Audit Report

Beef Trim N60 Addendum

CS Beef Packers, LLC
17365 South Cole Road
Kuna, Idaho 83634

Audit Date: July 19, 2022
Auditor: Enma Marroquin

Audit Summary

Company Name:	CS Beef Packers, LLC	Company ID:	AUCAVKUN
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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 defined as a hazard likely to occur.	
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:	Hot water pasteurization, lactic acid, Peracetic Acid (PAA), hypobromous acid (Bromine), and acidified sodium chlorite (ASC) were used as microbiological 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?
Lactic Acid or ASC on Pattern Lines	Concentration, Pressure, Temperature, and Coverage (includes pH if using ASC)
180º F Pre-evisceration Cabinet	Temperature, Pressure, and Coverage
Hot Water Pasteurization (CCP)	Temperature, Pressure, Dwell time, and Coverage (CCP)
Acid Cabinet Carcass Spray (CCP) (Lactic acid, ASC, or PAA)	Concentration, Pressure, Temperature, and Coverage (CCP)
Offal Acid Cabinet Spray (CCP) (Lactic acid, ASC, or PAA)	Concentration, Pressure, Temperature, and Coverage (CCP)
Hypobromous Acid Carcass Spray Chill	Concentration, Pressure, Temperature, and Coverage

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?

ASC Carcass Spray	Concentration, pH, Pressure, and Coverage
Lactic Acid or ASC Spray for Primals	Concentration, Temperature, Pressure, and Coverage
Lactic Acid or ASC Spray for Trimmings	Concentration, Temperature, Pressure, 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	Microbial Decontamination of Beef and Sheep Carcasses by Steam, hot Water Spray Washes , and Steam Vacuum Sanitizer. Journal of Food Protection Vol. 59, No 2, Pages 127-135 (1996)
Journal Article	Treatments Using hot Water Instead of Lactic Acid to 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, Pages 1808 - 1813 (2006)
Journal Article	Effectiveness of Spraying with Tween 20 and Lactic Acid in Decontaminating Inoculated *Escherichia coli* O157:H7 and Indegenous *Escherichia coli* Biotype I on Beef Meat Science and Muscle Biology Laboratory University of Wisconsin Madison Journal of Food Protection, Vol 65, No 1, Pages 26-32 (2002)
In-house Validation	Quarterly Process Validation for Anti-Microbial Interventions, July 2022

Journal Article	Efficacy of washing meat surfaces with 2% levulinic, acetic, or lactic acid for pathogen decontamination and residual Growth Inhibition. Journal of Meat Science 88. Pages 256-260. (2011)
In-house Validation	In-Plant Validation of Antimicrobial Interventions Used for Reduction of *Escherichia coli* O157:H7 on Beef Carcasses and Beef Trim, dated March 29, 2021.

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

Temperature probes were inserted into the flank, round, and clod of two carcass sides per period for surface temperature verification. Daily, one carcass out of 300 was sampled for Enterobacteriaceae and ECC in accordance with 9 CFR 310.25. CCP monitoring was conducted on an hourly basis for operational verification. Interventions were validated on a quarterly basis.

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: Lactic acid or ASC was applied to trimmings prior comboing or boxing.

2 Sampling Programs for Products Destined for Raw, Ground

		Result
2.1	Facility produces combo trim?	Yes
Comment:	Combo trimmings were produced.	
2.2	Written sampling program in place for combo trim	Yes
Comment:	N60 Plus Sampling Procedure, Traditional Excision N=60 Sampling Procedure, and Manual Sampling Device Procedure was utilized.	
2.3	Facility produces box trim?	Yes
Comment:	Boxed trimmings were produced.	
2.4	Written sampling program in place for box trim	Yes
Comment:	Traditional Excision N=60 Sampling Procedure was utilized.	
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, cheek meat, tongue trimmings, and heart meat were produced intended for raw ground use.	
2.8	Written sampling program in place for other raw beef components	Yes
Comment:	Traditional Excision N=60 Sampling Procedure was utilized.	
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:	Manual Sampling Device Cloth Sampling was used for combo trim. Traditional Excision N=60 was used for boxed trim and beef components (offal). N60 Plus sampling was used per customer requirements where needed.	
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:	Manual Sampling Device Cloth Sampling was used for combo trim. Traditional Excision N=60 was used for boxed trim and beef components (offal). N60 Plus sampling was used per customer requirements where needed.	

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	Traditional Excision N=60 was used in addition to Manual Sampling Device Cloth Sampling

2.12	If procedure is modified from traditional excision, is there validation documentation?	Yes
Comment:	N60 Plus Sampler Validation - Comparison of the IEH N60 Plus Sampler to Surface Excision Testing, 2017. Cloth Sampling Validation Comparison of Fremonta's MicroTally(TM) Swab Manual Sampling Device to IEH N60 Plus Sampler (TM) and N=60 Surface Excision Sampling, 2018.	
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:	Third party laboratory verified sample counts. Piece count verification was conducted for variety meat samples by the plant, once daily and documented on QA paperwork. Sample count was not applicable to Manual Sampling Device and N60 Plus Sampling.	
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 for each sample collected and documented on the Sample Equipment Log. The laboratory verified each sample weight prior to testing. Traditional N60 Excision samples were required to be between 375 to 400 g. N60 Plus Samples were required to be between 174 to 180 g. Target weights were not established.	

2.15	Does sampling program target – where possible - surface tissue over internal tissue?	Yes
Comment:	Sampling methods targeted surface tissue over internal tissue.	
2.16	Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces?	Yes
Comment:	Traditional N60 Excision trim, variety meat samples, and cloth sampling were collected from distinctly different pieces of trim.	
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.	Not Applicable
Comment:	Large pieces were excluded from trim.	
2.18	Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	Yes
Comment:	Slow fill combo bins were given a distinctive combo identification number. Combo bins included start and stop times.	
2.19	OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	Yes
Comment:	Samples were collected aseptically and according to company procedure. Sampling equipment was sanitized with 180° F water prior to sampling and between samples. Sampling personnel sanitized gloves with hypochlorite based sanitizer at 200 ppm sanitizer. Sterile whirl pak style bags were utilized.	
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:	Training for sample collection was conducted on an annual basis. Records for sampling personnel were reviewed and demonstrated compliance. Direct observation of sampling procedures were conducted on a daily basis at minimum and recorded on the Sample Tracking Form.	
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:	Lot identification was specified in sampling programs.	

Lot Size

Type	Lot Size	Comment
Trim	Combos	Lot identification was from one to five combos.
Boxes	Pallets	Lot identification was from one to five pallets.
Offal	Production Day	Lot identification was the entire production day.
Other Products	Other	Primals were lotted per customer specification. FTB, BLBT, LT were not produced.

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:	Verification samples were collected on a quarterly basis for the first and fourth quarters, and monthly for the second and third quarters.	
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:	Verification testing was conducted after receiving negative *E. coli* O157:H7 results for the initial combo bin test. If verification samples were taken prior to the initial receipt of lab results a new verification sample was taken for non-negative results.	
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:	Verification samples were taken from ground product.	
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:	Verification samples were collected on a quarterly basis during the first and fourth quarters and collected monthly during the second and third quarters. Verification dates reviewed were 2-8-22, 4-14-22, 5-27-22, and 6-23-22. Sample results were negative.	
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:	N60 verification samples were observed once per year by a third party auditor. Laboratory testing was conducted by a third party laboratory.	
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:	Verification sample collection was verified during the third quarter by a third party auditor. Results were not requested by the customer. A third party lab was utilized for testing.	
3.7	Aseptic technique being followed when performing verification testing.	Yes
Comment:	Samples were collected aseptically and according to company procedure. Sampling equipment was sanitized with 180° F water prior to sampling and between samples. Sampling personnel sanitized gloves with hypochlorite based sanitizer at 200 ppm sanitizer. Sterile whirl pak style bags were utilized.	
3.8	Where possible, surface tissue being targeted over internal tissue.	Not Applicable

Comment:	Sample was collected from ground beef.	
3.9	Excision sub-samples are being collected from distinctly different pieces.	Not Applicable
Comment:	Samples were collected from a ground sample.	
3.10	List piece count of the final sample if applicable.	Not Applicable
Comment:	Not Applicable - collected from a ground sample.	
3.11	List weight of the final sample.	Comment Only
Comment:	Final ground verification sample weight was 375 grams.	

4 Testing Laboratory

Result

Laboratory Information

Lab Name	Lab Location
FSNS	Boise, ID

List Accreditation and/or Third Party Audit & date.

Laboratory was certified to ISO 17025:2017 and accredited through A2LA. Certificate was valid through 7-31-23.

4.2	If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas.	Not Applicable
Comment:	Laboratory was located off site. On site laboratory testing was not performed.	
4.3	Controls to prevent pathogen contamination are in place.	Not Applicable
Comment:	Laboratory was located off site. On site laboratory testing was not performed.	
4.5	There is a program for running positive controls/cultures with documented records for all analyses.	Yes
Comment:	Positive controls were ran with each sample set.	
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:	Proficiency testing program was conducted in accordance with ISO 17025 Accreditation. Records were available for review; most recent was performed on 4-22-22.	

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:	Samples were enriched as intact slices where applicable.	
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 performed.

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 performed.

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 conducted for detecting *E. coli* O157:H7

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
BAX PCR DNA Amplification	AOAC - RI 102003 *E. coli* O157:H7 RT	Incubation of 8 hours, warmed to 45C, dilution was 1:9.
BAX PCR DNA Amplification	AOAC- RI 031002 USDA, MLG Chapter 5 (*E. coli* O157:H7 Exact RT)	Incubation time was 12 to16 hours, temperature 42F, dilution 1:9

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

Comment: Wet compositing was not performed.

5.7	Presumptive positives are deemed positive if not culturally confirmed.	Yes

Comment: Presumptive positive samples were culturally confirmed.

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 cultural confirmation results.

5.9	Confirmation capability of the lab is validated.	Yes

Comment: USDA MLG Chapter 5, 5A method was used for cultural confirmation.

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: High Event Period Procedure was derived from the FSIS compliance guideline and reviewed when multiple non-negative results were obtained.

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:	COAs listed each result by the combo bin identification number. Combo bins were grouped by purchase order number.	
6.2	All laboratory results are subject to a minimum of a dual review and approval process.	Yes
Comment:	Laboratory samples were subjected to a dual review.	
6.3	Each Certificate of Analysis has its own unique number or identifier.	Yes
Comment:	Each Certificate of Analysis had an individual Report Number.	
6.4	COA's that are revised indicate a revision date, revision reason and are traceable to the original COA.	Yes
Comment:	Revisions were indicated in the remarks section and included a revision date, reason, and was included on the original COA by third party laboratory at the request of the establishment.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	Yes
Comment:	Analytical Results was indicated at the top of the Certification of Analysis.	
6.6	The type of test and testing method used are listed on the Certificate of Analysis.	Yes
Comment:	COAs included methods used for each sample result.	
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, Enma Marroquin, did not have a conflict of interest with this auditee.	