Audit Report

Beef Trim N60 Addendum

Caviness Beef Packers - Hereford
3255 U.S. Highway 60
Hereford, Texas 79045

Audit Date: August 15, 2023
Auditor: Michael Sanders

Audit Summary

Company Name:	Caviness Beef Packers - Hereford	Company ID:	AUCAVHER
Address:	3255 U.S. Highway 60 Hereford, Texas 79045		

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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 potential hazard likely to occur in the 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 used a 180°F pre-evisceration wash cabinet, a 180°F final hot water pasteurization cabinet (CCP), ASC (Acidified Sodium Chlorite) was used as an either/or processing aid in conjunction with the 180°F pre-wash cabinet. Lactic acid was applied to carcass sides just prior to entering the chilling cooler (CCP). Hypobromous acid was applied to carcasses in the spray chill. ASC was applied to carcasses prior to fabrication. Lactic acid was applied to sub-primals at the end of boning tables before packaging, and to trimmings just prior to combo fill.	

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?
180°F pre-evisceration wash cabinet	Temperature, pressure, operation.
180°F final hot water pasteurization cabinet (CCP)	Temperature, pressure, operation.
ASC (Acidified Sodium Chlorite) was used as an either/or processing aid in conjunction with the 180°F pre-wash cabinet	Concentration, nozzle function.
Lactic acid was applied to carcass sides just prior to entering the chilling cooler (CCP)	Concentration, temperature, coverage.

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?
ASC was applied to carcasses prior to fabrication.	Concentration, nozzle function.
Lactic acid was applied to sub-primals at the end of boning tables before packaging, and to trimmings just prior to combo fill.	Concentration, temperature, 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
In-house Validation	SQA-6 Carcass Wash Cabinet 5/31/2023
In-house Validation	SQA B-3 CCP3 - Lactic Acid - 5/31/2022

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

On-going verifications included hourly monitoring of operating parameters, quarterly Process Validations, which consisted of sampling carcasses pre and post interventions for APC, generic *E. coli*, and coliforms, and sampling of one out of every 300 carcasses produced for 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 trimmings prior to combo fill.

2 Sampling Programs for Products Destined for Raw, Ground

		Result
2.1	Facility produces combo trim?	Yes
Comment:	Combo trim produced.	
2.2	Written sampling program in place for combo trim	Yes
Comment:	CP1 N60/IEH N60 Plus Sampling CP12 MSD Micro Tally Cloth Sampling	
2.3	Facility produces box trim?	Yes
Comment:	Boxed trim produced.	
2.4	Written sampling program in place for box trim	Yes

Comment:	Fab SOP4 Boxed Trimmings	
2.5	Facility produces FTB, BLBT, LTB, AMR or similar material?	Not Applicable
Comment:	Such materials were not produced.	
2.6	Written sampling program in place for FTB, BLBT, LTB, AMRor similar material	Not Applicable
Comment:	Such materials 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 salivary glands were produced.	
2.8	Written sampling program in place for other raw beef components	Yes
Comment:	CP18 Offal Slaughter	
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:	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.	
2.10	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 using a cloth manual sampling device, or by modified excision using a fluted tip sampling device.	

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	Samples were collected using a cloth manual sampling device, or by modified excision using a fluted tip sampling device.

2.12	If procedure is modified from traditional excision, is there validation documentation?	Yes
Comment:	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:	Piece count was not applicable to neither the MSD or N60 Plus sampling method. Piece count was not conducted on variety meat samples.	
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:	Weights were verified on each sample and recorded on the Sample Submission Form. Target or maximum weights were not specified for MSD sampling. Minimum weight pick of was 7 grams. Target weights for the IEH method ranged from 154 grams to 166 grams based on the lean type. Minimum or maximum weights were not specified.	
2.15	Does sampling program target – where possible - surface tissue over internal tissue?	Yes
Comment:	Sampling protocols required targeting external tissue.	
2.16	Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces?	Yes
Comment:	IEH samples were collected from each corner and the center of the combo. Cloth samples were collected from 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.	Not Applicable
Comment:	Larger product pieces did not inhibit the sampling methods so there were no exceptions.	
2.18	Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	Yes
Comment:	Start and stop times were recorded on each combo bin	
2.19	OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	Yes
Comment:	Samples were collected according to written protocols. Sampling equipment was sanitized and samples collected hygienically.	
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:	Employees were trained on sampling procedures and refreshed annually. Training records dated January and February were available.	
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 lot sizes were defined in sampling programs.	

Lot Size

Type	Lot Size	Comment
MSD Micro Talley Cloth Method	Combos	Single combo bins
IEH N60 Plus	Combos	Single combo bins
Boxed trim	Pallets	Up to two pallets
Variety Meats	Production Shift	Production shift

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:	The site ground negatively tested trimmings at a sister facility and tested the finished product for *E. coli* O157:H7 on a weekly basis.	
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 from combo bins previously tested and found negative.	
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
Pending onsite review		
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 sampling was conducted weekly.	
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 was observed by a third party annually, with the previous observation occurring in November 2022. Samples were tested 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.	No
Comment:	The site used a third party laboratory. Third party observations typically occurred annually in November.	
3.7	Aseptic technique being followed when performing verification testing.	Yes
Pending onsite review		
3.8	Where possible, surface tissue being targeted over internal tissue.	Yes
Pending onsite review		
3.9	Excision sub-samples are being collected from distinctly different pieces.	Yes
Pending onsite review		

3.10	List piece count of the final sample if applicable.	Comment Only

Pending onsite review

3.11	List weight of the final sample.	Comment Only

Pending onsite review

4 Testing Laboratory

Result

Laboratory Information

Lab Name	Lab Location
FSNS	Amarillo, TX

List Accreditation and/or Third Party Audit & date.

ISO/IEC 17025:2017, valid through 2/29/24.

4.2	If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas.	Not Applicable
Comment:	Testing was conducted offsite.	
4.3	Controls to prevent pathogen contamination are in place.	Not Applicable
Comment:	Testing was conducted offsite.	
4.5	There is a program for running positive controls/cultures with documented records for all analyses.	Yes
Comment:	Positive controls were run daily	
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 records were available for the previous three events. LGC was used for proficiency testing.	

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 intact.	
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 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

Comment: Wet compositing not utilized.

5.4 Rapid screen method is either: Yes
(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].

Comment: PCR DNA

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	9 hours at 42C and a 1:10 dilution factor (traditional excision)
Method 2	PCR BAX AOAC RI 031002	Cloth 200ml, 42C, 8 hours; traditional excision or IEH N60 Plus Shaver samples 42C 8 18 hours, 1:4 dilution(combos)
Method 3		

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

Comment: Wet compositing 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 program outlined procedures for event days.

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.	Yes
Comment:	If a COA was revised, reasons for the revision and a reference to the original COA were recorded in the 'remarks' section of the report.	
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, Michael Sanders, do not have a conflict of interest with this auditee.	