Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
101417 | 92242

AUDIT RATING
97
Excellent

DECISION DATE
10/21/2019

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
07/26/2020

AUDIT DATES
08/05/2019 - 08/08/2019

EXPIRATION DATE
10/09/2020

ISSUE DATE
10/22/2019

Facility & Scope

Smithfield Packaged Meats Corp. (45735)
Smithfield Packaged Meats Corp. - Cudahy
One Sweet Apple Wood Lane
Cudahy, WI 53110
United States

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

Products:
Dry Sausage, Semi-Dry Sausage, Bacon, Cooked Sausage, Luncheon Meats Precooked Bacon, Sausage Links

Scope of Certification:
Dry Sausage, Semi-Dry Sausage, Bacon, Cooked Sausage, Luncheon Meats Precooked Bacon, Sausage Links

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: Bergman, Tiffany (123637)
Technical Reviewer: Luttrell, Sandra (132944)

Hours Auditing: 30
Hours Writing Report: 12

Non-Conforming

11.2.2 Floors, Drains, and Waste Traps

Minor: The floor in the injection room was observed with exposed aggregate in multiple areas and damaged epoxy. Comment: The floors in the other production and product storage areas were well maintained and properly designed for the drainage of water. The drains at the plant were in good condition and located in areas that are accessible for cleaning. N/A: The facility does not have a waste trap system.

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: MINOR

EVIDENCE: Minor: The floor in the injection room was observed with exposed aggregate in multiple areas and damaged epoxy.

ROOT CAUSE: The sanitation chemicals used nightly has damaged the epoxy over time in the S Pump Dept.

CORRECTIVE ACTION: The floor in the S Pump Dept. is scheduled for repair and will be completed by 10/31/19.

VERIFICATION OF CLOSEOUT: The quote and time line for the completion of the flooring improvements were reviewed and approved by Tiffany Bergman.

COMPLETION DATE: 10/31/2019 **CLOSEOUT DATE:** 09/02/2019

11.2.5 Lightings and Light Fittings

Minor: The Microwave Bacon Pack-off area was observed with at least 4 dirty light fixtures. An overhead light fixture was dirty in line 7 & 8 packaging area. The Pre-Press Cooler was observed with three dirty lights. The J-Pump Room had a broken and dirty light over the conveyor (no product risk). Comment: The lighting throughout the site was adequate for sanitation, pest control, and inspections.

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: MINOR

EVIDENCE: Minor: The Microwave Bacon Pack-off area was observed with at least 4 dirty light fixtures. An overhead light fixture was dirty in line 7 & 8 packaging area. The Pre-Press Cooler was observed with three dirty lights. The J-Pump Room had a broken and dirty light over the conveyor (no product risk).

ROOT CAUSE: Issue was brought to the attention of QA and Supervisors in Dept.

CORRECTIVE ACTION: The J Pump Room light cover was replaced during the SQF audit (repaired on 8/7/19). The Pre-Press Cooler light covers were replaced on 8/27/19. The Microwave Dept. light fixtures were cleaned on 8/10/19.

VERIFICATION OF CLOSEOUT: The photos of the replaced lighting were reviewed and approved by Tiffany Bergman.

COMPLETION DATE: 08/27/2019 **CLOSEOUT DATE:** 09/02/2019

11.4.1 Staff Engaged in Food Handling and Processing Operations

Minor: The hooks used for the storage of frocks for employees leaving the packaging area for lines 5 & 6 were observed with gloves stored on top of them. The two hose ends in the employee frocking area before lines 5 & 6 were observed to be stored directly on the floor. In the slicing area a white bin labeled for edible product had two sticker guns and labels stored in it. The table in the press room identified for edible was observed with rubber gloves being stored on it. Comment: The site conducts all sensory away from the production lines.

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: MINOR

EVIDENCE: Minor: The hooks used for the storage of frocks for employees leaving the packaging area for lines 5 & 6 were observed with gloves stored on top of them. The two hose ends in the employee frocking area before lines 5 & 6 were observed to be stored directly on the floor. In the slicing area a white bin labeled for edible product had two sticker guns and labels stored in it. The table in the press room identified for edible was observed with rubber gloves being stored on it.

ROOT CAUSE: Issue was brought to the attention of QA and Supervisors in Dept.

CORRECTIVE ACTION: The rubber gloves stored on the press room table were removed and the table was washed/sanitized when identified during the audit. Verbal retraining for the deficiencies was completed for all departments involved.

VERIFICATION OF CLOSEOUT: The training, cleaning, and review of the area were reviewed and approved by Tiffany Bergman.

COMPLETION DATE: 08/21/2019 **CLOSEOUT DATE:** 09/02/2019

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Tricia Campbell
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** tcampbell@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:** Tiffany Bergman: Auditor, Tricia Campbell: Food Safety Supervisor, Sandra Dodd: FSQA Supervisor, Ben Lindstrom: Food Safety Manager, Debra Albright: FSQA Manager, Rob Fons: Assistant Plant Manager, Philip Rizzo: Bacon Superintendent, Gentiana Agolli: Microwave Supervisor, Kevin Fehlhaber: Safety Manager, Rick Tooketz: Environmental Manager, Paul Wasielewski: Plant Engineer, Brian Zimmerman: Warehouse Manager, Craig Gabor: Quality Assurance, Agron Hajdari: Dry Sausage Superintendent, Bill McWilliams: Senior Director of Manufacturing, Bob Stamm: Plant Manager, Christine Kiel: Assistant Plant Controller, Sarah Ruby: HR Supervisor, Phil Moher: Senior HR Manager, Juan Soto: Production Supervisor.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** The auditor recommends the facility maintain their SQF Food Safety and Food Quality Certification with the closure and approval of all corrective actions.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Tiffany Bergman: Auditor, Tricia Campbell: Food Safety Supervisor, Sandra Dodd: FSQA Supervisor, Ben Lindstrom: Food Safety Manager, Debra Albright: FSQA Manager, Rob Fons: Assistant Plant Manager, Philip Rizzo: Bacon Superintendent, Gentiana Agolli: Microwave Supervisor, Kevin Fehlhaber: Safety Manager, Rick Tooketz: Environmental Manager, Paul Wasielewski: Plant Engineer, Brian Zimmerman: Warehouse Manager, Agron Hajdari: Dry Sausage Superintendent, Bill McWilliams: Senior Director of Manufacturing, Bob Stamm: Plant Manager, Sarah Ruby: HR Supervisor, Phil Moher: Senior HR Manager, Juan Soto: Production Supervisor.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** The Patrick Cudahy facility is located in a mixed use area of Cudahy, WI. The plant was originally built in the late 1800's. The facility has had multiple additions over the years and a rebuild of part of the plant seven years ago. The facility is approximately 940,000 square feet in total size. The facility employs approximately 1,000 employees working two shifts, 5 - 6 days per week. Sanitation is completed by a contracted cleaning company (Q-Vest) during third shift. The facility maintains USDA establishment # 28 and P28. The plant has three HACCP plans covering the production of microwave bacon and bacon/certified bacon, dry and semi dry sausages, and Fresh Sausage, Sausage and Luncheon Meats. The pressure treated cooked deli meats HACCP plan was inactive at the time of the audit. The refinery process was excluded from the scope of certification. The corrective actions from the previous were completed and maintained at the time of the audit.

Section Responses

2.1.1 Food Safety Policy

The Safe Quality Foods (SQF) Policy Statement states the team has a commitment to supplying quality safe foods, meeting customer expectations, use of continuous improvement, training, involvement of all staff, and communication. This was signed by the Plant Manager 7-23-19 and available in English, Spanish, Albanian, and Serbian. The Policy Statement was posted in areas throughout the site for employee awareness.

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 Organizational chart was available for each of the areas of the site and included the Product Development – Food Safety personnel from June 2019. The plant management team has provided resources for the support of SQF for security cameras, increased capacity for cooling, monitors in the lunch rooms for employee communication, food contact glove change, lab re-organization, and casing improvements. The site is in the process of implementing the use of tablets for gathering QA check information on the production floor. The SQF Practitioner and back up are full time employees and have the authority for decision making for food safety and food quality issues. The SQF Practitioner completed HACCP training on 11-15-17 and the back up on 9-2-10. Both demonstrated a strong knowledge of the SQF Code and HACCP during the audit. During the audit the employees in different departments and shifts were asked about their responsibilities for food safety and food quality at the plant. The personnel responsible for the CCP monitoring demonstrated how they check the temperatures and explained it was an important check to control the growth of bacteria that could harm their customers. The personnel responsible for the visual inspections and packaging of the products explained how they remove the product from the lines and the proper handling of the material to keep it safe. The employees demonstrated strong knowledge and pride in their products, followed GMP's very well, and handled the products properly. The Position Descriptions were reviewed for the Food Safety & Technical Manager 9-2018, Food Safety and Quality Assurance Supervisor 11-2018, Quality Assurance Supervisor 9-2018, and Laboratory Scientist 9-2018, and these include regulatory compliance, visual inspections for cleanliness, sanitation program, investigation, continuous improvement, and SQF support. N/A: The facility audit was announced.

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: NOT APPLICABLE

EVIDENCE: N/A: The facility audit was announced.

2.1.3 Management Review

The Management Review Procedure 5-15-19 includes the personnel responsible, review of policies, audit results, corrective actions, preventive actions, complaints, changes to SQF, and documentation. The SQF Management Review Meeting Minutes were available for the annual review 7-30-19 and included the review of the SQF policies, audit results, corrective actions, consumer complaints, and contingency plans. The sign in sheet was available for the team. The monthly SQF meeting notes were available for 6-17-19, 4-17-19, 2-8-19, and 11-26-18.

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 Complaint Management Procedure 6-20-18 includes the customer contact, communication of issues, investigation, root cause analysis, corrective actions, information required, and documentation. The site creates a complaint report monthly to show the trends for consumer complaints for the totals, types, and division which are posted on the SharePoint. These trends were reviewed for 2018 through 2019 YTD. The corporate customer complaint system is used to track the complaints and the corrective actions and these were reviewed for 12-12-18, 3-11-19, 6-14-19, and 6-20-19 and the investigation and corrective actions were completed in a timely manner.

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 Emergency Response Call List - Patrick Cudahy included the Name, Extension, Primary number, and the Secondary Number. The Smithfield Foods Crisis Manual 6-2019 includes the responsibilities of the team members, company contact information, continuity of operations plan, contact information for the Executive Teams, recall requirements, contact information, outside support contact information, and documentation. The plant specific Crisis Work Instruction Guide for Product Crisis 10-30-18 includes the control of product on site, records review, effectiveness checks, use of a cross functional team, responsibilities of the team, investigation, and documentation. The Mock Disaster Business Continuity Plan Exercise 6-12-19 included a scenario of bellies arriving at the site above 44 degrees F. The team met to review the product information, current temperatures, review of the product, communication to corporate, alternate product handling, food safety/quality items discussed, and documentation.

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 SQF Policy was reviewed and signed by the SQF Practitioners on 7-26-19. The policy includes the supporting programs for the food safety and food quality at the site, the scope of certification, organizational chart, food safety plans, food quality plans, and recordkeeping.
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 Document & Record Management Procedure 1-15-19 includes the personnel responsible, use of a document controller, following USDA guidelines, legibility, proper correction of mistakes, secure storage of records, retention of records, types of records, laboratory records, and record destruction. The site maintains a Food Safety/Quality - Policy Manual Table of contents which provides the list of the programs supporting SQF. The site can access all of the documents in the corporate SharePoint. The records requested during the audit were readily accessible and in good condition.
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 Document & Record Management Procedure 1-15-19 includes the personnel responsible, use of a document controller, following USDA guidelines, legibility, proper correction of mistakes, secure storage of records, retention of records, types of records, laboratory records, and record destruction. The Pre-operational inspection, condensation monitoring, cook yield, metal detector, and label audit forms were reviewed for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed, signed, and verified.

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 Product Development Start-Up Policy 7-6-16 includes the corporate responsibilities for development of new products, plant support, allergen control, control of any sample product, communication, responsibilities of the departments, labeling review, plant implementation, specification maintenance, and documentation. The facility conducts shelf life testing and the Shelf Life Reports were reviewed for 1-3-19, 1-15-19, 2-14-19, and 2-19-19. The site has not had any new products introduced since the previous SQF audit.

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

The corporate team is responsible for the creation and maintenance of all of the specifications which are accessible to the plant through a SharePoint. The corporate group is responsible for the verification and validation of the specifications. During the audit the label for the Hickory Wood Smoked Bacon produced during the audit was compared to the specification from 8-7-19 and the packaging information all matched. The WIP Codes and Finished Product Register was available for 2019 and included the Plant, Material number, and Description. The Packaging Materials 2019 included the Material Number, Description, Vendor, and Status (active/not active). The Approved Protein Vendors Register 4-9-19 includes the Vendor Type, Vendor Name, Vendor Location, and Est. number. The Ingredient Listing 2019 includes the material, description, and supplying plant. The information can also be pulled from QualTrax which is a corporate program on the SharePoint.

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

The contract service providers must be approved through corporate and go through training at the plant annually. The Contract Services Register 5-15-19 includes the Provider, Service, and Training.

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 use 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 use 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 use 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 use any contract manufacturers.

2.3.5 Finished Product Specifications

The corporate group is responsible for the development and control of all finished product specifications. The WIP Codes and Finished Product Register was available for 2019 and included the Plant, Material number, and Description.

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

The Food Legislation Procedure 5-21-19 includes the personnel responsible, use of the USDA brand, membership in AMI, NAMP, AAMP, email updates, notification of SQFI and the certification body in case of incidents, and documentation. The QA personnel receive emails from the USDA and FDA to keep abreast of recalls and regulatory updates.

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 GMP Rules 10-9-18 includes the control of office areas, use of gloves, clothing requirements, head coverings, jewelry control, maintenance control, service people, hand washing, tool control, shoes, product control and covering, box storage area, utensils, hair control, eating in designated areas, and shipping.

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 facility has a cross functional Food Safety Team and the meeting notes were available for 6-13-19. The facility maintains 4 HACCP plans Bacon/Microwave Bacon (heat treated fully cooked, not shelf stable & shelf stable bacon) 3-30-19, Dry & Semi Dry Sausage (product with secondary inhibitors, heat treated, shelf stable) 4-9-19, Fresh Sausage/Sausage and Luncheon Meat (fully cooked, not shelf stable) 4-26-19, and Fat Products (heat treated, shelf stable) 6-26-19. The HACCP plan for Heat Treated, Fully Cooked, Not shelf Stable, and shelf stable Microwave Bacon 3-30-19 was reviewed and signed by the cross functional team. The Product Description included the Processing Category, Product Type, Product Names, How it Will be Used, Packaging, Shelf Life, Where it Will be Sold, Labeling Instructions, and Special Distribution Control. The HACCP plan Ingredients Used form provides the Processing Category, Product Type, Meats, and Non-Meat Ingredients. The flow chart for the bacon product included the receipt of meat products, non-meat products, packaging, injection, heat treatment, metal detection, packaging, slicing, cooking (CCP #1), cooling, dicing, preparing portioning, final distribution, rework, and distribution. The Hazard Analysis includes the Ingredients/Process Step, Potential Hazards, Significance of the Food Hazard, Justification for the Decision, Control Measures, and Identification of Critical Control Points. The site has identified the Cooking Step of the process as CCP #1 for the control of pathogens. The control measure is an internal temperature of 160 degrees F according to the USDA Appendix A. The HACCP summary includes the Processing Step (Cooking), Critical Limits (160 degrees F internal temperature), Monitoring Procedures (sampling requirements, one sample every 75 minutes, quality control technician), Corrective Actions (eliminate the cause of deviation, control of CCP, prevent reoccurrence, product control), Records, and Verification.

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 Vendor Approval Policy 1-28-19 states the corporate FS/QA de-departments are responsible for the approval of all vendors, the information they require for each type of vendor, review of the information, monitoring the performance of suppliers, approval of suppliers temporarily for 60 days only, and documentation. The food defense and food fraud programs include the security of the incoming trailers and potential transportation issues. The site can access the approval supplier information in SAP. The approved vendors for the facility are available in QualTrax.

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 Nonconforming Product Holds 3-22-19 provides the types of holds, color coding, sampling for testing quarterly, customer product control, and documentation. The Returned Product Procedure 4-5-19 provides the guidelines for inspection and control of product returned to the plant. The QC Hold Log includes the Tag Number, Weight Count, Item number, tag by, date, Manager OK, Released by, date, SAP HU number, and Comments. The materials are also placed on a blocked status on SAP and stored in a sealed trailer. The records were reviewed for 9-7-18, 9-20-19, 11-5-18, 11-30-18, 2-4-19, 2-22-19, 4-6-19, 5-9-19, 6-8-19, and 7-19-19 and all were closed in a timely manner.

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 site only conducts rework in the dry sausage area. The Refrigerated Rework Age Usage Limits procedure 6-4-19 includes the types of rework, personnel responsible, inspection of rework, age tracking, shelf life, percentage of rework, definition of rework, and documentation. The rework is tracked in SAP through the process.

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 Preshipment Records Review Procedures includes the information to be reviewed for each department, parameters, and the release of product in SAP. The Preshipment Record Review forms were reviewed for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed and signed. The release of materials is documented in SAP.

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 Smithfield Package Meat Pre-Operational Swabbing Program 3-13-19 includes the areas to be swabbed, frequency, timing of 12-5-18 swabbing, compliance rating, corrective actions, and documentation. The Environmental Monitoring RTE Lines & Areas procedure includes the target organisms, areas to be swabbed, frequency, use of a random generator for sample sites, types of swabs to be used, product contact surfaces, non-contact surfaces, tear down sampling, investigative sampling, corrective actions, and documentation. The Listeria spp. results for the Costco line were reviewed for October 2018, and January, April, and July 2019. The Corrective Action Record For Environmental Positive Incident forms were reviewed for 4-11-19 and 7-13-19 and the corrective actions were completed in a timely manner with retesting completed. The Product Pathogen Testing Policy 7-11-19 includes the personnel responsible, target organisms, types of products, control of the product, frequency, corrective actions, and documentation. The Pre-Operational Swabs were reviewed for the weeks of 10-7-18, 10-14-18, 1-6-19, 1-13-19, 4-7-19, 4-14-19, 7-7-19, and 7-21-19.

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 Validation and Validation Schedule includes the Program, Monitor Activity, Monitoring Frequency, Person Monitoring, Verification Activity, Verifier, Validation, Limits, Why, and Date Completed. The Quality Plan SQF Verification Validation Schedule includes the Program, Monitor Activity, Monitor Frequency, Person Monitoring, Verification Activity, Verify Frequency, Verifier, Validation, Limits, Why, Verification Date Completed, Validation Date Completed. The Verification for the Bacon Quality Plan CQP 1 was completed on 3-28-19, Verification for the Bacon Quality Plan CQP 3-8-19, Fully cooked and Fresh Sausage, Fermented Dry Sausage CQP 1 3-4-19. The Validation Activity Forms were reviewed for the Bacon CQP 5 on 8-2-19, 8-2-19, Bacon CQP 3 validation was completed on 8-2-19, and Bacon CQP-1 8-2-19. The Validations were completed for Pest Control 7-15-19, Personnel Practices 7-29-19, Personnel Processing Practices 7-29-19, Training 7-29-19, Calibration 7-15-19, supplier approval 7-15-19, HACCP 7-16-19, Bacon Chill 7-16-19, Bacon HACCP Plan 7-16-19, and Potable Water 7-15-19.

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 Validation and Validation Schedule includes the Program, Monitor Activity, Monitoring Frequency, Person Monitoring, Verification Activity, Verifier, Validation, Limits, Why, and Date Completed. The verifications are completed quarterly and the areas are changed. The verification of Pest Control was completed on 5-23-19, Personnel Practices on 6-28-19, Training on 6-27-19, Sanitation 6-7-19, Supplier Approval 6-28-19, and Bacon Chill on 6-24-19.

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 Corrective and Preventative Action Procedure 5-20-19 includes the personnel responsible, identification of the nonconformance, types of nonconformities, root cause analysis, forms used for tracking corrective actions, follow up for completion, and documentation. The Paperwork Deviation Report forms were reviewed from 4-10-19 and 4-12-19 and showed the deviation, corrective action, and preventive measures. During the audit the corrective actions were reviewed for the internal audits, consumer complaints, and nonconforming product and all were completed in a timely manner.

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 General Product Sampling, Inspection, and Analysis Procedure 5-22-19 includes the personnel responsible, frequency, use of standards methods, materials requiring sampling, finished product testing, and documentation. The site conducts proficiency testing for micro (once per year) 6-8-19 and chemical testing (4 times per year). The ISO certificates were available for the Smithfield Packaged Meats Corporate Laboratory for biological testing is valid to 4-30-20 The ISO certificate was available for Matrix Sciences International micro testing valid to 10-20-20. During the audit the records were reviewed for the Microwave Bacon Food Service Attributes Check form, The Net Weight Control for Food Service, The Precook Packaging Check Sheet forms, and the Microwave Bacon Label Audit form for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed, signed, and verified.

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

The internal Facility Audit procedure 1-17-18 includes the personnel responsible, use of GFSI audits annually, use of a cross functional team, identification of deficiencies, review of corrective actions, corporate audits, and documentation. The SQF Internal Auditor Schedule 2018-2019 includes the Clause, Subject, Month of review, and the personnel responsible. The SQF Internal Audit Forms include the areas reviewed, observations, non-conformances observed, 10-15-18, 11-21-18, 11-27-19, 1-3-19, 2-28-19, 4-24-19, 6-27-19, and 8-1-19. The QA group conducts daily walk through of the production and non-production zones for GMP's, equipment, product handling, trash removal, and hand washing and these were reviewed for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed, signed, and verified.

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

The facility labels the products with stickers created from SAP. The Product Identification and Product Trace Procedure 5-23-19 includes the personnel responsible, identification of materials at receipt, WIP, finished products, identification of lots during processing, finished product labeling, use of SAP for tracking, and documentation. The Microwave Bacon Label Audit forms are used to show the correct product is being placed in the correct packaging and these were reviewed for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed.

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 Product Identification and Product Trace Procedure 5-23-19 includes the personnel responsible, identification of materials at receipt, WIP, finished products, identification of lots during processing, finished product labeling, use of SAP for tracking, and documentation. During the audit the site completed a trace exercise on a finished product one step back to a raw material and one step forward to shipping. The finished product was a customer specific Ends & Pieces product which is packed 384 packages per combo with lot number 0110920564. The site produced 60 combos and showed they still had 16 combos in inventory and 44 combos shipped for a 100% recovery. The raw material selected for this product was the belly with item number 90070800717647. The site tracked the raw material back to at least 11 products and multiple lot codes showing the finished product came from 2,311,094 pounds which was also used for other products. The exercise was completed in < 4 hours.

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 Mock Recall Policy 3-29-19 includes the completion of two mock recalls, materials to be recalled, tracking of time, success rate, goals (within 4 hours minimum 99% recovery), corrective actions, and documentation. The Crisis Management & Continuity Planning procedure includes the use of a cross functional team for the tracking and recovery of product that may have an issue, communication, corporate team responsibilities, use of the corporate Crisis Manual, and documentation. The Smithfield Crisis Manual includes a section for the Recall Process which includes a flow chart for decision making, responsible personnel, location and control of product, risk assessments, record review, communication with outside agencies, notification of SQFI and the certification body, effectiveness checks, and documentation. The facility has not had a recall in the past year. The plant completed a mock recall on 4-11-19 on the 533 finished product cases of sliced bacon with item number 7525818709 and lot number 9064906464. The site showed 433 had shipped for 100% recovery and the exercise was completed in < 1 hour.

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 Food Defense Program includes the use of a cross functional team, use of a self assessment annually, use of background checks, perimeter control, control of access to the site, employee awareness training, product anti-tampering measures, securing of bulk ports, and technology security. The Food Defense Self-Assessment was completed on 1-22-19. The food defense team meeting was held on 8-1-19. The food defense plan was challenged on 5-16-18. During the audit the site was observed controlling access to the site through the use of security guards, a controlled perimeter, employee control, visitor sign in, truck driver sign in, and security cameras.

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

The Smithfield Corporate Food Safety/Quality Assurance food fraud 11-20-18 includes the use of a cross functional team, ingredients covered, questions reviewed, and the evaluation results. The Food Fraud Vulnerability Self-Assessment Report was completed on 5-22-19. The site did not have any high risk materials for food fraud due to the control of suppliers, programs, and regulatory guidelines.

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 is currently allergen free but conducts allergen training for employees. The site may conduct reboxing or slicing from sister facilities and a label check is conducted to ensure that allergens are not present. The Reboxed Product Allergen Check 6-3-13 includes the types of allergens, control of the batch number, corrective actions if the product contains allergens (place on hold, complete deviation procedure), and documentation. Three examples of the Reboxed Product Allergen Checklist form was reviewed for 8-1-19 and showed that no allergens were present, an incoming label, and the outgoing label and this was properly completed. The Allergen Control procedure is maintained at the site to ensure control of materials but the site does not currently handle any allergen containing materials.

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: COMPLIANT

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: COMPLIANT

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: COMPLIANT

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: COMPLIANT

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: COMPLIANT

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: COMPLIANT

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: COMPLIANT

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: COMPLIANT

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: COMPLIANT

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 or components.

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 or components.

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 or components.

2.8.3 Allergen Management for Manufacturers of Animal Feed

N/A: The facility does not produce any 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 produce any 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 produce any animal feed.

2.9.1 Training Requirements

The Food Safety and Quality Employees Training 6-4-19 procedure includes the personnel responsible, new hire training requirements, annual training requirements, job specific training, refresher training for updates, maintenance of training records, use of a training skills register, and documentation. The Food Safety & Quality Employee Training 1-10-18 includes the personnel responsible, types of training required, frequency, tracking of the completion of training, on the job training, and documentation.

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 second quarter GMP training was completed by 97% of the employees with a goal of 95%. The SQF training was completed during the first quarter of 2019. The training for GMP's is completed throughout the year with multiple topics each quarter. The Food Defense and HACCP training were completed at the plant during the third quarter of 2018. The Allergen training was completed during the first quarter of 2019.

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 site provides translations into other languages for procedures as needed.

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 personnel responsible for the monitoring of the CCP's was completed on 4-3-19.

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

The training and training materials are available in all four languages at the site (English, Spanish, Serbian, and Albanian).

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 provides refresher training annually for food safety and food quality topics and will provide it if employees do not understand the information.

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 HR group maintains training records for on the job training for job capabilities. The site conducts yearly refreshers for the specific jobs. The HACCP training is maintained in the food safety group and HR can run a list of all employees for the training records.

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

The facility is located in an industrial area of Cudahy, WI and the surrounding buildings do not pose a risk to the site. The plant produces product under the USDA establishment number of 28 and P-28.

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

The product contact and non-product contact surfaces were well maintained, smooth, and cleanable.

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

Minor: The floor in the injection room was observed with exposed aggregate in multiple areas and damaged epoxy. Comment: The floors in the other production and product storage areas were well maintained and properly designed for the drainage of water. The drains at the plant were in good condition and located in areas that are accessible for cleaning. N/A: The facility does not have a waste trap system.

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: MINOR

EVIDENCE: Minor: The floor in the injection room was observed with exposed aggregate in multiple areas and damaged epoxy.

ROOT CAUSE: The sanitation chemicals used nightly has damaged the epoxy over time in the S Pump Dept.

CORRECTIVE ACTION: The floor in the S Pump Dept. is scheduled for repair and will be completed by 10/31/19.

VERIFICATION OF CLOSEOUT: The quote and time line for the completion of the flooring improvements were reviewed and approved by Tiffany Bergman.

COMPLETION DATE: 10/31/2019 **CLOSEOUT DATE:** 09/02/2019

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: NOT APPLICABLE

EVIDENCE: N/A: The facility does not have a waste trap system.

11.2.3 Walls, Partitions, Floors and Ceilings

The walls throughout the production zones were in good condition and clean. The junctions between the floors and walls and walls and ceilings were smooth and cleanable. The overheads were well maintained and clean. The doors in the production and storage areas were clean and in good condition. N/A: The facility does not have any drop ceilings.

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: NOT APPLICABLE

EVIDENCE: N/A: The facility does not have any drop ceilings.

11.2.4 Stairs, Catwalks and Platforms

The stairs, catwalks, and platforms were well constructed and clean during the audit.

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

Minor: The Microwave Bacon Pack-off area was observed with at least 4 dirty light fixtures. An overhead light fixture was dirty in line 7 & 8 packaging area. The Pre-Press Cooler was observed with three dirty lights. The J-Pump Room had a broken and dirty light over the conveyor (no product risk). Comment: The lighting throughout the site was adequate for sanitation, pest control, and inspections.

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: MINOR

EVIDENCE: Minor: The Microwave Bacon Pack-off area was observed with at least 4 dirty light fixtures. An overhead light fixture was dirty in line 7 & 8 packaging area. The Pre-Press Cooler was observed with three dirty lights. The J-Pump Room had a broken and dirty light over the conveyor (no product risk).

ROOT CAUSE: Issue was brought to the attention of QA and Supervisors in Dept.

CORRECTIVE ACTION: The J Pump Room light cover was replaced during the SQF audit (repaired on 8/7/19). The Pre-Press Cooler light covers were replaced on 8/27/19. The Microwave Dept. light fixtures were cleaned on 8/10/19.

VERIFICATION OF CLOSEOUT: The photos of the replaced lighting were reviewed and approved by Tiffany Bergman.

COMPLETION DATE: 08/27/2019 **CLOSEOUT DATE:** 09/02/2019

11.2.6 Inspection / Quality Control Area

The areas designated for the inspection of product had good lighting, access to product bins, and hand washing.

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

The external windows and doors at the facility were properly sealed against dust and pests. The ILT's were located in areas that did not pose a threat to the product or equipment.

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

The facility had adequate ventilation for the removal of heat, cooling of product, and comfort of employees.

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

The plant maintains a Color Coded Utensil Policy 8-24-11 which shows the colors for Gloves, tools, shovels, utensils, and tubs and the various areas they are to be used. The Coat Usage Policy 7-13-13 includes the color coding for frocks worn by maintenance, RTE employees, electricians, and visitors/employees in non-RTE areas. The equipment at the facility was well designed for sanitation and inspections. The tables used in the production areas were well constructed and part of the inspection process during pre-op. The bins used for the handling of product and inedible were in good condition, well identified, and used properly. The clothing worn by employees was well constructed and did not pose a risk to the product. The company supplied hooks throughout the site for the storage of frocks when leaving the production areas.

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 Premises and Equipment Maintenance Procedure 8-2-18 includes the personnel responsible, use of scheduled maintenance, unplanned repairs, following of GMP's in the production zones, protection of product, cleaning of areas following repairs, and control of outside contractors. The facility uses SAP for tracking the preventative maintenance tasks and the maintenance team reviews the PM completion rates weekly to ensure they are completed. The maintenance personnel were observed following good GMP's when working in the production areas. The shop area was clean and uncluttered.

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 site maintains calibration procedure for the QA Thermometers and Scales which includes the use of national standards, parameters, corrective actions, and documentation. The calibration for the weights are due on 11-1-19 and 4-21-20. The reference thermometer is due for calibration on 10-25-19. Shipping Department IR thermometers due 10-25-19. Metal Detectors due 6-26-20. The Thermometer Calibration form included the microwave department, bacon smoke houses, and the receiving department and were reviewed for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed, signed, and verified.

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 uses Ecolab for pest control and the frequency of service is weekly for the interior and the exterior twice per month. The Scope of Service was signed on 1-3-19. The ILT bulbs were changed on 5-8-19. The pest control files include the PCO license 12-31-19, proof of insurance 12-31-19, and business license 12-31-19. The interior and exterior of the plant did not show any signs of pest activity at the time of the audit. The devices were properly placed and maintained. The service reports include the areas reviewed, action items, target pests, sanitation issues, material summary, and were signed by the PCO and a company representative. The service reports were reviewed for 2-6-19, 2-13-19, 3-20-19,3-22-19, 5-22-19, 5-29-19, 7-21-19, and 7-31-19. The corrective actions required for findings were noted and dated when completed. The SDS's are available on line for the Advion Cockroach Gel Bait, and Niban Granular Bait which has been used at the facility. The pest control map was available from 1-5-19. The trend reports were available through June 2019 and included the bait stations, insect light traps, and interior stations. The facility does not store any pest control chemicals on site.

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:** COMPLIANT
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:** COMPLIANT

11.2.13 Cleaning and Sanitation

The cleaning procedures were reviewed and updated on 11-13-18. The cleaning procedures were reviewed for the TI Stuffing & New Marlen Stuffer, Comb Pullers, Dumpers, Slice Stackers, and Metal Detectors and each included the Pre-Cleaning Activities, safety, physical tasks, chemicals required, chemical quantity, cleaning equipment, inspection, and sanitizing. The procedures provided photo guidelines and detailed instructions. The Master Sanitation Schedules include the Areas for cleaning, Frequency, date completed, and verification. These were reviewed for the fourth quarter of 2018, the first and second quarter and the third quarter WTD 2019 and all were signed and verified. N/A: The facility does not conduct any CIP cleaning. The Pre-Operational Sanitation Reports were reviewed for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed, signed, and verified. The personnel conducting the inspections were well trained and were very thorough in their inspections. The staff amenities are monitored as part of the janitor position and the Shift Plant Services Janitor Daily Check List forms are used for documentation. These were reviewed for various areas for the months of July and August MTD and all were properly completed, signed, and verified. The effectiveness of cleaning is monitored through the APC results and visual inspections during pre-op. The Pre-Operational Swabs were reviewed for the weeks of 10-7-18, 10-14-18, 1-6-19, 1-13-19, 4-7-19, 4-14-19, 7-7-19, and 7-21-19. The Chemical & Sanitizer Titration Log forms include the Date, Day, Checked Area, Chemical Tested, and Initials. These were reviewed for December 2018 through July 2019 and all were properly completed and signed. The Chemical Label Training was completed on 6-7-19, Chemical Safety training 12-21-18 and GMP training was completed on 9-28-18. The SDS's were available for the Questar CAF and the Rub-Out cleaning chemicals which have been used at the facility.

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 conduct any CIP cleaning.

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 personnel at the facility were not observed suffering from any infectious disease or with any open wounds. The employees were eating, smoking, and drinking only in the designated areas of the plant at the time of the audit.

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

The hand washing areas were well maintained and had sinks that were cleanable, warm water, paper towels, liquid soap, trash bins, and sanitizers. The personnel at the site were observed changing their gloves as needed and using sanitizers.

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 clothing and frocks worn in the production areas were constructed of materials that did not pose a risk to the product. The employees were in clean clothing and frocks and if they became soiled they would change into a new clean one.

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 employees in the production areas were not observed wearing any jewelry at the time of the audit.

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

The visitors to the facility are required to show identification and sign in at the guard shack as well as sign in when they enter the offices. The visitors must review and sign the Smithfield safety and GMP guidelines and are escorted at all times. The visitors must follow all GMP requirements when working in the production zones.

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

The staff amenities at the plant had good lighting and ventilation during the audit.

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

The locker rooms at the facility were located away from the production areas and had good lighting, were well maintained, and clean. The site provides employee lockers for the storage of personal items.

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: COMPLIANT

11.3.8 Laundry

The facility uses Aramark for supplying and laundering of frocks and uniforms and a copy of their HACCP plan was available for review during the audit.

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

The restrooms at the facility were located away from the production zones and were properly sized for the site. The areas had properly stocked hand washing areas and signs to remind personnel to wash their hands. The restrooms were clean at the time of the audit. The sanitary drainage is separate from the other drainage.

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 areas were well sized and located away from the production zones. The areas had lunch storage areas, refrigerators, microwaves, and a sink. The areas were clean and in good condition.

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

Minor: The hooks used for the storage of frocks for employees leaving the packaging area for lines 5 & 6 were observed with gloves stored on top of them. The two hose ends in the employee frocking area before lines 5 & 6 were observed to be stored directly on the floor. In the slicing area a white bin labeled for edible product had two sticker guns and labels stored in it. The table in the press room identified for edible was observed with rubber gloves being stored on it. Comment: The site conducts all sensory away from the production lines.

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: MINOR

EVIDENCE: Minor: The hooks used for the storage of frocks for employees leaving the packaging area for lines 5 & 6 were observed with gloves stored on top of them. The two hose ends in the employee frocking area before lines 5 & 6 were observed to be stored directly on the floor. In the slicing area a white bin labeled for edible product had two sticker guns and labels stored in it. The table in the press room identified for edible was observed with rubber gloves being stored on it.

ROOT CAUSE: Issue was brought to the attention of QA and Supervisors in Dept.

CORRECTIVE ACTION: The rubber gloves stored on the press room table were removed and the table was washed/sanitized when identified during the audit. Verbal retraining for the deficiencies was completed for all departments involved.

VERIFICATION OF CLOSEOUT: The training, cleaning, and review of the area were reviewed and approved by Tiffany Bergman.

COMPLETION DATE: 08/21/2019 **CLOSEOUT DATE:** 09/02/2019

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: COMPLIANT

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 receives water from the City of Cudahy, WI. The site has adequate supplies of hot and cold water for sanitation and production. The backflow devices were tested on 4-10-19. N/A: The facility does not store any water on site.

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: COMPLIANT

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 store any water on site.

11.5.2 Water Treatment

The facility tests the incoming water and the maintenance utility group is responsible for the monitoring of the incoming water and will add chlorine only as needed.

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

The ice is received from an approved vendor.

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: COMPLIANT

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: COMPLIANT

11.5.4 Monitoring Water Microbiology and Quality

The facility receives water from the City of Cudahy, WI. The water potability testing was completed on 12-13-18 and 6-26-19 using reference methods. The water is also tested at the site weekly for HPC and Coliforms and the results were available from 10-10-18, 2-6-19, and 3-8-19. The ice is not tested as it is received from an approved vendor.

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 Air Sampling (TPC) results were reviewed for 10-24-18, 12-12-18, 2-22-19, 4-16-19, and 6-27-19. The Compressed Air testing (TPC and Yeast & Mold) were reviewed for 10-14-18, 1-10-19, 4-11-19, 7-11-19, and 8-1-19.

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 was observed storing materials properly to ensure correct temperatures and conditions were met. The site tracks the aging of materials and uses physical inventories to ensure materials are used FIFO. N/A: The facility does not require any overflow or temporary storage.

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 require any overflow or temporary storage.

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 require any overflow or temporary storage.

11.6.2 Cold Storage, Freezing and Chilling of Foods

The freezers and coolers was in good condition and clean during the audit. The discharge from the cooling units was well controlled. The facility has sufficient refrigeration capacity for cooling and storage of products. The facility has established temperature requirements for all areas of the site and the utilities group is responsible for the monitoring of the temperatures. The utilities group is on site 24/7.

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

The areas designated for the storage of dry goods and packaging were located away from the wet areas, well maintained, and clean. The racking in the areas was designed and located for cleaning, pest control, and inspection.

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

The chemical storage area was located away from the product storage and production areas. The area was secured and well identified. The areas were not used to store any production or product contact utensils or equipment. The plant used containment pallets for safety. The daily supplies of chemicals used in the production zones were well identified and stored properly. The facility does not store any pest control chemicals on site.

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

The Transportation Policy 6-20-18 includes the personnel responsible, cleanliness of vehicles, condition, bulk tankers must provide wash tags, refrigeration units, disposition of product if the specifications are not met, use of security seals, temperature requirements, maintenance of temperature during transport, and documentation. The personnel responsible for the handling of goods were observed protecting the product and ensuring the correct temperatures were maintained.

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 Cover Sheet for Departing Loads includes the condition of the trailers, temperatures, pallet review, seal number, and trailer information. These were reviewed for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19.

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

The Transportation Policy 6-20-18 includes the personnel responsible, cleanliness of vehicles, condition, bulk tankers must provide wash tags, refrigeration units, disposition of product if the specifications are not met, use of security seals, temperature requirements, maintenance of temperature during transport, and documentation. The site ensures the reefer temperatures are set properly before the trailer is loaded and checks the product temperatures as it is loaded.

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 Non-Meat Receiving Policy 12-23-13 includes the personnel responsible, trailer seal inspection, inspection of the trailer, product review, allergen identification, chemical storage, use of FIFO storage, product security, ingredient names for allergen categories, and documentation. The receiving Loading/Unloading Log forms were reviewed for 2-26-19, 2-25-19, 4-5-19, 7-31-19, and 8-6-19 and all were properly completed.

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

The process flow at the site was well designed to prevent cross contamination between the raw and cooked side as well as other areas.

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

The dry materials are received separate from the temperature controlled materials to prevent any issues.

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 any materials.

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 any materials.

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 any materials.

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 any materials.

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 any materials.

11.7.4 High Risk Processes

The facility controlled access to the various areas of the plant through the use of physical boundaries and employee traffic areas. The personnel at the site are assigned specific areas and must wear a color coded frock for identification. The plant used signage for employee guidance and provided hand washing areas before all product handling areas.

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 Foreign Material Control Policy 6-4-19 includes the use of a cross functional committee, review of areas for potential risks, employee awareness and training, reduce or eliminate loose objects, visual inspection of product, use of screens, metal detectors, glass/brittle plastic control, use of a glass register, inspections, detector standards, frequency of checks, corrective actions if issues are found, review of rejected product, product control if issues are found, corrective action guidelines, and documentation. The Operational/GMP Sanitation Report forms are used for the review of areas for potential foreign material and these were reviewed for 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed, signed, and verified. The pallets used in the areas were in good condition and clean. The Glass/Brittle Plastic Audit Report Check Sheets are completed monthly for each department and were reviewed for all of 2019 and were properly completed.

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: COMPLIANT

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 Magnet Collection Log forms are completed hourly and reviewed for 7-3-19, 7-16-19, and 7-24-19 and were properly completed. The X-ray forms were reviewed for 1-9-19, 1-15-19, 1-17-19, 3-13-19, 3-14-19, 3-25-19, 7-9-19, 7-30-19, and 7-31-19 and all were properly completed, signed, and verified. The Metal Detector Log forms were reviewed for 10-8-18, 10-9-18, 10-10-18, 1-8-19, 1-9-19, 1-10-19, 4-8-19, 4-9-19, 4-10-19, 7-8-19, 7-9-19, and 7-10-19 and all were properly completed, signed, and verified.

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

The foreign materials incident reports were reviewed for 1-29-19, 8-2-19, and 8-3-19 and included the deviation, product control, investigation, and corrective actions.

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 laboratory is located away from the production areas and designated as a restricted area. The lab does not create any laboratory waste that requires special handling.

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

The Waste Management and Disposal Procedure 7-6-13 includes the personnel responsible, regular removal of trash, cleaning of the waste accumulation areas, use of denaturant, recycling, and following of the Environmental Affairs Guidelines. The waste throughout the site was removed in a timely manner and no build up was observed. The waste storage areas were located away from the production zones. The carts and barrels used for the storage of waste were in good condition and clean during the audit.

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 building was observed to be in good condition. The grounds were well maintained and did not provide pest harborage. The roads and sidewalks were sealed.
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:** COMPLIANT
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