AUDIT REPORT

Fresh Beef E. coli O157:H7 Addendum

for:

STX Beef Company, LLC: Corpus Christi, TX

Report Date
July 09, 2019

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	

I. Interventions for Pathogen Reduction

Comments

1 Comment: The company currently has HACCP processes for beef slaughter, boning and grinding. The grinding process is archived, as no grinding has been done since the plant re-opened following ownership change. Both E. coli O157:H7 and non-O157 STEC are identified as hazards in all HACCP processes.

2 Comment: The company utilizes antimicrobial interventions in both active HACCP processes, as CCPs and as processing aids.

3 Comment: The company uses the following antimicrobials:

Slaughter Process
Chlorine is applied in the hide-on carcass wash. Acidified Sodium Chlorite (ASC) is applied at a 2% concentration in the pre-evisceration carcass wash, and Lactic Acid is applied as a CCP at 2% following a hot water carcass wash. The company monitors the concentration and temperature (135 degrees) for lactic acid.

Boning Process
The company applies 2% lactic acid as a spray on each boning belt, including on the trim belt prior to combo filling. Lactic acid is applied as a processing aid in the boning process.

4 Comment: IEH labs performed the initial validation of lactic acid, and re-validates the efficacy annually. Validation of processing aids is provided by scientific studies. Ongoing verification is provided by combo trim sampling.

5 Comment: In addition to the direct observation and record review verification procedures that are regulatory requirements, the company performs N=60 sampling of each combo of trim. When the grinding operations resume, finished ground product sampling will provide an additional verification.

6 Comment: There is a lactic acid spray on the trim belt prior to combo filling.

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

1.1 Comment: The company performs N=60 sampling on each lot of combo trim. There is a written program that describes sampling using the IEH core drill.

1.2 Comment: The company produces limited amounts of box trim for specific customers.

1.3 N/A: The company does not have any AMR capabilities.

1.4 Comment: The company does not currently produce head meat, cheek meat or hearts for grinding. This may change when the grinding process is resumed.

2 Comment: The IEH core drill has been validated as meeting N=60 efficacy. Box trim is sampled by knife excision per N=60 guidelines.

3.1 Comment: Beef trim combos are sampled with the IEH core drill, while box trim is sampled by knife excision.

3.3 Comment: Sample counts are verified for box trim sampling. The core drill does not produce discrete pieces.

3.4 Comment: The company checks sample weights for each sample collected.
For the IEH core drill, sample weights are 150-200g, and for knife excision the sample weight is at least 375g
The auditor observed sample collection using the IEH core drill. The sample weight was 170g

3.5 Comment: The IEH core drill has been validated as selectively collecting surface tissue.

3.6 Comment: Knife excision samples are collected from individual pieces.

3.7 Comment: There are no fast or slow fill combos.

3.8 Comment: The auditor observed sample collection using the IEH core drill. The employee explained and demonstrated core drill sanitizing prior to collection, sampling in five different areas of the combo, aseptic transfer of the sample to the bag and weighing of the sample. The program was followed precisely as written.

5 Comment: The majority of trim lotting is one combo per lot, but for some customers up to five combos constitute a lot. Typically all box trim is one lot, as boxes are produced infrequently for a specific customer and fill less than one pallet.

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 a verification sample by grinding beef from a previously sampled negative lot monthly for verification sampling. The frequency is doubled during the high prevalence season from April through October.

3 Comment: The auditor provided 3rd party verification of sampling procedures during this audit.

3.1 Comment: The company employee explained and demonstrated how aseptic technique was followed.

3.2 Comment: The auditor observed sampling with the IEH core drill, which has been validated to preferentially select surface tissue.

3.3 N/A: The auditor did not observe knife excision sampling.

3.4 N/A: There are no discrete pieces with core drill sampling.

3.5 Comment: The weight of the finished sample was 170g. The target weight for N=60 sampling with the core drill is 150-200g

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 IEH lab located in a separate trailer on site at the plant. The lab is accredited against ISO 17025:2005 standards by ANAB with expiration 11/15/19

2 Comment: The lab is in a separate trailer on site.

3 Comment: The lab receives annual proficiency testing by API

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: IEH core drill samples are enriched as a composite sample. Knife excision samples are enriched individually.

2 Comment: The screening method MB 217.01 is a rapid PCR test, following AOAC 100701 protocol. The methodology describes the enrichment process as 8-48 hours at 42 degrees C.

3 Comment: Positive samples are confirmed at the lab.

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: The auditor reviewed COAs from IEH from the first week of July 2019.

2 Comment: Each lot sampled is identified on the COA and showed negative sample results.

3 Comment: There is review of each COA prior to release of sampled trim.

4 Comment: There is a unique number for each COA for each lot.

5 Comment: The document is identified as a Certificate of Analysis.

6 Comment: Each COA identifies the MB 217.01 screening method, which is a rapid PCR.