AUDIT REPORT

Fresh Beef E. coli O157:H7 Addendum

for:

Sam Kane Beef Processors: Corpus Christi, TX

Report Date
March 20, 2018

Audit by
Greg Sherman

Merieux NutriSciences Certification LLC

I. Interventions for Pathogen Reduction

Interventions for Pathogen Reduction	Rating
1. E. coli O157:H7 is a hazard likely to occur in the facility's HACCP plan.	Yes
2. Facility uses one or more recognized microbiological intervention technologies in its process. Acceptable technologies include steam pasteurization, hot water pasteurization, organic acid rinses, steam vacuums, or antimicrobial treatments.	Yes
3. List all microbiological interventions and pathogen reduction processing aids. Include both slaughter and fabrication related interventions that are applied. Additionally, facility must have at least one of the interventions designated as a Critical Control Point (CCP) in its HACCP plan to address E. coli O157:H7. Document what the facility is monitoring (ex. concentration, temperature, dwell time) for each intervention and identify which interventions are CCPs.	Yes
4. Any microbiological intervention technology designated as a CCP has been validated against E. coli O157:H7. Validation studies (may be a 3rd party challenge study, journal paper, in-house study, etc.) are on file. List validation materials and date of validation. [Note - If not thermal (steam or hot water), intervention must be validated and demonstrated as equal or better to thermal systems for microbial-pathogen reduction. Validation materials must be provided to support equivalency or reduction capabilities.]	Yes
5. List all ongoing verification programs for microbiological interventions and pathogen reduction processing aids. (Auditor to list in Comments in section below)	
6. Does facility have a direct product treatment intervention on trim prior to N60 sampling?	Yes

Possible Points	**0**
Actual Points	**0**
Percentage	

Comments

1 Comment: The hazard analysis includes both E. coli O157:H7 and non-O157 STEC as hazards reasonable likely to occur in the slaughter, boning and grinding processes.

2 Comment: The slaughter process describes a sequential application of chlorine as a hide-on wash, an acidified sodium chlorite (ASC) pre-evisceration wash, and post inspection hot water and lactic acid applications. The boning process utilizes ASC and lactic acid as antimicrobial applications.

3 Comment: In the slaughter process, the facility monitors psi and water temperature at the hot water pasteurization CCP, water temperature, psi and lactic acid concentration for the lactic acid CCP, and 10 carcasses and 20 pieces of variety meats (head meat, cheek meat and hearts) every hour for zero tolerance CCP.
The same parameters for ASC and Lactic Acid are monitored on the processing side.

4 Comment: Initial validation studies were performed by IEH labs for all antimicrobials and processing aids. Validation studies are conducted annually based on trending from the ongoing verification database. The company samples every combo of trim as well as finished ground beef for the identified biological hazards. The finished product sampling serves as ongoing verification of the antimicrobial intervention.

5 Comment: The company samples every combo of trim as well as finished ground beef for the identified biological hazards. The finished product sampling serves as ongoing verification of the antimicrobial intervention.

6 Comment: There is a lactic acid application on the beef trim line.

II. Sampling Programs for Components Destined for Raw Ground

Sampling Programs for Components Destined for Raw Ground	Rating
1. A minimum of N=60 testing per lot for E. coli O157:H7 is performed on all beef trim and other raw beef components [i.e., head meat, hearts, etc.] produced in the plant that are 'intended for raw ground use'. Sampling programs must be written and supported with validation data and documentation. Related documents shall be available for review upon request.	Yes
1.1. Facility produces combo trim? Written sampling program in place for combo trim?	Yes
1.2. Facility produces box trim? Written sampling program in place for box trim?	Yes
1.3. Facility produces FTB, BLBT, LTB, AMR? Written sampling program in place for FTB, BLBT, LTB, AMR?	
1.4. Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc)? Written sampling program in place for other raw beef components?	Yes
2. Sampling program is demonstrated and validated as robust and rigorous and is equivalent or better to the N=60 'best practice' program for 95% or better statistical confidence. If not N=60, describe sampling process and list N value in Comments.	Yes
3. Sampling program specifics [Note- Auditor should distinguish differences, where applicable, in sampling programs. For example, combo trim programs may differ from FTB programs]:	
3.1. How are the samples collected? [For example, traditional excision, modified excision or mechanical. NOTE- Traditional excision is defined as the USDA sampling method.] (Auditor to list in Comments in section below).	
3.2. If procedure is modified from traditional excision, is there validation documentation?	Yes
3.3. Does the facility verify sample counts? List the frequency in Comments (ex. X times by plant per week, X times by lab per week).	Yes
3.4. Does the facility check sample weights? Describe the process and list the frequency in Comments. List sample weight minimum, maximum, and target.	Yes
3.5. Does sampling program target, where possible, surface tissue over internal tissue?	Yes
3.6. Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces? Does the sampling program account for exceptions for extremely large pieces of product where it may not be possible to sample individual pieces (2 piece-chucks, goosenecks)? Describe exception.	Yes
3.7. Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	Yes
3.8. Auditor should observe sample collection and report accuracy against specified method. (Auditor to list in Comments in section below).	
4. Employees performing sampling programs are trained to complete sampling tasks? Is training documented?	Yes
5. Lotting methods and lot sizes are defined and designed to cover all 'intended for raw ground' meat components produced in plant. Lotting programs must be supported with documentation. List lot size(s) for the following [lot size may be in pounds, combos, pallets, boxes, etc., list most accurate description]: (a)Combo trim (b)Box trim (c)FTB, BLBT, LTB (d)Other raw beef components	Yes

II. Sampling Programs for Components Destined for Raw Ground

Possible Points	**0**
Actual Points	**0**
Percentage	

Comments

1 Comment: Combos of beef trim are sampled either via the IEH core sampler or by traditional excision sampling, depending on the customer request. Both methods meet N=60 criteria. Excision sampling is also used to sample head meat, cheek meat and hearts. There are written sampling programs that provide direction for sampling.

1.1 Comment: The facility does produce, and sample combo beef trim. Typically each combo is an individual lot.

1.2 Comment: The company does product box trim for specific customers. Sampling is per N=60 excision sampling.

1.3 N/A: The company does not have these processes.

1.4 Comment: There is a written sampling program for head meat, cheek meat and hearts. Sampling is by excision and meets N=60 standards.

2 Comment: Combo beef trim is typically sampled with the IEH core drill, which has been validated as meeting N=60 standards. All other beef sampling is by knife excision per N=60 guidelines.

3.2 Comment: Beef trim combos are sampled with the IEH core sampler. The combo is drilled in the center and in each of the four corners. The IEH core sampler has been validated to achieve N=60 equivalence

3.3 Comment: The core drill does not provide discrete pieces, but weight is monitored. Excision samples have the sample count verified for each production lot.

3.4 Comment: The facility does collect sample weights. The target weight for the IEH core drill is 150g. The sample that the auditor observed was 195g.

3.5 Comment: Excision sampling targets surface tissue. The core drill is validated as preferentially sampling surface tissue.

3.6 Comment: The written program emphasizes collecting only one sample per piece of surface tissue.

3.7 Comment: Every combo is an individual production lot.

3.8 Comment: The auditor observed an employee collect a sample of combo beef trim. The employee was able to explain each step in detail and easily answered all questions.

4 Comment: All employees tasked with sampling are extensively trained, both in writing as well as ojt, until proficient. Training was conducted most recently 2/19/18

5 Comment: Beef trim combos are individual production lots, but up to five combos may be composited.

III. Verification Testing / Check Sample Program

Verification Testing / Check Sample Program

	Rating
1. As an ongoing verification/check of the sampling and testing procedures in the plant, the facility conducts quarterly verification/check samples of N=60 tested trimmings by subjecting a negative tested 'lot' to grinding and subsequent finished product testing. [NOTE - If the facility wishes to take the verification sample prior to the receipt of the initial ECH7 lab results, this is permissible to save time. However, the facility must confirm that the initial N=60 sample is negative, and if the results are not negative, a new verification sample must be taken. Further, the verification sample is required to be taken from finished (ground) product. If there are variances from this in the facility's protocol, customers must be notified.]	Yes
2. Verification/check sampling and testing are increased to a monthly frequency for 2nd and 3rd quarters (April - September). Auditor is to list the dates of the last 3 quarters verification/check samples in the comments section.	Yes
3. N60 verification/check samples shall be observed by an independent 3rd party auditor minimally 1x/year, and lab testing shall be conducted at a 3rd party lab minimally 1x/year. [NOTE- At least one of the 3rd party observations shall occur between April-September of the calendar year. Results are to be reported directly to customer (as requested). Additionally, if the facility utilizes a 3rd party lab, the observation sample does not need to go to a different lab.] (Auditor to list in Comments in section below).	Yes
3.1. Is aseptic technique being followed?	Yes
3.2. Where possible, is surface tissue being targeted over internal tissue?	Yes
3.3. Are the excision sub-samples being collected from distinctly different pieces?	
3.4. What is the piece count of the final sample? (Auditor to list in Comments in section below).	
3.5. What is the weight of the final sample? (Auditor to list in Comments in section below).	

Possible Points	**0**
Actual Points	**0**
Percentage	

III. Verification Testing / Check Sample Program

Comments

1 Comment: The company collects verification samples from production lots that have previously tested negative for pathogenic E. coli

2 Comment: Verification samples are collected weekly and tested for E. coli O157:H7; non-O157 STEC samples are collected quarterly. The frequency of the latter is increased to monthly from April thru October.

3 Comment: The auditor observed sample collection with the core drill. Aseptic techniques were correctly followed, and the employee was able to explain each step in the collection and sample preparation procedures to the auditor.

3.2 Comment: The IEH core drill is validated to preferentially collect surface tissues.

3.3 N/A: There was no excision sampling conducted at the time of the observation period.

3.4 N/A: The IEH core drill does not provide discrete pieces.

3.5 Comment: The target weight is at least 150g, and the collected sample weighed 195g.

IV. Testing Laboratory

Testing Laboratory

	Rating
1. The laboratory must be operated under a Quality System that supports the chosen ECH7 method, which, at a minimum includes validation of employee training, sample traceability, timely transmission of COA's, and recordkeeping. Evidence of compliance is either accreditation or auditing by an independent 3rd party. A Quality System that meets ISO 17025 is acceptable. Validation documents shall be provided upon request. (a)List Lab Name & Location (b)List Accreditation and/or 3rd Party Auditor & date.	Yes
2. If the testing for E. coli O157:H7 is on-site, the laboratory is physically isolated from production areas. Controls to prevent pathogen contamination are in place. There is a program for running positive controls/cultures with documented records for all analyses.	Yes
3. Internal/External laboratory participates in a proficiency testing program to assure accuracy of its results. Records are available for review. List proficiency program.	Yes

Possible Points	**0**
Actual Points	**0**
Percentage	

Comments

1 Comment: The company uses the IEH lab that is in a trailer on site. IEH is accredited to ISO 17025:2005 by ANAB, dated 2/2/18 with expiration 1/4/20

2 Comment: The lab is located on site in a trailer adjacent but separate from the facility itself.

3 Comment: The IEH lab is evaluated annually for proficiency by the American Proficiency Institute.

V. Lab Methods

Lab Methods

	Rating
1. All sampled slices from a 'lot' shall be enriched and tested. Sampled pieces shall be enriched as intact slices [massaged], and not ground in the enrichment sample. (a)If "wet" compositing is being used, list what an enrichment represents (EXAMPLES: N=15 per combo for 5 combos; N=60 per combo; 9 minute ground beef sample). (b)If "wet" compositing is being used, list the number of enrichments that make up the "wet" composite (EXAMPLE: If N=60 per combo completed on 5 different combos, each N=60 is enriched, each of the enrichments are used to make up one "wet" composite, then the answer would be 5).	Yes
2. Rapid screen method is either (a) PCR DNA amplification, or (b) ELISA-based tests, which is capable of detecting known pathogenic strains of E. coli O157:H7 [including Cluster A strains]. For the following, please note if methodologies differ based on product types (ex. trim testing has different enrich time versus ground product): (a)Document all methods being used by facility. (b)Document incubation time, temperature and dilution factor. (c)If method includes "wet" compositing, is the method validated?	Yes
3. Product disposition: (a)Presumptive positives are deemed positive if not culturally confirmed. (b)Product disposition is determined on presumptive positives. (If "wet" compositing is being used, describe how product disposition is determined on a presumptive positive.) (c)Confirmation capability of the lab is validated. (d)Facility has an Event Day (or Multiple Positive Day) program outlining procedures and corrective actions in the event that multiple presumptive positives are detected in one production day.	Yes

Possible Points	**0**
Actual Points	**0**
Percentage	

Comments

1 Comment: Beef trim samples collected with the IEH core drill are enriched as composite samples. Samples collected by knife excision are enriched individually.

2 Comment: The screening method MB 217.01 is a rapid PCR test. The methodology describes the enrichment process as 8-48 hours at 42 degrees C.

3 Comment: Disposition is based on laboratory confirmed positive analysis results. The company has a written Event Day Program.

VI. Certificate of Analysis

Certificate of Analysis

	Rating
1. [Note - Auditor shall review a Certificate of Analysis to confirm the presence, or record the absence, of the items listed below. This document may also be identified under a different name, Certificate of Conformance, Analytical Results, Laboratory Report, Testing Declaration, etc.]	
2. Product produced as 'intended for raw ground use' is accompanied with a Certificate of Analysis [COA] showing a negative result for each tested 'lot', at or before time of receiving. COA identifies the 'lots' covered by the test results, and is applicable to all product received in a shipment or order.	Yes
3. All laboratory results are subject to a minimum of a dual review and approval process.	Yes
4. Each Certificate of Analysis has its own unique number or identifier. *COA's that are revised indicate a revision date, revision reason and are traceable to the original COA.	Yes
5. The document clearly identifies that it is a Certificate of Analysis. List identifier.	Yes
6. The type of test and testing method used are listed on the Certificate of Analysis.	Yes

Possible Points	**0**
Actual Points	**0**
Percentage	

Comments

1 Comment: Each COA is lot specific. While the COA may have sample results for multiple lots, each lot has a unique identifier and is a stand-alone production lot.

4 Comment: There is a unique identifier for each production lot listed on the COA

5 Comment: The certificate is identified as a Certificate of Analysis (COA)

6 Comment: The COA lists the methodology as AOAC 100701 MB 217.01, which is the rapid screen test based on PCR analysis.