Audit Report

Beef Trim N60 Addendum

Caviness Packing Company - Hereford
3255 U.S. 60
Hereford, Texas 79045

Audit Date: November 13, 2020
Auditor: Lacey Vinson

Audit Summary

Company Name:	Caviness Packing Company - Hereford	Company ID:	AUCAVHER
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PLEASE NOTE: A “NO” answer does not necessarily represent a deficiency in a facility’s programs or processes.

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:	Steam pasteurization, hot water wash cabinets, lactic acid, acidified sodium chlorite (ASC), and hypobromous acid (Bovibrom) were utilized 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?
Hock steam vacuum	Pressure, temperature
Lactic acid on midline opening patterns, and bung area	Concentration, pressure, application
Pre-Evisceration CHAD cabinet (hot water and/or lactic acid)	Concentration, temperature, application, pressure, coverage
ASC applied to carcasses at rail-out	Concentration, application, coverage
Variety meat lactic acid (head, tongue, tail, heart, kidney, liver) (CCP)	Coverage, pressure, concentration, application, temperature (CCP)
Hot water final carcass wash (CCP)	Temperature, pressure, coverage, application (CCP)
Lactic acid carcass wash (CCP)	Concentration, temperature, pressure, application, coverage (CCP)
Hypobromous acid spray chill application	Concentration, application, coverage

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?
ASC sales cooler pre-fabrication cabinet	Concentration, temperature, pH, coverage, application, flow
Lactic acid on sub-primal and trim belts and off-line combo area	Concentration, pressure, application

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
In-house Validation	Hot Water Wash Cabinet Stand Alone Intervention Validation - January and February 2020.
Journal Article	Effects of Steam-Vacuuming and Hot Water Spray Wash on the Microflora of Refrigerated Beef Carcass Surface Tissue Inoculated with *Escherichia coli* O157:H7, *Listeria* innocula and *Clostridium* sporogenes. Journal of Food Protection. Vol. 60, No. 2, Pages 114-119.
Journal Article	Use of Hot Water for Beef Carcass Decontamination. Journal of Food Protection. Vol. 60, Pages 19-25.
Journal Article	Treatment 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 1808-1803.

Journal Article	Evaluation of Commonly Used Antimicrobial Interventions for Fresh Beef Innoculated with Shiga-Toxin Producing *Escherichia coli* Serotypes O26, O45, O103, O111, O121, O145, and O157:H7. Journal of Food Protection. Vol. 75, No. 7, 2012. Pages 1207-1212.
Other	FSIS Directive 7120.1
Challenge Study	Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Establishments - Penn State University 2005.
In-house Validation	ASC Vs. Lactic Acid - July 2020
Challenge Study	Lactic Acid Validation January 2020
Journal Article	Efficacy of Organic Acids Against *Escherichia coli* O157:H7 Attached to Beef Carcass Tissue Using a Pilot Scale Model Carcass Washer. Journal of Food Protection. Vol. 57, No. 2, Pages 97-103.
Journal Article	Evaluation of Various Antimicrobial Interventions for the Reduction of *Escherichia coli* O157:H7 on Bovine Heads During Processing. Journal of Food Protection. Vol. 71, No. 3, 2008. Pages 621-624.
Journal Article	Comparison of the Efficacy of a Sulfuric Acid Sodium Sulfate Blend and Lactic Acid for the Reduction of *Salmonella* on Pre-rigor Beef Carcass Surface Tissue. Journal of Food Protection. Vol. 80, No. 5, 2017. Pages 809-813.
Journal Article	Comparison of Water Wash, Trimming, and Combined Hot Water and Lactic Acid Treatments for Reducing Bacteria of Fecal Origin on Beef Carcasses. Journal of Food Protection. Vol. 61, No. 7, 1998. Pages 823-828.

Journal Article	Lactic Acid Sprays Reduce Bacterial Pathogens on Cold Beef Carcass Surfaces and in Subsequently Produced Ground Beef. Journal of Food Protection. Vol. 64, No. 1, 2001. Pages 58-62.

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

One out of every 300 carcasses processed was swabbed for generic *E. coli* per regulatory requirements. Products intended for raw ground use were sampled and tested for *E. coli* O157:H7. Sampling and testing of finished products for non-O157 STEC, Salmonella, and indicator organisms including APC, coliforms, and generic *E. coli* was based on customer-specific requirements. Quarterly process validation swabs were collected on ten carcasses pre and post interventions; swabs were tested for APC, coliforms, and generic *E. coli*.

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 was applied to trim belts and combos through off-line lactic acid drops prior to sampling.

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:	N60/IEH N60 Plus Sampling procedure defined sampling requirements.	
2.3	Facility produces box trim?	Yes
Comment:	Boxed trim was produced.	
2.4	Written sampling program in place for box trim	Yes
Comment:	N60/IEH N60 Plus Sampling procedure defined sampling requirements.	
2.5	Facility produces FTB, BLBT, LTB, AMR or similar material?	No
Comment:	Not produced.	
2.6	Written sampling program in place for FTB, BLBT, LTB, AMR or similar material	Not Applicable
Comment:	Not produced.	
2.7	Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc.)?	Yes
Comment:	Head meat, cheek meat, hearts, and tongue trim were produced and sampled.	

2.8	Written sampling program in place for other raw beef components	Yes
Comment:	Offal Sampling Program 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:	N60 sampling methods were utilized.	
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:	Samples were collected via traditional excision, the MSD cloth, and the IEH N60 Plus Shaver.	

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	

2.12	If procedure is modified from traditional excision, is there validation documentation?	Yes
Comment:	Samples were collected via MSD cloth, traditional excision, or IEH N60 Plus shaver with one lot identified as from one to five combos. Validation for sampling methods included Comparison of Fremonta's Microtally Swab Manual Sampling Device to IEH N60 Plus Sampler and N=60 Surface Excision Sampling - 4/23/18, and a Letter of No Objection for N60 Plus Sampler-10/9/08.	
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 for each sampler and results documented on the N60 Sampling Verification form.	
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 by the laboratory and on each sample collected by the plant (where applicable), and were documented on the N60 Verification Form. Target sample ranges for samples collected via traditional excision were 375-400g with a target of 375g. Samples collected via the IEH N60 Plus Shaver targeted from 150-180 grams. Target sample weights for this method were defined based on lean point of the combo sampled.	
2.15	Does sampling program target – where possible - surface tissue over internal tissue?	No

Comment:	Sampling programs required samples collected from external tissue where available. The following was observed: The Offal Sampling Program stated surface tissue would be targeted where available, however, observed samples were collected from sterile tissue located on the cheek bone after cheeks were sliced into for examination by USDA on the head chain, instead of from surface tissue on the outside of the cheek.	
2.16	Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces?	Yes
Comment:	Sampling protocols required samples 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
2.18	Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	Yes
2.19	OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	No
Comment:	Trim sampling using MSD cloth, IEH N60 Plus Shaver, and traditional excision methods was observed and was consistent with program requirements; sampling equipment, gloves, and sleeves were sanitized prior to sample collection. Sampling of cheek meat was also observed during this assessment. Samples were being collected from sterile tissue remaining on the cheek bone of eleven heads on the head chain instead of from one randomly selected piece per box as required by the Offal Sampling Program. Additionally, cheek meat samples were observed not fully placed inside the sample bag and were observed contacting the outside of the sample bag which did not meet aseptic sampling requirements.	
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:	Verification of sampling techniques, sample weight and piece count (where applicable) were documented once daily on the N60 Verification Sheet. Records reviewed from 2020 evidenced program compliance. Training for personnel collecting samples was provided from 2020 and evidenced program compliance.	
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 methods and requirements were defined within sampling protocols.	

Lot Size

Type	Lot Size	Comment
Combo Trim	Combos	One to five combos comprised one lot.
Boxed Trim	Pallets	One to five pallets comprised one lot.
Head meat, hearts, cheek meat, and tongue trim	Production Day	

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 quarterly during the first and fourth quarters and monthly during the second and third quarters. Verification samples were collected from ground product that previously tested negative for *E. coli* O157:H7.	
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 samples were collected after negative *E. coli* O157:H7 samples were received for the lot selected for verification 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:	Verification samples were collected from ground products. If a non-negative result was achieved, a new lot was chosen for verification sampling. Sample results were reported as requested.	
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 typically collected quarterly during the first and fourth quarters and monthly during the second and third quarters. Results from most recent samples included 1/1/20, 2/24/20, 3/21/20, 4/14/20, 5/27/20, 6/24/20, 7/18/20, 8/11/20, 9/9/20, 12/6/19.	
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:	Verification sampling processes were observed by a third party once per year. A third party laboratory was utilized for testing of verification samples.	
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; observation for 2020 was delayed due to the Covid-19 pandemic. Samples were sent to a third party laboratory for testing.	
3.7	Aseptic technique being followed when performing verification testing.	Yes
Comment:	Employee gloves and sleeves were sanitized with an alcohol based sanitizer and were allowed to dry prior to sample collection.	

3.8	Where possible, surface tissue being targeted over internal tissue.	Yes
Comment:	Surface tissue was targeted through sampling methods utilized.	
3.9	Excision sub-samples are being collected from distinctly different pieces.	Yes
Comment:	Distinctly different trim pieces were targeted through sample methods utilized.	
3.10	List piece count of the final sample if applicable.	Not Applicable
Comment:	Initial sample was collected using the MSD cloth.	
3.11	List weight of the final sample.	Comment Only
Comment:	325g.	

4 Testing Laboratory

Result

Laboratory Information

Lab Name	Lab Location
Food Safety Net Services	Amarillo, TX

List Accreditation and/or Third Party Audit & date.

ISO 17025:2017 accreditation through A2LA with a certificate valid until 2/20/22.

4.2	If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas.	Not Applicable
Comment:	The laboratory was not located on-site.	
4.3	Controls to prevent pathogen contamination are in place.	Yes
Comment:	The laboratory was not located on-site.	
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 set of samples, and results were maintained for review.	
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:	Laboratory participated in proficiency testing through LGC and AOAC at a minimum of annually. Most recent proficiency tests were provided for review, and demonstrated acceptable results.	

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 composition was not utilized.	
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
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	Biocontrol Assurance GDS AOAC 2005.04	Cloth - 200ml, 42C, 8 hours; traditional excision or IEH N60 Plus Shaver samples - 42C 8-18 hours, 1:4 dilution
Method 2	PCR BAX AOAC -RI 031002	42C +/- 1C, 15 hours, 1:4 Dilution
Method 3		

5.6	If method includes “wet” compositing, is the method validated?	Not Applicable
Comment:	Wet composition 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:	High Event Period CP 21 defined requirements for high event period reporting, investigation, and implementation of corrective actions.	

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 COA that listed negative *E. coli* O157: H7 results for each product lot covered by the COA.	
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:	Report number was the unique identifier for each set of test results.	
6.4	COA's that are revised indicate a revision date, revision reason and are traceable to the original COA.	Not Applicable
Comment:	COA information was manually entered, and were not permitted revised.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	Yes
Comment:	Test results were titled "Analytical Results".	
6.6	The type of test and testing method used are listed on the Certificate of Analysis.	Yes
Comment:	Test type and method of analysis were listed on each COA.	
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, Lacey Wooten, do not have a conflict of interest with this auditee.	