Audit Report

Beef Trim N60 Addendum

Iowa Premium, LLC
3337 L Avenue
Tama, Iowa 52339

Audit Date: November 14, 2023
Auditor: Curtis Pittman

Audit Summary

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Beef Trim -- N60 Addendum

1 Interventions for Pathogen Reduction

		Result
1.1	*E. coli* O157:H7 is a hazard likely to occur in the facility's HACCP plan(s)	yes
Comment:	*E. coli* O157:H7 was identified as a biological hazard that was reasonably likely to occur in facility HACCP plans.	
1.2	The 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. (List the technologies utilized)	yes
Comment:	The site utilized bacteriophage, PAA (200-800ppm), lactic acid (2.5-5%), Bovibrom (200-1,000ppm) and hot water (180°F or greater) as antimicrobial interventions.	

List all microbiological interventions and pathogen reduction processing aids. Include both slaughter and fabrication related interventions that are applied. Additionally, the 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 (Identify which interventions are CCPs by putting (CCP) after intervention). Document what the facility is monitoring (Ex. concentration, temperature, dwell time, etc.) for each intervention and identify which interventions are CCPs.

Slaughter Interventions	What parameters are monitored?
Bacteriophage applied to live cattle at receiving	Monthly viability sample
Lactic acid applied to hide opening pattern marks	Concentration, coverage
Pre evisceration cold water carcass wash	Concentration, coverage, nozzle function
Hot Water carcass CHAD cabinet (CCP)	Temperature, pressure (CCP) coverage and nozzle function (control point)
Lactic acid carcass cabinet	Concentration, temperature, nozzle function, coverage
PAA application to hearts, livers, tails, heads, tongues (CCP)	Concentration, coverage (CCP)
Hypobromous acid carcass spray chill application	Concentration

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?
Pre fabrication cabinet PAA	Concentration and coverage
Trim line spray PAA	Concentration and coverage
Subprimals at packaging PAA	Concentration and coverage

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.]

Study Type	Study Name
Journal Article	Treatments Using Hot Water Instead of Lactic Acid Reduce Levels of Aerobic Bacteria and Enterobacteriaceae and Reduce the Prevalence of *Escherichia coli* O157:H7 on Pre evisceration Beef Carcasses. Journal of Food Protection. Vol. 69, No. 8, 2006. 1808-1813.
Journal Article	Immersion in Antimicrobial Solutions Reduces Salmonella enterica and Shiga Toxin Producing *Escherichia coli* on Beef Cheek Meat. Journal of Food Protection. Vol. 77, No. 4, 2014. 538-548.
Journal Article	Interventions for the Reduction of *Salmonella typhimurium* DT 104 and Non O157:H7 Enterohemorrhagic *Escherichia coli* on Beef Surfaces. Journal of Food Protection. Vol. 63, No. 10, 2000. 1326-1332.
In-house Validation	CHAD Water Wash CCP Est. 8 Tama Validation 9/18/2023
In-house Validation	Heart Acidified Peracetic Wash Est 8 Tama Plant Microbial Validation – 9/18/2023
In-house Validation	Head Wash PAA Acid EST. 8 Tama Plant Microbial Validation- 7/10/2023

In-house Validation	Pre-Evisceration Peracetic Wash Est. 8 Tama Validation- 7/10/2023

List all on-going verification programs for microbiological interventions and pathogen reduction processing aids.

Finished product testing for *E. coli* O157:H7 was conducted on offal and trim. Trim samples were taken from each combo produced; offal samples were taken per period. Samples were collected from 1 out of every 300 head produced per regulatory requirements in harvest and analyzed for generic *E. coli*. Carcass mapping swabs were collected from the round and chuck of three carcasses post-hide removal, post-PECS (pre evisceration) cabinet, post-hot carcass wash, and pre-fabrication for APC. The facility sampled two trim types per day by excision sampling for APC.

1.4 Does the facility have a direct product treatment intervention on trim prior to N60 sampling? Note if facility treats trim or trim belts prior to sorting, boxing, or comboing of product. — yes

Comment: PAA was applied to trim belts prior to comboing of trim.

2 Sampling Programs for Products Destined for Raw, Ground

		Result
2.1	Facility produces combo trim?	yes
Comment:	Combo trim was produced.	
2.2	Written sampling program in place for combo trim	yes
Comment:	Sampling and Testing Procedures MCT Combo Individual Combo Sub Samples MicroTally Swab Combo Sampling and Testing Procedure and Beef *E. coli* O157:H7 and STEC Testing program defined combo sampling requirements.	
2.3	Facility produces box trim?	no
Comment:	Boxed trim was not produced.	
2.4	Written sampling program in place for box trim	Not Applicable
Comment:	Boxed trim was not produced.	
2.5	Facility produces FTB, BLBT, LTB, AMR or similar material?	no
Comment:	FTB, BLBT, LTB, AMR were not produced.	
2.6	Written sampling program in place for FTB, BLBT, LTB, AMR or similar material	Not Applicable
Comment:	FTB, BLBT, LTB, AMR were not produced.	
2.7	Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc.)?	yes
Comment:	Head meat, hearts, cheek meat, and tongue root were produced.	
2.8	Written sampling program in place for other raw beef components	yes
Comment:	Variety Meats Sampling (RGBC) defined sampling requirements.	
2.9	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

Comment: N=60 excision sampling was utilized on variety meats. MicroTally Cloth Sampling was utilized for trim samples. Results indicated MicroTally cloth sampling was statistically better than IEH N60+ shaver sampling at recovery of targeted indicator organisms.

2.10 How are the samples collected? [For example, traditional excision, modified excision, mechanical, or cloth method. NOTE – Traditional excision is defined as the USDA sampling method.] Remark

Comment: Variety meat samples were collected via traditional excision. Trim samples were collected via MicroTally cloth.

Sampling Method

Question	Method	Comment
How are the samples collected? [For example, traditional excision, modified excision or mechanical. NOTE – Traditional excision is defined as the USDA sampling method.]	Other	Variety meats were sampled via traditional excision. Trim was sampled via microtally cloth.

2.12 If procedure is modified from traditional excision, is there validation documentation? yes

Comment: National Beef Tama Est. 8 MARC Manual Sampling Device Validation Study, dated 5/13/21, compared MSD sampling vs. IEH N60+ shaver sampling. Results indicated MicroTally cloth sampling was statistically better than IEH N60+ shaver sampling at recovery of targeted indicator organisms.

2.13 Facility verifies sample counts? List the frequency in Comments (ex. X times by plant per week, X times by lab per week).
How is sample count verification documented? yes

Comment: Sample counts were verified daily by the site for variety meat samples, and were documented on the Variety Meat Sampling Sample Collection Form. The laboratory verified sample counts per sample. Sample counts were not applicable to Microtally sampling techniques. Records from August 2023 were provided and demonstrated compliance with the facility's procedure.

2.14 Facility verifies sample weights? Describe the process and list the frequency in Comments. List sample weight minimum, maximum, and target.
List how weight verification is documented. yes

Comment: Sample weights were verified per sample by both the site on the Variety Meat Sampling Sample Collection Form and the laboratory. Sample weight ranges were identified as 375-425g for variety meats with a target of one pound. Sample weight for MicroTally sampling was a minimum of 5 grams. Maximum pickup was not specified for MSD cloth.

2.15 Does sampling program target – where possible - surface tissue over internal tissue? yes

Comment: External surface was targeted per sampling plans.

2.16 Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces? yes

Comment: Samples were required collected from distinctly different trim pieces.

2.17	Sampling program should 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
Comment:	Such were sampled via MicroTally cloth per the facility's procedure.	
2.18	Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	yes
Comment:	Combos were identified by lot number, combo identification sequence number, and fill times. Per sampling protocols, combos that took beyond 2 hours to fill were sent to a customer with a full lethality treatment step.	
2.19	OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	yes
Comment:	Observed trim and variety meat sampling was conducted per program requirements using aseptic techniques. Sterile one-time use gloves and alcohol based sanitizer was used. Sanitizer was sprayed on the gloves and allowed to dry before sample collection.	
2.20	Employees performing sampling programs are trained to complete sampling tasks and training is documented. Verification of employee sampling techniques are visually reviewed (direct observation) at an established frequency. Reviews are documented.	yes
Comment:	Sample technique was verified once each period daily on the Verification of *E. coli* O157:H7 MicroTally Cloth Sampling for Trimmings/Naked in Combo Primals sheet and the Variety Meat Sampling Sample Collection Form. Training was conducted upon hire and annually thereafter; records reviewed for employees observed sampling during this assessment were current from 2023.	
2.21	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.	yes
Comment:	Lotting methods and supporting documentation were included in sampling plans.	

Lot Size

Type	Lot Size	Comment
Combo	Combos	Single Combo Lot
Variety Meats (Head meat, hearts, cheek meat, tongue root)	Production Day	A production day was considered a lot.

3 Verification Testing / Check Sample Program

		Result
3.1	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.	yes
Comment:	Monthly Process Assessments were conducted for *E. coli* O157:H7 and non-O157 STEC. Samples were collected simultaneously, with the non-O157 STEC sample collected from ground product.	

3.2	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.	yes
Comment:	Process assessment samples for both *E. coli* O157:H7 and non-O157 STEC were tested simultaneously. In the event of a non-negative result, a new product was randomly selected for process assessment testing.	
3.3	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. Verification sample should be taken from finished (ground) product	yes
Comment:	The 375 g minimum verification sample was collected from a 50 pound sample collected by coring random locations from a randomly selected trim combo that was ground twice before the sample was collected. Variety meat verification samples were collected via traditional excision and were ground.	
3.4	Verification/check sampling and testing are increased to a monthly frequency for second and third quarters (April – September). Auditor is to list the dates of the last three quarters verification/check samples in the comments section.	yes
Comment:	Monthly Process Assessment dates were as follows: Trim: 10/17/23, 9/21/23, 8/8/23, 7/18/23, 6/13/23, 5/4/23, 4/11/23, 3/21/23, 2/7/23, and 1/18/23. Variety Meats: 10/17/23, 9/13/23, 8/8/23, 7/18/23, 6/13/23, 5/4/23, 4/11/23, 3/21/23, 2/7/23, and 1/18/23	
3.5	OBSERVATION OF VERIFICATION / CHECK SAMPLING - N60 verification/check samples shall be observed by an independent third party auditor minimally one time per year, Lab testing shall be conducted at a third party lab minimally one time per year.	yes
Comment:	Process assessment observations were observed by a third party annually, at a minimum. Samples collected were sent to a third party laboratory for testing.	
3.6	At least one of the third 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 third party lab, the observation sample does not need to go to a different lab.	yes
Comment:	Third party observation was typically conducted between April and September of the calendar year, most recently on 9/20/2023. The observed sample was sent to a third party laboratory for testing. Results were reported to customers as required.	
3.7	Aseptic technique being followed when performing verification testing.	yes
Comment:	Sampling equipment, gloves, and sleeves were sanitized and allowed to dry prior to sample collection. A sterile sample bag was used for collecting both the *E. coli* O157:H7 and non O157 STEC samples.	
3.8	Where possible, surface tissue being targeted over internal tissue.	Not Applicable
Comment:	Sample was collected via a single core drill.	
3.9	Excision sub-samples are being collected from distinctly different pieces.	Not Applicable
Comment:	Initial sample was collected using MicroTally cloth. The verification sample was collected from ground product. Sample that was ground was collected from a single core drill.	

3.10	List piece count of the final sample if applicable.	Not Applicable
Comment:	The sample was collected from ground product.	
3.11	List weight of the final sample.	Comment Only
Comment:	385 grams	

4 Testing Laboratory

Result

Laboratory Information

Lab Name	Lab Location
Eurofins Microbiology Laboratories, Inc.	Des Moines, IA
Food Safety Net Services	San Antonio, TX

List Accreditation and/or Third Party Audit & date.

Eurofins: ISO 17025:2017 certificate through A2LA valid until 10/31/25.
FSNS: ISO 17025:2017 certificate through A2LA valid until 9/30/24

4.2	If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas.	Not Applicable
Comment:	Lab was offsite	
4.3	Controls to prevent pathogen contamination are in place.	Not Applicable
Comment:	Lab was offsite	
4.5	There is a program for running positive controls/cultures with documented records for all analyses.	yes
Comment:	Positive controls were ran daily at a minimum.	
4.6	Laboratory participates in a proficiency testing program to assure accuracy of its results. Records are available for review. List proficiency program used.	yes
Comment:	The laboratory underwent proficiency testing quarterly through LGC. Results for 2023 were available for review.	

5 Lab Methods

Result

5.1	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.	yes
Comment:	Variety meat sample slices were enriched intact. Trim combos were sampled using Microtally cloth.	
5.2	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).	Not Applicable
Comment:	Wet compositing was not being used.	

5.3 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). — Not Applicable

Comment: Wet compositing was not being used.

5.4 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]. — yes

Comment: PCR DNA amplification was utilized for *E. coli* O157:H7 screening.

For the following, please note if methodologies differ based on product types (ex. trim testing has different enrich time versus ground product).

Method	Document all methods being used by facility.	Document incubation time, temperature, and dilution factor
Method 1	AOAC RI 031002 (PCR BAX RT)	Micro Tally 200 ml enrichment 42º C for 8 15 hours; Variety Meats: 42º C for 12 hours, 1:5 dilution
Method 2	AOAC RI 091301 (MPX TOP 7 STEC)	42º C for 12 hours, 1:5 dilution
Method 3		

5.6 If method includes “wet” compositing, is the method validated? — Not Applicable

Comment: Such was not utilized

5.7 Presumptive positives are deemed positive if not culturally confirmed. — yes

Comment: Product disposition was based on initial screening results.

5.8 Product disposition is determined on presumptive positives. [NOTE: If “wet” compositing is being used, describe how product disposition is determined on a presumptive positive.]. — yes

Comment: Product disposition was based on initial screening results.

5.9 Confirmation capability of the lab is validated. — Not Applicable

Comment: Product disposition was based on initial screening results.

5.10 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

Comment: The High Event Period SOP defined high event period requirements.

6 Certificate of Analysis

Result

6.1	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
Comment:	Products intended for raw ground use were accompanied by a certificate of analysis which detailed the lot information for products covered by the COA and listed negative testing results for *E. coli* O157:H7.	
6.2	All laboratory results are subject to a minimum of a dual review and approval process.	yes
Comment:	Test results were subjected to a dual review process.	
6.3	Each Certificate of Analysis has its own unique number or identifier.	yes
Comment:	COAs were uniquely identified by report date and sample code.	
6.4	COA's that are revised indicate a revision date, revision reason and are traceable to the original COA.	yes
Comment:	Revised COA serial number, reason for revisions, and date were linked to the original COA in the comments.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	yes
Comment:	Analytical Results was listed at the top of each set of test results.	
6.6	The type of test and testing method used are listed on the Certificate of Analysis.	yes
Comment:	Test type and method were present on each Certificate of Analysis.	
7	The Auditor declares that he/ she does not have a conflict of interest with this auditee and the audit has been carried out independently and impartially.	yes
Comment:	I, Curtis Pittman, do not have a conflict of interest with this auditee and the audit has been carried out independently and impartially.	