

Fresh Beef E. coli O157:H7 Addendum

for:

**Sam Kane Beef Processors: Corpus
Christi, TX**

**Report Date
September 25, 2009**

**Audit by
Stacy Bartlett**

Silliker, Inc.

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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?	No

Possible Points **0**

Actual Points **0**

Percentage

Comments

- 2** NOTE: This facility uses hot water cabinet carcass rinse (at ≥ 190) and Lactic Acid cabinet carcass application (at 3-5% lactic acid concentration), with both applied in a carcass rinse application cabinet. Both of these interventions have been validated, on a daily basis, with documentation available for review. In addition, prior to hide removal all carcasses go through a hide-on chlorinated (at 200 ppms) water wash cabinet.
- 3** NOTE: This facility applies Acidified Sodium Chlorite (800-900 ppms) to all carcasses, at pre-evisceration, and all applied to all carcass sides at pre-fabrication.
- 4** NOTE: CCP 2 (B) - Hot water carcass rinse at ≥ 190 degrees CCP 3 (B) - Lactic Acid Rinse at 2-5% Microbial Populations on Animal Hides and Beef Carcasses at Different Stages of Slaughter in Plants Employing Multiple-Sequential Interventions for Decontamination, R.T. Bacon, K.E. Belk, J.N. Sofos, R.P. Clayton, J.O Reagan, and G.C. Smith, Journal of Food Protection, Vol. 63 No, 2000, pp 1080-1086. Evaluation Of A Steam Pasteurization Process In A Commercial Beef Processing Facility, Nutsch, Phebus, Riemann, Schafer, Boyer, Wilson, Leising, and Kastner, Journal of Food Protection, Vol. 60 No, 1997, pp 485 Comparison of Methods for Contamination Removal from Beef Carcass Surfaces, M.D. Hardin, G.R. Acuff, L.M. Lucia, J.S. Oman, and J.W. Savell, Journal of Food Protection, V Hot Water and Organic Acid Interventions to Control Microbiological Contamination on Hog Carcasses during Processing, Luisa Eggenberger-Solorzano, S.E. Niebuhr, G.R. Acuff, and J.S. Dickson, Journal of Food Protection, Vol. 65 No, 2002, p 1248. ol. 58 No, 1995, pp 368-374.
- 5** N/A comment: See comments below.

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** NOTE: This facility conducts N60 sampling on each lot number, which can be 60 total samples form one combo, if the lot number is assigned to just one combo, or up to 5 combos. Sampling method is conducted by the mechanized/drill IEH N60 plus sampler tool.
- 1.1** NOTE: This facility conducts N60 sampling on each lot number, which can be 60 total samples form one combo, if the lot number is assigned to just one combo, or up to 5 combos. Sampling method is conducted by the mechanized/drill IEH N60 plus sampler tool.
- 1.2** NOTE: This uses traditional excision, for collecting N60 samples from box trim and boxed hearts.
- 1.3** N/A comment: There are to FTB, BLBT, LTB or AMR processed at this facility.
- 1.4** NOTE: Just boxed hearts, no head meat. This uses traditional excision, for collecting N60 samples from box trim and boxed hearts.
- 2** NOTE: This facility conducts N60 sampling on each lot number, which can be 60 total samples form one combo, if the lot number is assigned to just one combo, or up to 5 combos. Sampling method is conducted by the mechanized/drill IEH N60 plus sampler tool. NOTE: A full drill head of samples, is equal to 200 cm³ per combo.
- 3** NOTE: This facility conducts N60 sampling on each lot number, which can be 60 total samples form one combo, if the lot number is assigned to just one combo, or up to 5 combos. Sampling method is conducted by the mechanized/drill IEH N60 plus sampler tool. NOTE: A full drill head of samples, is equal to 200 cm³ per combo, with every combo having a 200 cm³ sample taken with the IEH N60 tool.
- 3.1** N/A comment: See comment below.
- 3.2** NOTE: This facility conducts N60 sampling on each lot number, which can be 60 total samples form one combo, if the lot number is assigned to just one combo, or up to 5 combos. Sampling method is conducted by the mechanized/drill IEH N60 plus sampler tool. NOTE: A full drill head of samples, is equal to 200 cm³ per combo. NOTE: With sampling validations checks being documented every 2 hours.
- 3.3** NOTE: With sampling validations checks being documented every 2 hours.
- 3.4** NOTE: With sampling validations checks being documented every 2 hours.
- 3.6** NOTE: This facility conducts N60 sampling on each lot number, which can be 60 total samples form one combo, if the lot number is assigned to just one combo, or up to 5 combos. Sampling method is conducted by the mechanized/drill IEH N60 plus sampler tool. NOTE: A full drill head of samples, is equal to 200 cm³ per combo. NOTE: With sampling validations checks being documented every 2 hours.
- 3.8** N/A comment: See comments below.

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 NOTE: Daily validations are conducted on a daily basis, since this facility has an on-site ground beef operation, which only uses internal beef trim .
- 2 NOTE: Daily validations are conducted on a daily basis, since this facility has an on-site ground beef operation, which only uses internal beef trim .
- 3 NOTE: Daily validations are conducted on a daily basis, since this facility has an on-site ground beef operation, which only uses internal beef trim .
- 3.2 NOTE: A full drill head of samples, is equal to 200 cm³ per combo, with every combo having a 200 cm³ sample taken with the IEH N60 tool.
- 3.3 N/A comment: No excision samples are taken on beef trim.
- 3.4 NOTE: A full drill head of samples, is equal to 200 cm³ per combo, with every combo having a 200 cm³ sample taken with the IEH N60 tool.
- 3.5 NOTE: A full drill head of samples, is equal to 200 cm³ per combo, with every combo having a 200 cm³ sample taken with the IEH N60 tool.

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 NOTE: This facility has an on-site, segregated IEH laboratory, which is a pilot laboratory of IEH Laboratories; Colorado. This laboratory is A2LA certified for ISO-17025, in 2009. and API proficiency tests have been conducted in 2009, with results available for review.
- 2 NOTE: This facility has an on-site, segregated IEH laboratory, which is a pilot laboratory of IEH Laboratories; Colorado. This laboratory is A2LA certified for ISO-17025, in 2009. and API proficiency tests have been conducted in 2009, with results available for review. And, control positives are being used by the on-site laboratory.
- 3 NOTE: This facility has an on-site, segregated IEH laboratory, which is a pilot laboratory of IEH Laboratories; Colorado. This laboratory is A2LA certified for ISO-17025, in 2009. and API proficiency tests have been conducted in 2009, with results available for review.

V. Lab Methods

Lab Methods

Rating

<p>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).</p>	Yes
<p>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?</p>	Yes
<p>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.</p>	Yes

Possible Points **0**

Actual Points **0**

Percentage

Comments

- 1 NOTE: A massaged, wet composite sample of N60 per combo/lot number, samples are ground prior to enrichment, except for the finished product verification samples. If a composite sample is pre-sumptive positive, then the 1 to 5 separate lot number samples are enriched and tested individually.
- 2 NOTE: Test method used: Version 006 with MB217:PCR 0157 N60 with AOAC approval.
- 3 If a composite sample is pre-sumptive positive, then the 1 to 5 separate lot number samples are enriched and tested individually. Event day procedures were available for review, and included all required elements.

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 N/A comment: The auditor reviewed several COAs and all reviewed COAs included all of the required elements.
- 3 NOTE: The Colorado IEH Laboratory manager/director and the Cactus, TX laboratory manager review all results through document review and real-time video camera/web camera shots for the initial results of all test kits used.