsibilities were reviewed for Quality Assurance Food Safety Manager, HACCP Supervisor, and Plant Manager. The QA Manager, HACCP Specialist and members of the management team demonstrated SQF, Food Safety and Product Quality understanding and knowledge.

2.1.3 Management Review	2.1.3.1	Compliant	
	2.1.3.2	Compliant	
	2.1.3.3	Compliant	
	2.1.3.4	Compliant	

Section Summary: The facility management conducts a monthly and a quarterly Food Safety and product Quality Meetings to review the SQF System. The facility management completes the Annual SQF Management Review by holding monthly meeting to review all aspects of Food Safety and Product Quality Plans. The Monthly SQF Management Review Meetings include food safety and product quality issues. The review is conducted by the plant management and verified by the SQF Practitioner. The monthly reviews are in the Monthly Food Safety Meeting Notes. The meetings included the reviews food safety and product quality issues, policy manual, internal/external audit finding, customer complaints corrective/preventive actions, pre-requisite programs, recall program, finding in mock recalls, food safety programs/HACCP, food defense, HACCP deviation issues, non-conforming product, quality goals and equipment, product release program and food defense plan. Monthly SQF Management Reviews were reviewed for meeting held 2/26/19 and 3/14/19. The Management of Change for New Process or process Change outlines the SQF practitioners and management staff responsibilities for validating changes to food safety fundamentals and food quality plans. Major and minor changes to the food safety plan are required to be reviewed by the SQF practitioners. Food safety fundamentals, perquisites changes and quality procedures are documented under the SQF Management Review document, and under HACCP Plan Reassessment (3/22/2019) and Quality Plan Reassessment (2/26/2019. Document changes are validated by the SQF Practitioners.

2.1.4 Complaint Management	2.1.4.1	Compliant	
	2.1.4.2	Compliant	
	2.1.4.3	Compliant	
	2.1.4.4	Compliant	

Section Summary: The methods and responsibility for handling and investigating internal and external customer complaints are outlined in the Customer and Consumer Complaint – 1/24/2019. The plan covers complaints due to food safety, product quality and/or regulatory issues. The programs include corporate and plant management responsibilities for handling and investigating the root cause and resolution of customer complaints. Complaints are documented in the Consumer Incident by Plant and Reason Form. Complaints are analyzed based on the complaint issue (Food Safety, Product Quality and Packaging/Labeling issues) on a monthly basis by the plant management staff during the Monthly Review Meetings (SQF Management Review). The complaint reviews include trend analysis and the specific complaint issues. The complaints program includes complaints from regulatory complaints, foreign materials, illness, injuries, miss-branded, quality (weight, texture, flavor, color, appearance, and packaging). Customer complaints are reported and tracked through the Customer Complaint System in the company intranet. Customer complaint reports were reviewed for dates of 1/23/19, 1/28/19, 2/15/19 and 2/18/19 due to Quality issues. Report records included reference number, date, product code/identification, product description, complaint description, corrective action, preventive action and responsible. Customer complaint trends were reviewed for total per year for total complaints per year by quality and food issues (January to December 2018).

2.1.5 Crisis Management Planning	2.1.5.1	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	2.1.5.2	Compliant	
	2.1.5.3	Compliant	
	2.1.5.4	Compliant	
Section Summary: A Corporate Crisis Management Plan - (2/5/9) was implemented based on the facility area specific known threats due to food safety and/or quality issues. The procedure was reviewed 2/5/2019. The plan includes a product food safety and product quality assessment conducted before releasing raw materials, ingredients, packaging or finished products by the QA Team and approved by Plant Manager. Threats such as natural disasters, active shooting, fire, floods, electrical failure and product recalls were covered under the Crisis Manual. The facility QA Manager conducted a crisis drill for a water damaged due to a water pipe burst on 1/4/19. The result of the drill was documented in the Business Continuity Plan Test/Verification Sheet.			
2.2.1 Food Safety Management System	2.2.1.1	Compliant	
	2.2.1.2	Compliant	
Section Summary: The facility Food Safety/Quality Team with members from Operations, management, QA/FS, have developed and implemented a Food Safety Program for RTE Heat-Treated Fully Cooked- Not-Shelf Stable Meat Products (Poultry, pork, beef). The plan covers one HACCP Plan developed based on seven HACCP principles and was available in hard and electronic versions. The Food Safety Plan includes the HACCP Team (HACCP Steering Committee), facility organizational chart, the methods used to meet the requirements of the SQF System for product food safety, quality policies levels, the scope of certification for all products, product descriptions, process risk assessment, ingredients and raw material risk assessment, food safety plans and pre-requisites control limits monitoring guidelines. The hazard analysis identified biological (Salmonella, E coli) physical and chemical hazards.			
2.2.2 Document Control	2.2.2.1	Compliant	
	2.2.2.2	Compliant	
	2.2.2.3	Compliant	
Section Summary: A Document Management Program (Document and Records Management – 1/15/2019) is in place that outlines the methods and responsibilities for the control of documents (programs, procedure and policies), including development, approvals, revisions, maintenance, access, document history tracking, retention guidelines and periods, and destruction of obsolete documents, and the responsibilities and policies for monitoring records and logs activities (completed, dated signed, verification). The facility had on file a Procedures Register managed by a computer based system (Qualtrax) that contains programs, procedures and policies. Document register includes; document number, title, last review, reviewed by, last revised, approved by, supersede and original date. Records Retention and Destruction Procedure outlines the protocols to store and disposition of documents and records.			
2.2.3 Records	2.2.3.1	Compliant	
	2.2.3.2	Compliant	
	2.2.3.3	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
Section Summary: A Document Management Program (Document and Records Management – 1/15/2019) is in place that outlines the methods and responsibilities for the control of documents (programs, procedure and policies), including development, approvals, revisions, maintenance, access, document history tracking, retention guidelines and periods, and destruction of obsolete documents, and the responsibilities and policies for monitoring records and logs activities (completed, dated signed, verification). The facility had on file a Procedures Register managed by a computer based system (Qualtrax) that contains programs, procedures and policies. Document register includes; document number, title, last review, reviewed by, last revised, approved by, supersede and original date. Records Retention and Destruction Procedure outlines the protocols to store and disposition of documents and records. Records were dated, signed/verified by supervisor, readily accessible, retrievable, securely stored/retained in accordance with periods specified by a customer or regulations. During the audit the following records and logs were reviewed; CCP's monitoring records for CCP1B were reviewed for 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19. CQP monitoring records were reviewed for CQP1 /CQP2 - 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19. Records for Product Hold Tag Log were reviewed 3/22, 25, 26, 27, 28, 29/2019. Release HACCP Pre-Shipment Review Forms were reviewed for 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19. Daily Product quality sampling was reviewed for weight, solid fats, moisture, salt, protein, pH, color, flavor, aroma, casing, overall appearance, texture and shelf life for dates 3/25-29/2019. Documentation containing product identification and product traceability information were reviewed for the das of the audit 3/25-29/2019 for Truck receiving inspection, raw material receiving report, pack sheet, blend ID tag, grinding daily production sheet, pallet sheet, fresh meat grinding form, WIP Ticket/Transfer slip, line check sheet, rework combo tracking form, checker table/rework line sheet , blend record log /rework, blend tracker sheet, oven process cook sheet, label verification form, primary packaging material traceability form, HACCP pre-shipment review, shipping truck inspection log. Allergen change over very verifications were reviewed for 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19. Equipment calibration records were reviewed for; laboratory equipment – scales annual calibration – 12/21/18, annual thermometer calibrations – 1/17/19, moisture analyzer annual calibration - 12/6/19, daily oven HACCP thermometers and pH meters- 3/25-29/19, weekly thermometer (non-CCP) – 3/3, 10, 17, 24/19. Production equipment calibration; annual metal detector calibration – 2/10/19, annual scales calibration - 2/3/19. Master Cleaning Sanitation records for raw process and RTE area cleaning and related tasks were reviewed for daily and weekly cleaning – 2/10/19, 2/17/19 and 2/24/19. Records were reviewed for daily chemical concentration (titration), daily water temperature verification, cleaning company daily pre-operational cleaning verifications –3/4-9/19, 3/4-16/19, 3/18-23/19. Chemical product monthly product dispenser service and chemical inventory was reviewed for 3/2-29/2019. Records for QA conducted pre-operational inspections, daily ATP cleaning verification and daily cleaning and sanitizer chemical concentration (titration test) were reviewed for 4/2/19. Metal detector daily monitoring records were reviewed for 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19.			
2.3.1 Product Development and Realization	2.3.1.1	Compliant	
	2.3.1.2	Compliant	
	2.3.1.3	Compliant	
	2.3.1.4	Compliant	
	2.3.1.5	Compliant	
Section Summary: A corporate product development program was implemented (Product Development Start up Program). The plan outlines methods and responsibilities for the design, development and converting product concepts to commercial realization and production. This process is managed by the Corporate R&D, Corporate QA Director and by the QA Manager at plant level. The program includes product specification development, packaging material and finished products verifications, label review, shelf-life studies, product sensory evaluations, food safety and product quality evaluations and sampling. The plan requires a reassessment and validation of the HACCP Plan and Food Quality Plan for any new products, new formulations of existent products or new equipment installation. Per management, no new products or reformulations were developed since the last audit.			
2.3.2 Raw and Packaging Materials	2.3.2.1	Compliant	
	2.3.2.2	Compliant	
	2.3.2.3	Compliant	
	2.3.2.4	Compliant	
	2.3.2.5	Compliant	
	2.3.2.6	Compliant	
	2.3.2.7	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
Section Summary: Raw materials, ingredients and packaging material specifications are stored in a Corporate Intranet System (QualTrax). The intranet system is available to production and QA employees. All specifications reviewed included requirements chemical, physical, microbiological limits. Raw material, ingredient and packaging specifications maintenance is a corporate responsibility maintained by corporate R&D function. Validation of packaging materials is included in the letters of continued guarantee of compliance and certificate of analysis from the packaging suppliers. Letters of continued guarantee of compliance was on file from packaging material suppliers. The company maintains a current registers for raw materials (Approved protein Vendor Register), ingredients (Approved Ingredient Vendor Register) and packaging materials/suppler (Approved Packaging Vendor Register). All finished product labels are designed and approved by Corporate R&D based on food safety, quality attributes, regulatory requirements and customer specification requirements. Labels are verified for accuracy by the Plant QA during production runs.			
2.3.3 Contract Service Providers	2.3.3.1	Compliant	
	2.3.3.2	Compliant	
Section Summary: Specifications and training for contract services providers is managed by QA Manager. Specifications were outlined in the Contractor Service Providers program. The specifications included GMP guidelines training security practices and employee safety based on specific contractor requirements. A Facility Specific Contractor Services Providers Register was on file reviewed 10/16/18. Register includes; service provide description, contact information, training received/date.			
2.3.4 Contract Manufacturers	2.3.4.1	Not Applicable	
	2.3.4.2	Not Applicable	
	2.3.4.3	Not Applicable	
Section Summary: Co-packers are not used by this facility.			
2.3.5 Finished Product Specifications	2.3.5.1	Compliant	
	2.3.5.2	Compliant	
Section Summary: Finished product specifications were on file in a corporate intranet database. Finished product specifications were reviewed for product analysis protocol, product identification, product trace, microbial specifications, quality attributes, sampling plans, packaging requirements, label/legal requirements, nutritional information, storing /transportation parameters, shelf-life. A Finished Product Specification and Labels Register were on File in a computer database dated 2/19/19. Finished product specifications are created based on company and customer requirements for food safety, product quality and regulatory requirements.			
2.4.1 Food Legislation	2.4.1.1	Compliant	
	2.4.1.2	Compliant	
	2.4.1.3	Compliant	
Section Summary: The Corporate Food Safety Manager and the facility Quality Assurance Manager are responsible to maintain the plant staff aware regarding regulatory requirements. The Corporate Compliance Manager is responsible to maintain the facilities up to date. Label legal requirements are verified by the corporate office for domestics and foreign customers (Canada). This requirement to SQFI and the certification body is covered in the Product Withdrawal/Recall Program under the Crisis Management Program.			
2.4.2 Good Manufacturing Practices	2.4.2.1	Compliant	
	2.4.2.2	Compliant	
Section Summary: Documented GMP were outlined in the documented GMP Procedure (3/14/18) were in place. The procedures include personal hygiene, glove use (RTE Areas), hand washing practices, dress code (uniform use), disease control, tools handling, color coding, allergen manipulation guidelines, food safety and processing /handling practices, employee traffic flow guidelines, management and non-management responsibilities, training and training verification. Employees were observed following established GMP's in the raw and RTE processing areas. During the audit employees were observed following GMP's based on the company policy – 2/4/19.			
2.4.3 Food Safety Plan	2.4.3.1	Compliant	
	2.4.3.2	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	2.4.3.3	Compliant	
	2.4.3.4	Compliant	
	2.4.3.5	Compliant	
	2.4.3.6	Compliant	
	2.4.3.7	Compliant	
	2.4.3.8	Compliant	
	2.4.3.9	Compliant	
	2.4.3.10	Compliant	
	2.4.3.11	Compliant	
	2.4.3.12	Compliant	
	2.4.3.13	Compliant	
	2.4.3.14	Compliant	
	2.4.3.15	Compliant	
	2.4.3.16	Compliant	
	2.4.3.17	Compliant	
Section Summary: A documented Food Safety plan (HACCP Plan) was implemented and maintained by a multidisciplinary Food Safety/Quality Team (operations, management, FS/QA, led by the Food Safety Manager. The food safety includes one HACCP plan developed based on product category for RTE Heat-Treated Fully Cooked- Not-Shelf Stable Meat Products (Poultry, pork, beef). The HACCP Plan identified one CCP for CCP1B –Product Internal Temperature for >158F (beef/pork) and >165F (poultry). The HACCP Plan included process flow chart, product description, process description, biological, physical, chemical and radiological risk associated with the products, a process hazard analysis, raw product, ingredient and packaging material risk analysis, critical control points, monitoring guidelines, justification and validations for CCP's identified, as well as the HACCP plan annual reassessment conducted on 3/22/19. Employees with CCP monitoring responsibilities were interviewed. All employees interviewed understood the monitoring responsibilities and processes as well as corrective actions. CCP's monitoring records for CCP1B were reviewed for 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19. Records reviewed were complete, dated, and up to date and signed by the employees responsible and verified by QA.			
2.4.4 Approved Supplier Program	2.4.4.1	Compliant	
	2.4.4.2	Compliant	
	2.4.4.3	Compliant	
	2.4.4.4	Compliant	
	2.4.4.5	Compliant	
	2.4.4.6	Compliant	
	2.4.4.7	Compliant	
	2.4.4.8	Compliant	
	2.4.4.9	Compliant	
	2.4.4.10	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
Section Summary: The facility has in place a Corporate Supplier Approval Program (Vendor Approval Program – 1/28/2019). The program covers raw material, process aids, and packaging material suppliers. Supplier approval guidelines include Suppliers Quality, food safety and regulatory expectations. All suppliers are approved by the Quality Assurance Team. The supplier approval guidelines included in the Supplier Food Safety Expectation Manual cover quality and food safety requirement, pre-requisite requirement control, HACCP Plan validation, allergen control statement, 3rd party audit program, animal handling audit (meat suppliers) regulatory compliance, product temperature requirements, chemical and microbial limits, COA. Packaging materials and service providers are provided from pre-approved suppliers only. A list for Approved Suppliers for raw material and packaging materials was documented and maintained current in a computer based system database. The list includes Supplier Monitoring, COA's, Supplier Status, Supplier ID, Suppliers Name, Inspections and Approval Requirements. The facility maintains on file Suppler Approval Requirement that includes company description, product provided, level of risk, supplier status, letters of guarantee, product specifications, SDS, COA's, Food Safety Audit, HACCP plan, and product identity status. The program includes a list /register of approved suppliers, for meat, non meat/ingredients and packaging material.			
2.4.5 Non-conforming Product or Equipment	2.4.5.1	Compliant	
	2.4.5.2	Compliant	
Section Summary: The monitoring and control for non-conforming /on-hold product and equipment is documented and implemented in the Hold and Release Procedure. The non-conforming product is tagged with the hold date, product description and moved to the designated hold area and place on hold in an electronic inventory system. The QA area is responsible for releasing non-conforming product. This procedure applies to raw material, packaging material, finished product, rework, returned product and non-conforming equipment. The procedure covers, the identification of non-conforming /equipment, documentation, disposition, product / equipment release, returned product and critical control. The process included product destruction and product rejection guidelines. On hold product is recorded in the Product Hold Tag Log. Records were reviewed 3/22, 25, 26, 27, 28, 29/2019. The log includes product description, code date, production line, shift, reason for hold, quantity, inspector, release information, quantity release, disposition, release date and responsible. Finished product stays on hold through a Positive On-Hold Program for micro testing for Salmonella, Listeria, E. Coli and APC.			
2.4.6 Product Rework	2.4.6.1	Compliant	
	2.4.6.2	Compliant	
Section Summary: Product rework responsibility and methods are outlined in the Product Rework Control Policy. The product rework applies to raw and finished products and is based on product quality food safety compliance, including product weight/quantity, ingredient identification, blend number/batch number, lot number/production code. Rework product information records are documented in the Formulation Check Sheet Report. Rework products is like-to-like, identified by color tag by product at no more than 5% and no more than 5 days old. Rework product records were reviewed for 3/25-29/2019.			
2.4.7 Product Release	2.4.7.1	Compliant	
	2.4.7.2	Compliant	
Section Summary: Product release is managed by the Product Release Procedure based on Food Safety, Quality and Legal Requirements compliance. Release HACCP Pre-Shipment Review Forms were reviewed for 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19.			
2.4.8 Environmental Monitoring	2.4.8.1	Compliant	
	2.4.8.2	Compliant	
	2.4.8.3	Compliant	
	2.4.8.4	Compliant	
Section Summary: The facility had implemented and maintains an Environmental Monitoring Plan for the RTE Product Lines and Areas (12/5/2018, based on an area/equipment risk assessment conducted by QA. The plan including food contact and non-food contact surfaces testing. The QA/FS Team is responsible for maintaining and executing the plan. The plan requires testing for Listeria spp. 9 sites per day (3 sites from food contact, 2 employee gloves, 3 sites from non-contact, 1 exploratory sample, testing a minimum of 50 ml. of brine solution and 20% of drains). The swabs are collected after two hours of producing. Corrective actions in case of presuming positives deep cleaning and tear down practices are included in the Plan. Testing results are recorded in the Environmental Monitoring Summary.			
2.5.1 Validation and Effectiveness	2.5.1.1	Compliant	
	2.5.1.2	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
Section Summary: Verifications and validation guidelines, frequencies, responsibilities and activities are outlined in the Verification and Validation Activities Schedule, Verification and/or Validation Form and in the SQF Verification Schedule for CCP and Pre-requisites. Verification activities include; program, monitor activities, monitoring frequency, responsible, verification activity/method, verification frequency, verification date,/SQF Practitioner, observation. Validation activities include; validation program, validation frequency, validation criteria, SQF Practitioner, validation date, validation activity and observation. Records for validation activities documented the SQF Pre-requisites Validation Sheet conducted by the SQF Practitioners were reviewed for validations/verifications completed 2/4/19 for personnel practices, employee training, calibration of equipment, cleaning and sanitation plan, control of physical contaminants, allergen control, food safety/HACCP plan-CCP1, and quality plan.			
2.5.2 Verification Activities	2.5.2.1	Compliant	
	2.5.2.2	Compliant	
	2.5.2.3	Compliant	
Section Summary: Verifications and validation guidelines, frequencies, responsibilities and activities are outlined in the Verification and Validation Activities Schedule, Verification and/or Validation Form and in the SQF Verification Schedule for CCP and Pre-requisites. Verification activities include; program, monitor activities, monitoring frequency, responsible, verification activity/method, verification frequency, verification date,/SQF Practitioner, observation. Validation activities include; validation program, validation frequency, validation criteria, SQF Practitioner, validation date, validation activity and observation. Records for validation activities documented the SQF Pre-requisites Validation Sheet conducted by the SQF Practitioners were reviewed for validations/verifications completed 2/4/19 for personnel practices, employee training, calibration of equipment, cleaning and sanitation plan, control of physical contaminants, allergen control, food safety/HACCP plan-CCP1, and quality plan.			
2.5.3 Corrective and Preventative Action	2.5.3.1	Compliant	
	2.5.3.2	Compliant	
Section Summary: Procedures and criteria for corrective actions are outlined in the Corrective and Preventive Policy. Corrective procedures include non-conforming products due to food safety or quality issues; internal/external audits findings, customer complaints, sanitation pre-operational inspections and internal audit findings. Records for corrective actions were reviewed for customer complaints reported 1/23/19, 1/28/19, 2/15/19 and 2/18/19, pre-operational inspections conducted 4/2/19, 4/4/19, self audit conducted 1/7/19 and 2/28/19.			
2.5.4 Product Sampling, Inspection and Analysis	2.5.4.1	Compliant	
	2.5.4.2	Compliant	
	2.5.4.3	Compliant	
	2.5.4.4	Compliant	
Section Summary: Finished product sampling and WIP requirements are outlined in the Finished Product Quality Inspection and Work Orders Instructions procedure. Samples were taken every hour and analyzed for compliance to finished product specification. Finished Product is inspected prior to packaging. Deviations are reported by QA Staff to production operators who then adjust the process. Daily Product quality sampling was reviewed for weight, solid fats, moisture, salt, protein, pH, color, flavor, aroma, casing, overall appearance, texture and shelf life for dates 3/25-29/2019.			
2.5.5 Internal Audits and Inspections	2.5.5.1	Compliant	
	2.5.5.2	Compliant	
	2.5.5.3	Compliant	
	2.5.5.4	Compliant	
	2.5.5.5	Compliant	
Section Summary: The facility has implemented a total Annual SQF System Audit conducted by QA/FS Team. A GMP/Food Safety Internal Audit is conducted on a monthly basis that cover all physical areas of the facility, documentation compliance, pest control, GMP's, sanitation, plant and equipment conditions and employee practices. Annual SQF based audit reports were reviewed for audit finalized 12/13/18. Monthly audit records were reviewed for 1/7/19 and 2/28/19. Employee conducting audit are trained as auditor. Last training was conducted 2/2/17. Audit reports included findings, corrective actions, investigations, due dated, completion dates and responsible to complete the task.			
2.6.1 Product Identification	2.6.1.1	Compliant	
	2.6.1.2	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	2.6.1.3	Compliant	
Section Summary: The methods and responsibility for identifying and track products during all stages of production and storage are documented in the Product Identification and Product Trace Procedures, and in the Trace and Recall Program. Raw material, ingredients and packaging is identified at receiving by lot number, pallet tags, item identification code and receiving date. Work in progress (blending/grinding) is traced by production date, ingredients lot numbers, and product description. Finished products are identified by UPC, Julian date, packed on date, sell by date and by specific customer requirements. Documentation containing product identification and product traceability information were reviewed for the das of the audit 3/25-29/2019 for Truck receiving inspection, raw material receiving report, pack sheet, blend ID tag, grinding daily production sheet, pallet sheet, fresh meat grinding form, WIP Ticket/Transfer slip, line check sheet, rework combo tracking form, checker table/rework line sheet, blend record log/rework, blend tracker sheet, oven process cook sheet, label verification form, primary packaging material traceability form, HACCP pre-shipment review, shipping truck inspection log.			
2.6.2 Product Trace	2.6.2.1	Compliant	
	2.6.2.2	Compliant	
Section Summary: The methods and responsibility for identifying and track products during all stages of production and storage are documented in the Product Identification and Product Trace Procedures, and in the Trace and Recall Program. Raw material, ingredients and packaging is identified at receiving by lot number, pallet tags, item identification code and receiving date. Work in progress (blending/grinding) is traced by production date, ingredients lot numbers, and product description. Finished products are identified by UPC, Julian date, packed on date, sell by date and by specific customer requirements. Documentation containing product identification and product traceability information were reviewed for the das of the audit 3/25-29/2019 for Truck receiving inspection, raw material receiving report, pack sheet, blend ID tag, grinding daily production sheet, pallet sheet, fresh meat grinding form, WIP Ticket/Transfer slip, line check sheet, rework combo tracking form, checker table/rework line sheet, blend record log/rework, blend tracker sheet, oven process cook sheet, label verification form, primary packaging material traceability form, HACCP pre-shipment review, shipping truck inspection log. Per the Testing of the Product trace System and Continuity Plan– (11/16/18), the facility conducts four mock recalls per year. The facility conducted a mock recall 2/201/19 for1440 cases of 1.3 oz pork sausage patty, product code 10070247180350, batch date 2/18/19, shipped 2/18/19. The facility identified and traced 100% ingredients, raw materials, finished product and destination with in 30 minute.			
2.6.3 Product Withdrawal and Recall	2.6.3.1	Compliant	
	2.6.3.2	Compliant	
	2.6.3.3	Compliant	
	2.6.3.4	Compliant	
	2.6.3.5	Compliant	
Section Summary: A Corporate Recall Program documented under the Crisis Plan - (2/5/9) is in place and maintained by the QA Manager. The program includes responsibilities for recall coordinator and team, sources of legal and expert advice by the Corporate Director of Regulatory Affairs and Compliance, communication coordinator, communication channels for customers, consumers, recall procedures, mock recall policy, certification body, and regulatory authority. Based on the Recall Program, the facility conducts a minimum of four mock recalls per year and several as a request during 3rd audits. During the audit the Production Scheduling Staff conducted a mock recall for pork trim, item number 90070800151199 (pork trim), 90027815900793 (turkey thigh), purchase order number, 6500151410/6500151416, received 3/19/19. The raw materials were used to produce 5393 of Pork/Turkey Sausage Patties (finished product), item number 8251602844, processed 3/18/19. Finished product, ingredients, packaging materials and product destinations were identified and traced within thirty minutes.			
2.7.1 Food Defense Plan	2.7.1.1	Compliant	
	2.7.1.2	Compliant	
	2.7.1.3	Compliant	
	2.7.1.4	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
Section Summary: The facility has a written food defense plan (Facility Security Manual – 1/23/19) which identifies how access to the site is controlled, raw material, packaging material, finished product, chemical product safety, employee security, laboratory security and documentation security. The site uses building entrance code pads, visitor and driver control, and employee training for food security support. The program is managed by the Safety Manager and Security Team. The Program was reassessed and tested 1/23/19. During the audit, the interior and exterior areas were observed secured. No doors were left open and unattended. The facility has security protocols for visitors implemented. Employees are background checked before being hired. Guidelines for the inspection of LTLs is implemented and documented. The facility requires for all truck driver to be identified. Truck seals were recorded in the inbound truck inspection records.			
2.7.2 Food Fraud	2.7.2.1	Compliant	
	2.7.2.2	Compliant	
	2.7.2.3	Compliant	
	2.7.2.4	Compliant	
Section Summary: The company Corporate Food Safety Manager (Food Fraud Vulnerability Assessment Team) with members from Corporate Food Safety/Product Quality, Vendor Compliance and Purchasing developed and implemented a Company Food Fraud Vulnerability Plan (last revision 11/20/2018). The plan includes a risk vulnerability assessment and mitigation based on country of origin, supplier reputation/history, product type, product composition, delectability technology, methods for adulteration, and internal controls.			
2.8.1 Allergen Management for Food Manufacturing	2.8.1.1	Compliant	
	2.8.1.2	Compliant	
	2.8.1.3	Compliant	
	2.8.1.4	Compliant	
	2.8.1.5	Compliant	
	2.8.1.6	Compliant	
	2.8.1.7	Compliant	
	2.8.1.8	Compliant	
	2.8.1.9	Compliant	
	2.8.1.10	Compliant	
	2.8.1.11	Not Applicable	The facility has in place a documented Allergen Control Program.
Section Summary: An Allergen Control Plan (Allergen SOP) is in place that includes Food Safety Team responsibilities, employee allergen training policies, receiving and storage segregation practices, production control/scheduling, rework process, change over practices, labeling, allergen product traceability, cleaning / sanitation practices, cleaning verification/validation and allergen information for customers. Allergen materials are clearly identified with the type of allergen contained during receiving and processing steps. Allergens were correctly identified according to regulations on finished product labels and traceable by product lot numbers. A master list (Food Allergens and Sensitive Ingredients Register – 1/21/19) of allergen product including ingredients and finished product was in place. Allergens present in this facility are milk, wheat, soy and mustard (product sold in Canada). As part of the Food Safety and Preventive Control Plan, the facility has in place a Finished Product Allergen Label Verification. Allergen change over very verifications were reviewed for 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19.			
2.8.2 Allergen Management for Pet Food Manufacturing	2.8.2.1	Not Applicable	
	2.8.2.2	Not Applicable	
Section Summary: The facility does not manufacture pet foods.			
2.8.3 Allergen Management for Manufacturers of Animal Feed	2.8.3.1	Not Applicable	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	2.8.3.2	Not Applicable	
Section Summary: The facility does not manufacture animal feed.			
2.9.1 Training Requirements	2.9.1.1	Compliant	
	2.9.1.2	Compliant	
Section Summary: Per the Training Program, Management training is conducted as part of the general annual training for all employees. Training includes, pre-requisites, food safety, product quality, HACCP, GMP, product specifications, CQP/CCP monitoring practices. Management training for food safety, quality policies records were reviewed for 3/22, 26/19. QA Techs training was reviewed for food quality practices and food safety controls limits monitoring completed 9/18/2018.			
2.9.2 Training Program	2.9.2.1	Compliant	
Section Summary: A documented training program (Food Safety and Quality Employee Training) was in place outlining the training competencies and needs for management and non-management employees. The program includes training requirement for New Hire Orientation Training, Annual Refresher Training, and Job Specific Training. The training includes GMP, HACCP, SQF, quality standards, Pre-requisites (food safety, food defense/facility security, sanitation, allergen control, foreign material prevention, pest control, preventive cross-contamination) and specific job related responsibilities.			
2.9.3 Instructions	2.9.3.1	Compliant	
Section Summary: Job specific Instructions explaining how all tasks to meet product specifications, maintenance of food safety, quality and process were available to all employees.			
2.9.4 HACCP Training Requirements	2.9.4.1	Compliant	
Section Summary: Per the Training Program, Management training is conducted as part of the general annual training for all employees. Training includes, pre-requisites, food safety, product quality, HACCP, GMP, product specifications, CQP/CCP monitoring practices. Management training for food safety, quality policies records were reviewed for 3/22, 26/19. QA Techs training was reviewed for food quality practices and food safety controls limits monitoring completed 9/18/2018.			
2.9.5 Language	2.9.5.1	Compliant	
Section Summary: Training is conducted in English			
2.9.6 Refresher Training	2.9.6.1	Compliant	
Section Summary: Annual training includes Food Safety, Food Defense, GMP, HACCP, SQF, Sanitation Practices (cleaning/sanitation, allergen Control, chemicals handling and specific job related responsibilities. Training files for 2018-2019 training cycle were on file.			
2.9.7 Training Skills Register	2.9.7.1	Compliant	
Section Summary: A current training skills register (2018 -2019 training cycle) was available for review, describing training topic, frequency, schedule, employee, completion date.			
11.1.1 Premises Location and Approval	11.1.1.1	Compliant	
	11.1.1.2	Compliant	
Section Summary: The location of the premises and adjacent plant buildings, operations and land use do not interfere with safe and hygienic operations. The facility had on file a Grant of Inspection issued on 2/19/2019 by the US Department of Agriculture Food Safety and Inspection Services. The facility is USDA registered facility with Establishment Number 2121 /P-2121			
11.2.1 Materials and Surfaces	11.2.1.1	Compliant	
Section Summary: The plant design and construction is specifically for the processing of meat products. The facility building and equipment was observed in good conditions, organized, clean and did not represent a food safety or quality risk to the products or packaging materials.			
11.2.2 Floors, Drains, and Waste Traps	11.2.2.1	Compliant	
	11.2.2.2	Compliant	
	11.2.2.3	Compliant	
	11.2.2.4	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
Section Summary: Floors were well maintained and constructed of materials specific for food processing plants. Floors were graded to drain the water directly to drains located in specific areas to avoid contamination.			
11.2.3 Walls, Partitions, Floors and Ceilings	11.2.3.1	Compliant	
	11.2.3.2	Compliant	
	11.2.3.3	Compliant	
	11.2.3.4	Compliant	
	11.2.3.5	Compliant	
	11.2.3.6	Compliant	
	11.2.3.7	Compliant	
Section Summary: Floors were well maintained and constructed of materials specific for food processing plants. Floors were graded to drain the water directly to drains located in specific areas to avoid contamination. Ceilings, pipes and ducts were observed constructed with durable materials, well maintained and in good conditions. Walls, man-doors and overhead doors, including dock were observed constructed with durable materials, well maintained and in good conditions and did not represent a product risk.			
11.2.4 Stairs, Catwalks and Platforms	11.2.4.1	Compliant	
Section Summary: Stairs, catwalks and platforms were safely installed, protected and in good conditions and did not represent a risk to the safety or quality of the products.			
11.2.5 Lightings and Light Fittings	11.2.5.1	Compliant	
	11.2.5.2	Minor	Minor - A light cover was observed with a crack above packaging area (RTE).
	11.2.5.3	Compliant	
Section Summary: Light intensity was appropriate in all areas of the plant. Light in processing, handling or storing areas were protected or shatterproof. Minor - A light cover was observed with a crack above packaging area (RTE).			
11.2.6 Inspection / Quality Control Area	11.2.6.1	Compliant	
	11.2.6.2	Compliant	
Section Summary: Product inspection takes place in well conditioned areas in the production areas. Areas designated as product quality/sensory inspection was observed suitable for the product inspected.			
11.2.7 Dust, Insect, and Pest Proofing	11.2.7.1	Compliant	
	11.2.7.2	Compliant	
	11.2.7.3	Compliant	
	11.2.7.4	Compliant	
Section Summary: Windows, ventilation openings, external doors, receiving overhead doors and other openings were observed with good seal and closed during the audit.			
11.2.8 Ventilation	11.2.8.1	Compliant	
	11.2.8.2	Compliant	
	11.2.8.3	Compliant	
Section Summary: Ventilation units with air flow were installed in all processing areas and cooler units. Extraction hood were installed above the product fryers. Condensation was not observed.			
11.2.9 Equipment, Utensils, and Protective Clothing	11.2.9.1	Compliant	
	11.2.9.2	Minor	Minor – Two blue plastic containers used for allergen ingredients were used for not the indent purpose.

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	11.2.9.3	Compliant	
	11.2.9.4	Compliant	
	11.2.9.5	Compliant	
	11.2.9.6	Compliant	
	11.2.9.7	Compliant	
	11.2.9.8	Compliant	
Section Summary: Minor – Two blue plastic containers used for allergen ingredients were used for not the indent purpose. Food processing and food handling equipment is hygienically designed for the manufacture of safe food is easily cleaned in place or dismantled for cleaning out of place and did not pose a food safety risk. Water accumulation was not observed.			
11.2.10 Premises and Equipment Maintenance	11.2.10.1	Minor	Minor – A plastic-glass cover was observed broken in one of the fillers at the RTE area.
	11.2.10.2	Compliant	
	11.2.10.3	Compliant	
	11.2.10.4	Compliant	
	11.2.10.5	Compliant	
	11.2.10.6	Compliant	
	11.2.10.7	Compliant	
	11.2.10.8	Compliant	
	11.2.10.9	Compliant	
	11.2.10.10	Compliant	
	11.2.10.11	Compliant	
Section Summary: Minor – A plastic-glass cover was observed broken in one of the fillers at the RTE area. A preventive and emergency computer based maintenance program that includes all equipment and areas of the building is in place and documented based on pre-set maintenance calendar. The work orders include the sign off for control and cleaning of tools, sanitation of the area, and release of area to the production group. The Maintenance food safety guidelines address the protection or disposition of product affected by maintenance activities. Same guidelines describe the equipment sanitation, tools and parts retrieval after maintenance activities. The facility uses only food grade lubricants for food processing equipment. During the audit the facility equipment was observed well maintained. The maintenance staff was observed following plant's GMP requirements. The facility controls/verified the equipment is clean and ready to be used by the Food Safety program. The program includes the verification that tools, part and maintenance equipment is removed and that the equipment is cleaned and sanitized.			
11.2.11 Calibration	11.2.11.1	Compliant	
	11.2.11.2	Compliant	
	11.2.11.3	Compliant	
	11.2.11.4	Compliant	
	11.2.11.5	Compliant	
	11.2.11.6	Compliant	
Section Summary: Laboratory and processing equipment calibration procedures are documented in the Calibration Procedures, thermometer calibration procedures, scales calibration procedures, metal detector verification policy, pH Meter and Co2 Analyzer. Calibrations is conducted based on manufacturer specifications or based on equipment use frequency. Equipment calibration records were reviewed for; laboratory equipment – scales annual calibration – 12/21/18, annual thermometer calibrations – 1/17/19, moisture analyzer annual calibration - 12/6/19, daily oven HACCP thermometers and pH meters- 3/25-29/19, weekly thermometer (non-CCP) – 3/3, 10, 17, 24/19. Production equipment calibration; annual metal detector calibration – 2/10/19, annual scales calibration - 2/3/19. Policies for the segregation of affected product tested or verified with defective equipment id outlined in the equipment calibration Policy.			

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
11.2.12 Pest Prevention	11.2.12.1	Compliant	
	11.2.12.2	Compliant	
	11.2.12.3	Compliant	
	11.2.12.4	Compliant	
	11.2.12.5	Compliant	
	11.2.12.6	Compliant	
	11.2.12.7	Compliant	
	11.2.12.8	Compliant	
	11.2.12.9	Compliant	

Section Summary: A third party pest control company program to control rodent and in-sects in all areas of the facility was in place and documented. The program covers PCO responsibilities and facility staff pest control responsibilities, inspection frequency and methods for pest control. The pest control program revised on 3/28/2019 includes approved chemical list/use (Authorized Product List – 2019), pest control device map (3/26/19, products SDS, facility employee pest control awareness training, PCO training documentation, pest control inspector and company license with an expiration date of 12/31/19, target pest and methods to control/prevent pest issues and pest activity trending reports. Weekly inspections for insect and rodent are performed by trained PCO for internal and external areas. Pest Control Company weekly inspections were reviewed for dates 3/5, 12, 19, 26/2019. All records reviewed were up to date and complete. The facility does not store pesticides or other toxic chemicals on site.

11.2.13 Cleaning and Sanitation	11.2.13.1	Compliant	
	11.2.13.2	Compliant	
	11.2.13.3	Compliant	
	11.2.13.4	Compliant	
	11.2.13.5	Compliant	
	11.2.13.6	Compliant	
	11.2.13.7	Compliant	
	11.2.13.8	Compliant	
	11.2.13.9	Minor	Minor – A non-labeled plastic spray bottle was used at the women's bathroom.
	11.2.13.10	Compliant	
	11.2.13.11	Compliant	

Section Summary: A documented Cleaning and Sanitation Plan (Cleaning Procedure Manual – 2/26/2019) for wet and CIP was implemented and maintained by facility Sanitation Manager and Sanitation Staff. The cleaning and sanitation task are conducted by a 3rd party sanitation company. The plan included employee training (food safety, GMP's, chemical cage security, sanitation practices, chemical handling), equipment and facility areas SSOP's (chemical dilution, water temperature, cleaning/sanitizing instructions, safety equipment needed, cleaning frequency), chemical titration procedure, chemical concentration verification, sanitizer rotation schedule pre-operational practices guidelines by sanitation company and facility QA staff, cleaning equipment color coding chemical SDS, product chemical inventory, empty container procedures. Master Cleaning Sanitation records for raw process and RTE area cleaning and related tasks were reviewed for daily and weekly cleaning – 2/10/19, 2/17/19 and 2/24/19. Records were reviewed for daily chemical concentration (titration), daily water temperature verification, cleaning company daily pre-operational cleaning verifications –3/4-9/19, 3/4-16/19, 3/18-23/19. Chemical product monthly product dispenser service and chemical inventory was reviewed for 3/2-29/2019. Records for QA conducted pre-operational inspections, daily ATP cleaning verification and daily cleaning and sanitizer chemical concentration (titration test) were reviewed for 4/2/19. Records for chemical handling and safety training were reviewed for 3/21/19. Minor – A non-labeled plastic spray bottle was used at the women's bathroom.

11.3.1 Personnel	11.3.1.1	Compliant	
	11.3.1.2	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	11.3.1.3	Compliant	
	11.3.1.4	Minor	Minor – A disposable coffee cup was observed inside the uniform room.
Section Summary: Minor – A disposable coffee cup was observed inside the uniform room. A documented GMP program was in place and documented. The program includes personal hygiene, glove use, hand washing practices, dress code, food safety, housekeeping practices and processing /handling practices. Employees were observed following established GMP's.			
11.3.2 Hand Washing	11.3.2.1	Compliant	
	11.3.2.2	Compliant	
	11.3.2.3	Compliant	
	11.3.2.4	Compliant	
	11.3.2.5	Compliant	
	11.3.2.6	Compliant	
Section Summary: A documented GMP program was in place and documented. The program includes personal hygiene, dress code, food safety and processing /handling practices. Employees were observed following established GMP's. Hand-free hand wash stations made of stainless steel were located adjacent to the production area and at the entrance of the processing areas. The stations were equipped with hot/cold water, soap, paper towels and a waste container, hand wash signs. Employees were observed washing hands and wearing gloves upon entering processing area. This is a GMP policy requirement.			
11.3.3 Clothing	11.3.3.1	Compliant	
	11.3.3.2	Compliant	
	11.3.3.3	Compliant	
	11.3.3.4	Compliant	
	11.3.3.5	Compliant	
Section Summary: Staff working in the RTE areas is required to change into different color and clean clothing before entering the area. Staff clothing in all area of the facility was observed clean and in good conditions. Glove use is included in the facility GMP policy, including hand washing before use of gloves. Glove and disposable protective equipment use guidelines are included in the facility GMP policy, including hand washing before use of gloves.			
11.3.4 Jewelry and Personal Effects	11.3.4.1	Compliant	
Section Summary: Employees in processing and non-processing areas were not observed wearing loose objects or jewelry. This practice is included in the GMP guidelines.			
11.3.5 Visitors	11.3.5.1	Compliant	
	11.3.5.2	Compliant	
	11.3.5.3	Compliant	
	11.3.5.4	Compliant	
	11.3.5.5	Compliant	
Section Summary: Per documented guidelines, all visitors, including contractors, suppliers or company visitors must follow same GMP guidelines.			
11.3.6 Staff Amenities	11.3.6.1	Compliant	
Section Summary: Employee welfare areas were supplied with adequate lighting, ventilation, dressing areas, and lockers for appropriate storage of personal items.			
11.3.7 Change Rooms	11.3.7.1	Compliant	
	11.3.7.2	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	11.3.7.3	Compliant	
	11.3.7.4	Compliant	
Section Summary: All employees are provided with looker rooms to store their personal items. Change rooms are provided to all employees, including a separated change room for employees working in the RTE processing area. Uniforms are cleaned by a 3rd party service provider.			
11.3.8 Laundry	11.3.8.1	Compliant	
Section Summary: Employee uniforms and laboratory staff frocks are cleaned by an external cleaning company.			
11.3.9 Sanitary Facilities	11.3.9.1	Compliant	
	11.3.9.2	Compliant	
	11.3.9.3	Compliant	
Section Summary: Sanitary facilities were located separated from food processing and handling areas. The facilities were built in a way that does not represent a risk to the products. Hand wash sinks are provided inside toilet rooms and designed following requirements in section 11.3.2.2.			
11.3.10 Lunch Rooms	11.3.10.1	Compliant	
	11.3.10.2	Compliant	
	11.3.10.3	Compliant	
	11.3.10.4	Compliant	
Section Summary: The lunch/break room for raw and RTE areas are located in separated area away from processing and product storage/handling areas, well lighted and equipped with ventilation, hand wash sinks, refrigeration and heating facilities.			
11.4.1 Staff Engaged in Food Handling and Processing Operations	11.4.1.1	Compliant	
	11.4.1.2	Not Applicable	Sensory evaluations are only performed in the facility laboratory.
	11.4.1.3	Compliant	
Section Summary: Employees were observed to be in compliance with the company's hygiene policy. Employees involved with product sensory evaluations were following hygiene practices, in areas equipped for this purpose. The process areas were well maintained. Doors were observed to be closed when not moving materials. False fingernails and fingernail polish were not observed. Waste was collected in trash cans and emptied as needed. product sensory evaluations are performed in the QA Area.			
11.5.1 Water Supply	11.5.1.1	Compliant	
	11.5.1.2	Compliant	
	11.5.1.3	Compliant	
	11.5.1.4	Compliant	
	11.5.1.5	Compliant	
Section Summary: Hot and cold water used at this facility is sourced from municipal potable water from the City of New Kensington PA. Water lines backflow preventers test are conducted on an annual basis by an external plumber. Last pressure test was conducted 10/14/2018.			
11.5.2 Water Treatment	11.5.2.1	Not Applicable	
	11.5.2.2	Not Applicable	
	11.5.2.3	Not Applicable	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	11.5.2.4	Not Applicable	
Section Summary: Water for processing purposes is not treated.			
11.5.3 Ice Supply	11.5.3.1	Not Applicable	
	11.5.3.2	Not Applicable	
Section Summary: Ice is not used.			
11.5.4 Monitoring Water Microbiology and Quality	11.5.4.1	Compliant	
	11.5.4.2	Compliant	
	11.5.4.3	Compliant	
Section Summary: Water potability test are conducted every by an external laboratory for Coliforms, HPC and E.coli. Water potability test were reviewed for 1/28/19 from five sites.			
11.5.5 The Quality of Air and Other Gasses	11.5.5.1	Compliant	
	11.5.5.2	Compliant	
Section Summary: Compressed air quality is weekly tested for APC. Compressed air test results were reviewed for dates 3/11/19, 3/18/19 and 3/25/19.			
11.6.1 Storage and Handling of Goods	11.6.1.1	Compliant	
	11.6.1.2	Compliant	
	11.6.1.3	Compliant	
	11.6.1.4	Compliant	
	11.6.1.5	Not Applicable	The facility does not use temporary or overflow storage.
	11.6.1.6	Not Applicable	The facility does not use temporary or overflow storage.
Section Summary: Product stock rotation for raw materials, ingredients and packaging material is based on receiving and expiration date using FIFO criteria. The finished product rotation is based on production date using FIFO. Stock rotation procedures are outlined in the Stock Rotation Procedures. The facility does not use temporary or overflow storage.			
11.6.2 Cold Storage, Freezing and Chilling of Foods	11.6.2.1	Compliant	
	11.6.2.2	Compliant	
	11.6.2.3	Compliant	
	11.6.2.4	Compliant	
	11.6.2.5	Compliant	
Section Summary: Coolers, freezer, processing areas, chill areas, non-processing and receiving areas temperature monitoring is continuously monitored 24/7 by a system and verified daily by the QA Team. Cooler and freezer units were observed in good conditions. Cleaning activities for all rooms are managed by the Master Sanitation Schedule. Daily temperature verification checks (charts / reports) were reviewed for 3/1-31/2019. Monitoring records reviewed included Raw Cooler, Receiving Cooler, and Freezer. All coolers discharge from defrost and condensate lines are controlled and discharged to the drainage system.			
11.6.3 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods	11.6.3.1	Compliant	
	11.6.3.2	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
	11.6.3.3	Compliant	
Section Summary: Rooms used for the storage of product ingredients, packaging, and other dry goods are located away from wet areas and build with metal racks to store dry ingredients and packaging materials. All vehicles used in this facility were battery operated so as not to release any hydrocarbon emissions.			
11.6.4 Storage of Hazardous Chemicals and Toxic Substances	11.6.4.1	Compliant	
	11.6.4.2	Compliant	
	11.6.4.3	Compliant	
	11.6.4.4	Not Applicable	Pesticides, rodenticides, fumigants and insecticides are stored in the facility or handled by employees.
	11.6.4.5	Compliant	
Section Summary: Hazardous chemicals for cleaning, lubrication and other uses were appropriately stored in a well ventilated, secured location and separated from food processing, food handling, and food storage areas. Pesticides, rodenticides, fumigants and insecticides are not stored in the facility. This includes maintenance areas and cleaning product cage.			
11.6.5 Loading, Transport, and Unloading Practices	11.6.5.1	Compliant	
Section Summary: The practices and methods applied during loading, transport and unloading of food is documented in the receiving and shipping procedures and, implemented for raw materials, ingredients and packaging material, including bulk receiving. Loading and unloading practices observed during the audit were conducted according to the shipping and receiving standards.			
11.6.6 Loading	11.6.6.1	Compliant	
	11.6.6.2	Compliant	
	11.6.6.3	Compliant	
Section Summary: Shipping procedures are outlined in the Shipping Process Overview SOP. Procedures includes the verification of the transportation vehicle for temperature monitoring/pre-cooling verification (<-10F), general condition of the truck, seal verification, load temperature verification, load documentation verification (lot number, shipping quantity, destination, product description and transport description/driver verification. Shipping/Trailer/load Inspection records were reviewed for 3/25-29/2019.			
11.6.7 Transport	11.6.7.1	Compliant	
	11.6.7.2	Compliant	
Section Summary: Shipping procedures are outlined in the Shipping Process Overview SOP. Procedures includes the verification of the transportation vehicle for temperature monitoring/pre-cooling verification (<-10F), general condition of the truck, seal verification, load temperature verification, load documentation verification (lot number, shipping quantity, destination, product description and transport description/driver verification. Shipping/Trailer/load Inspection records were reviewed for 3/25-29/2019.			
11.6.8 Unloading	11.6.8.1	Compliant	
	11.6.8.2	Compliant	
Section Summary: Incoming materials are inspected according to the Receiving SOP and Trailer Inspection procedures. Transport inspections include cleanliness, odor, physical conditions, rodent/insect activity, cross-contamination, product damage, product temperature and seal verification. Product identification and traceability information includes; product description, COA's, expiration dates, lot coding, load quantity, truck seal verification and segregation of non-conforming loads. Receiving records were reviewed for 3/25-29/19.			
11.7.1 Process Flow	11.7.1.1	Compliant	
Section Summary: The production stream in this facility is designed in a continuous flow from receiving to shipping without the risk of cross-contamination to the product at any of the production steps. The facility has physical segregation of raw materials and ingredients with production and finished product areas as well as for the different production areas.			

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
11.7.2 Receipt of Raw and Packaging Materials and Ingredients	11.7.2.1	Compliant	
Section Summary: Dry ingredients and packaging materials are received and stored separately from raw materials. Refrigerated raw products are store in separated areas (raw product cooler).			
11.7.3 Thawing of Food	11.7.3.1	Not Applicable	
	11.7.3.2	Not Applicable	
	11.7.3.3	Not Applicable	
	11.7.3.4	Not Applicable	
Section Summary: The facility does not thawing redients or raw materials.			
11.7.4 High Risk Processes	11.7.4.1	Compliant	
	11.7.4.2	Compliant	
	11.7.4.3	Compliant	
	11.7.4.4	Compliant	
	11.7.4.5	Compliant	
Section Summary: Processing of high risk product is conducted in a manner to prevent contamination. RTE areas of the facility are separated from raw areas of the facility to prevent the chance of cross contamination. The RTE employees are required to wear different frocks with disposable protective equipment in high risk processing room. The RTE area has a separate area to allow employees to put on proper garments before entering the RTE area. The design of the process does allow for proper transfer of product from the raw area of the facility to the RTE and proper procedures are followed to prevent the chance of cross-contamination. The facility has an Environmental monitoring program for the testing of Listeria.			
11.7.5 Control of Foreign Matter Contamination	11.7.5.1	Compliant	
	11.7.5.2	Compliant	
	11.7.5.3	Compliant	
	11.7.5.4	Compliant	
	11.7.5.5	Compliant	
	11.7.5.6	Compliant	
	11.7.5.7	Compliant	
	11.7.5.8	Compliant	
	11.7.5.9	Compliant	
Section Summary: The facility has implemented a documented foreign material contamination control program revised 8/27/19. The program includes the responsibility for Management, Food Safety and QA Staff regarding foreign material contamination for metal (metal detectors/x-ray equipment), non-metal contamination, plastic palest checks, injector needle control, macerator blade control, grinder plate control, preventive maintenance, lubricant control, pre-operational inspections and glass/brittle plastic control. Processing equipment is maintained through a preventive maintenance program and verified during Pre-operational Inspections. The facility uses metal detector installed in raw processing areas and at the packaging lines. Loose objects were not observed during the audit.			
11.7.6 Detection of Foreign Objects	11.7.6.1	Compliant	
	11.7.6.2	Compliant	
	11.7.6.3	Compliant	

SECTION	ELEMENT	PRIMARY RESPONSE	EVIDENCE
Section Summary: A metal detector/x-ray procedure is in place that includes service frequency (annual calibration), daily verification frequency, testing limits, monitoring responsibilities and corrective actions. Metal detectors are located at all packaging lines, equipped with alarms and automatic stops and/or product rejection mechanism. Metal detectors are verified using control limits for all products at 1.5 mm. ferrous, 2.0 mm. non-ferrous, and 2.0 mm. stainless steel. Metal detector daily monitoring records were reviewed for 9/3-5/18, 11/5-7/18, 1/7-9/19 and 3/4-6/19.			
11.7.7 Managing Foreign Matter Contamination Incidents	11.7.7.1	Compliant	
	11.7.7.2	Compliant	
Section Summary: Policies and procedures are in place stating the requirement of the isolated, inspected or disposed of the product in case of foreign material contamination under the Glass and Brittle Plastic Policy, Metal Detector Verification Procedure and in Foreign Material Control Plan.			
11.8.1 Location	11.8.1.1	Compliant	
	11.8.1.2	Compliant	
	11.8.1.3	Compliant	
Section Summary: The on-site laboratory was operated only to conduct quality test. The laboratory is located separated from food processing and handling activities and were appropriately designed to restrict access only to authorized personnel. Laboratory waste is disposed of in a manner that does not pose a threat to food safety according to the Waste Management Program.			
11.9.1 Dry and Liquid Waste Disposal	11.9.1.1	Compliant	
	11.9.1.2	Compliant	
	11.9.1.3	Compliant	
	11.9.1.4	Compliant	
	11.9.1.5	Compliant	
	11.9.1.6	Compliant	
	11.9.1.7	Compliant	
	11.9.1.8	Compliant	
	11.9.1.9	Compliant	
Section Summary: The responsibility and methods used to collect and handle dry and wet waste is responsibility of operations and verified by QA. This process is outlined in the Inedible, Trash, Sewage Handling SOP – 3/7/2019. Waste management practices are a part of the daily hygiene operations and inspections and of the monthly internal GMP audits program. Waste was appropriate controlled and contained in the internal and external areas. The plan applies to organic and non-organic material, oil, lubricants and water.			
11.10.1 Grounds and Roadways	11.10.1.1	Compliant	
	11.10.1.2	Compliant	
	11.10.1.3	Compliant	
	11.10.1.4	Compliant	
	11.10.1.5	Compliant	
	11.10.1.6	Compliant	
Section Summary: Facility external paths, roadways and loading and unloading areas were well maintained clean and did not represent a food safety or product quality risk. The observation includes the Facility Distribution Center.			