Audit Report

Beef Trim N60 Addendum

Missouri Prime Beef Packers
5305 Highway H
Pleasant Hope, Missouri 65725

Audit Date: March 24, 2021
Auditor: Mark Sarratt

Audit Summary

Company Name:	Missouri Prime Beef Packers	Company ID:	AUMISPRI
Address:	5305 Highway H Pleasant Hope, Missouri 65725		

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Audit ID:	AO-001228
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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 hazard reasonably likely to occur in the site 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 facility utilized pre-evisceration cabinet with PAA, head wash cabinet with lactic acid, and lactic acid carcass spray.	

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?
PAA Application Carcass	Concentration <600 ppm measured through titration
Lactic Acid Application Carcass (CCP)	Concentration > 2% < 5% measured through titration
Lactic Acid Application Offal Products (CCP)	Concentration > 2% < 5% measured through titration

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?
PAA Application to trimmings and subprimals	Concentration <600 ppm measured through titration

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	"Investigation of Chemical Rinses Suitable for Very Small Meat Plants To Reduce Pathogens on Beef Surfaces", Sally Yoder et al 16th February 2011.
In-house Validation	Pre/Post reduction of generic *E. coli* sp. through application of Lactic Acid to carcass surfaces. March 2021

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

Ongoing verifications included generic *E. coli* sampling of one out of every 300 head harvested, and *E. coli* O157:H7 sampling of finished trimmings.

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 trimmings prior to accumulation for packaging.

2 Sampling Programs for Products Destined for Raw, Ground

		Result
2.1	Facility produces combo trim?	No
Comment:	At the time of this assessment, combo trim was not produced.	
2.2	Written sampling program in place for combo trim	Yes
Comment:	A written program for sampling combo trim was in place.	
2.3	Facility produces box trim?	Yes
Comment:	Box trim was produced.	
2.4	Written sampling program in place for box trim	Yes
Comment:	A written program for sampling box trim was in place.	
2.5	Facility produces FTB, BLBT, LTB, AMR or similar material?	Not Applicable
Comment:	These materials were not produced.	
2.6	Written sampling program in place for FTB, BLBT, LTB, AMRor similar material	Not Applicable

Comment: These materials were not produced.

2.7 Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc.)? Yes

Comment: Other beef components were in production.

2.8 Written sampling program in place for other raw beef components Yes

Comment: A written program for sampling other beef components was in place.

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: The site used traditional N=60 excision methods.

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 excision using knife or shears was performed.

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.]	Traditional Excision	Traditional excision using knife or shears was performed.

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

Comment: Traditional excision using knife or shears was performed.

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: Plant programs specified verification of sample counts weekly.

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: Plant programs specified verification of sample weights weekly. Sample target was 375 grams with a maximum of 375 grams and minimum of 365 grams.

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

Comment: Sampling program specified selection of external tissue.

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

Comment: Sampling program specified sampling for different 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.	No
Comment:	This distinction was not made within the program.	
2.18	Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	Yes
Comment:	By program, combos were given a start and stop time to allow for fill times.	
2.19	OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	Yes
Comment:	At the time of this assessment, trim sampling was not being performed and trim was sold as untested. Testing protocol was demonstrated and was compliant with methods specified in the company SOP.	
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 of samplers was documented and presented as verification. By program, sampling was verified weekly by senior FSQA personnel.	
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 sizes were specified in sampling protocols and were associated with validation information that supported sampling procedures.	

Lot Size

Type	Lot Size	Comment
Combo trim	Combos	Combos were considered single
Boxed trim	Pallets	Maximum 36 boxes were considered a lot.
Offal products	Pallets	Products were sublotted by pallet.

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.	No
Comment:	Verification sampling had not been initiated at the time of this assessment. By program, verification sampling was scheduled monthly.	
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.	No

Comment:	Verification sampling had not been initiated at the time of this assessment. By program, verification was conducted concurrently with testing for ECH7. A positive result for ECH7 resulted in taking of a new verification sample.	
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	No
Comment:	Verification sampling had not been initiated at the time of this assessment. By program, grinding of verification samples was required.	
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.	No
Comment:	Verification sampling had not been initiated at the time of this assessment. By program, verification sampling was conducted monthly through the calendar year.	
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.	Not Applicable
Comment:	Verification sampling had not been initiated at the time of this assessment.	
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.	Not Applicable
Comment:	Verification sampling had not been initiated at the time of this assessment.	
3.7	Aseptic technique being followed when performing verification testing.	Not Applicable
Comment:	Verification sampling had not been initiated at the time of this assessment.	
3.8	Where possible, surface tissue being targeted over internal tissue.	Not Applicable
Comment:	Verification sampling had not been initiated at the time of this assessment.	
3.9	Excision sub-samples are being collected from distinctly different pieces.	Not Applicable
Comment:	Verification sampling had not been initiated at the time of this assessment.	
3.10	List piece count of the final sample if applicable.	Not Applicable
Comment:	Verification sampling had not been initiated at the time of this assessment.	
3.11	List weight of the final sample.	Not Applicable
Comment:	Verification sampling had not been initiated at the time of this assessment.	

4 Testing Laboratory

Result

Laboratory Information

Lab Name	Lab Location

IEH	Spokane Washington

List Accreditation and/or Third Party Audit & date.

Accredited A2LA to ISO/IEC 17025:2017 standards valid through 2/3/22

4.2	If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas.	Not Applicable
Comment:	A laboratory was not located onsite.	
4.3	Controls to prevent pathogen contamination are in place.	Not Applicable
Comment:	A laboratory was not located onsite.	
4.5	There is a program for running positive controls/cultures with documented records for all analyses.	Not Applicable
Comment:	Sampling had not started at the time of this assessment so verification was not possible.	
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 was performed annually. The most recent results were presented as verification.	

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:	The testing protocol specified that 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:	The testing protocol specified that 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:	The testing protocol specified that 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:	The testing protocol specified that the testing method was PCR AOAC RI-100701	

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-100701	1:5 dilution 42C for 10 hours
Method 2		
Method 3		

5.6	If method includes “wet” compositing, is the method validated?	Not Applicable
Comment:	The testing protocol specified that wet compositing was not performed.	
5.7	Presumptive positives are deemed positive if not culturally confirmed.	Yes
Comment:	By program, product disposition was based on initial test 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:	By program, product disposition was based on initial test results.	
5.9	Confirmation capability of the lab is validated.	Yes
Comment:	Validation was performed annually and was presented as verification.	
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 company program "High Event Period" was written to define actions taken if non negative rates exceeded control limits.	

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.	Not Applicable
Comment:	The testing protocol specified that product destined for raw ground use was accompanied with a COA indicating it was tested for *E. coli* O157:H7 and found negative. COAs were not available for review.	
6.2	All laboratory results are subject to a minimum of a dual review and approval process.	Not Applicable
Comment:	The testing protocol specified that results were subjected to secondary review. COAs were not available for review.	
6.3	Each Certificate of Analysis has its own unique number or identifier.	Not Applicable
Comment:	The testing protocol specified that COAs were identified by report number that correlated to sample number. COAs were not available for review.	
6.4	COA’s that are revised indicate a revision date, revision reason and are traceable to the original COA.	Not Applicable
Comment:	The testing protocol specified that revised COAs referenced a revision date, reason for revision, and were traceable to the original COA. COAs were not available for review.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	Not Applicable

Comment:	The testing protocol specified that the document was headed "Certificate of Analysis". COAs were not available for review.	
6.6	The type of test and testing method used are listed on the Certificate of Analysis.	Not Applicable
Comment:	The testing protocol specified that test method and type were listed in the body of the report. COAs were not available for review.	
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, Mark Sarratt, do not have a conflict of interest with this auditee and the audit has been carried out independently, and impartially.	