Audit Report

Beef Trim N60 Addendum

Harris Ranch Beef Company
16277 South McCall Avenue
Selma, California 93662

Audit Date: September 19, 2023
Auditor: Rudy Hernandez

Audit Summary

Company Name:	Harris Ranch Beef Company	Company ID:	AUHARRIS
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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 in the HACCP plans. HACCP plans were reassessed annually, most recently on 09/07/2023.	
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 facility used a 180°F hot water pre-evisceration carcass wash, lactic acid, and bovibrom.	

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?
Hot water pasteurization (CCP) Harvest after hide off	Water temperature, pressure, and nozzle function (CCP)
Lactic Acid (CCP) Harvest after hot water pasteurization	Temperature, concentration, application, and nozzles. (CCP)
Bovibrom offal red meats	PPM

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?
Lactic acid	Temperature, concentration, application, and nozzles. (CCP)

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	Evaluation of Commonly Used Antimicrobial Interventions for Fresh Beef Inoculated with Shiga Toxin Producing *Escherichia coli* Serotypes 026, 045, 0103, 0111, 0121, 0145, and O157:H7. Journal of Food Protection, Vol. 75, No. 7 2012, Pages 12071212
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
In-house Validation	Scott et al., 2014 Bullard et al., 2018 Validation of Changes to HACCP CCP S 1 Operating Parameters Due to Facility and Equipment Improvements. Validation of Beefxide as an Antimicrobial intervention of Fresh Beef Carcass Surfaces.
Other	

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

Ongoing verification included CCP monitoring, shaving cream tests, ink tests, temperature data recording device attached to a carcass passed through the cabinet minimally twice daily, temperature decals attached to carcasses passed through the cabinet randomly, daily carcass mapping (sampling of carcasses post hide removal, pre and post evisceration, and post interventions) for APC, generic *E. coli*, and coliforms, and sampling of one out of every 300 carcasses for generic *E. coli*.

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

Comment: Lactic acid was applied to trimmings prior to combo fill and 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:	*E. coli* O157:H7 Testing Micro Tally (MSD) Sample Collection-Comb Bins SOP was implemented.	
2.3	Facility produces box trim?	yes
Comment:	Box trim was produced.	
2.4	Written sampling program in place for box trim	yes
Comment:	If the facility did box trim, it would be from a previously tested negative combo for which the *E. coli* O157:H7 Testing Micro Tally (MSD) Sample Collection-Comb Bins SOP was implemented.	
2.5	Facility produces FTB, BLBT, LTB, AMR or similar material?	yes
Comment:	AMR was produced but was not intended for raw ground use.	
2.6	Written sampling program in place for FTB, BLBT, LTB, AMR or similar material	Not Applicable
Comment:	AMR was not sampled. AMR was sent to cook only facility.	
2.7	Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc.)?	yes
Comment:	Head meat, cheek meat, tongue root trim, and hearts were produced.	
2.8	Written sampling program in place for other raw beef components	yes
Comment:	*E. coli* O157:H7 Testing Identification And Handling - Offal Product SOP was implemented.	
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:	Traditional N60 sampling was used for variety meat and sub-primals. N60 Plus, or MicroTally cloth sampling, was used for combo bins. Evaluation of Manual Sampling Device as a Sample Collection Method for Harris Ranch Research Report- Terry Arthur and Tommy Wheeler June 24, 2022 was provided as validation. Results indicated that MicroTally cloth sampling was statistically better than IEH N60+ shaver sampling at the recovery of targeted indicator organisms. Supporting validation for N60 Plus was the Final Report Comparison of Organism Recovery using Surface Excision Sampling and the IEH N60 PLUS Sampler for Beef Trim Harris Ranch Meats.	
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:	Traditional N60 sampling was used for variety meat and sub-primals. N60 Plus, or MicroTally cloth sampling, was used for combo bins. .	

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 N60 excision sampling was used for variety meat testing. Traditional N60 excision was used to sample sub-primals in a combo bin. MicroTally cloth sampling was used for combo bins.

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

Comment: Traditional N60 sampling was used for variety meat and sub-primals. N60 Plus, or MicroTally cloth sampling, was used for combo bins. Evaluation of Manual Sampling Device as a Sample Collection Method for Harris Ranch Research Report- Terry Arthur and Tommy Wheeler June 24, 2022 was provided as validation. Results indicated that MicroTally cloth sampling was statistically better than IEH N60+ shaver sampling at the recovery of targeted indicator organisms. Supporting validation for N60 Plus was the Final Report Comparison of Organism Recovery using Surface Excision Sampling and the IEH N60 PLUS Sampler for Beef Trim Harris Ranch Meats.

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 on a randomly selected sampler weekly and recorded on the Daily Check-Offal: Lab QA form. Records reviewed from the week of 4/24/2023 demonstrated compliance.

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 on a randomly selected sampler weekly and recorded on the Daily Check-Off: Lab QA form. The minimum and target weights were 150g, and the maximum was 180g for modified excision samples. For traditional N60, the target weight was 375g, a minimum of 367.5g, and a maximum of 382.5g. The target sample weight for the MSD sampling method was >25 grams. A maximum weight was not specified. Weights were verified on MSD samples daily and recorded on the Daily Check-Off: Lab QA monitoring form. The records reviewed demonstrated compliance.

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

Comment: Surface tissue was targeted.

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

Comment: Samples were required to be 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. yes

Comment: Traditional excision was used for larger pieces such as 2-piece chuck, goosenecks, and briskets.

2.18 Is there a program in place to address the handling of lotting for slow fill versus fast fill combos? Not Applicable

Comment: Slow-fill combos were not produced.

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.	
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 at hire and annually after that. Verification activities occurred daily and were documented on the Daily Check-Off: Lab QA form. Records presented evidenced 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:	Lotting methods and supporting documentation were included in sampling plans	

Lot Size

Type	Lot Size	Comment
Combos	Combos	Single combo lots
Variety Meats	Production Day	Entire production day
Boxed Trim	Combos	

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 sampling was completed quarterly in the first and fourth quarters of the year, and monthly in the second and third quarters of the year.	
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, and offal products that were sampled and reported as negative. If reports were non-negative, a new product was selected for verification sampling.	
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 of trim were collected with a 6 tube core sampler, and ground on a tabletop grinder. Offal samples were collected using the traditional N60 method than ground on a tabletop grinder.	

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:	Trim Verification: 9/16/2022 9/29/2022 10/22/2022 1/27/2023 4/14/2023 5/12/2023 6/16/2023 7/14/2023 8/11/2023 Offal Verification: 9/23/2022 10/28/2022 11/18/2022 12/29/2022 1/13/2023 2/25/2023 3/17/2023 4/14/2023 5/26/2023 6/16/2023 7/14/2023 8/25/2023	
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 an independent third party annually. The previous observation occurred on 9/27/2022. An accredited third-party laboratory performed 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:	Verification sampling was observed by an independent third party annually. The previous observation occurred on 9/27/2022. An accredited third-party laboratory performed testing.	
3.7	Aseptic technique being followed when performing verification testing.	yes
Comment:	Samples were collected aseptically. The sampling equipment was cleaned and sanitized before sample collection. Sterile microbags were used to collect samples.	
3.8	Where possible, surface tissue being targeted over internal tissue.	yes
Comment:	Surface tissue was targeted.	
3.9	Excision sub-samples are being collected from distinctly different pieces.	yes

Comment:	Samples were collected from distinctly different pieces.	
3.10	List piece count of the final sample if applicable.	Not Applicable
Comment:	The final sample verification was collected via core drill and ground.	
3.11	List weight of the final sample.	Comment Only
Comment:	The final sample weight was 375 grams.	

4 Testing Laboratory

Result

Laboratory Information

Lab Name	Lab Location
FSNS	Fresno, California

List Accreditation and/or Third Party Audit & date.

The laboratory was ISO 17025:2005 accredited through A2LA with a certificate valid until 9/30/23.

4.2	If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas.	Not Applicable
Comment:	The laboratory was not on site.	
4.3	Controls to prevent pathogen contamination are in place.	Not Applicable
Comment:	The laboratory was not on site.	
4.5	There is a program for running positive controls/cultures with documented records for all analyses.	yes
Comment:	Positive and negative controls were ran 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:	The laboratory was ISO 17025:2005 accredited through A2LA with a certificate valid until 9/30/223. The laboratory participated in proficiency testing three times per year with results available.	

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 was not conducted.	

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 conducted.

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: BAX RT test kits were utilized for routine and verification sample testing for *E. coli* O157:H7 through 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	BAX RT AOAC 031002 O157:H7	9 10 hours at 42°C (+/ 1°C) and a 1:5 dilution
Method 2	BAX RT AOAC 091301 STEC	9 hours at 42°C (+/ 1°C) and a 1:5
Method 3	BAX RT AOAC 031002 O157:H7 MicroTally	10 hours at 42°C with 200 ml enrichment

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

Comment: Wet compositing was not conducted.

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

Comment: Product disposition was based on initial 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 results.

5.9 Confirmation capability of the lab is validated. — yes

Comment: Cultural confirmation could be conducted using USDA MLG 5.5A methodology for data collection purposes, however, product disposition was based on initial test 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 program was documented in the HRBC, Est. #783 N60/MicroTally (MSD) High Event Day Justification 'Supporting Documentation/Reference Material'.

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:	A COA was required for raw trimmings destined for grinding.	
6.2	All laboratory results are subject to a minimum of a dual review and approval process.	yes
Comment:	Laboratory results were subject to tertiary review.	
6.3	Each Certificate of Analysis has its own unique number or identifier.	yes
Comment:	The Sales Order number or Report Number was the unique identifier.	
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 it retained the same Sales Order or Report Number and was identified as revised in the footer of the document.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	yes
Comment:	Certificate of Analysis was printed across the top of the page.	
6.6	The type of test and testing method used are listed on the Certificate of Analysis.	yes
Comment:	Test method and type were listed on the 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, Rudy Hernandez, do not have a conflict of interest with this auditee.	