Audit Report

Beef Trim N60 Addendum

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

Audit Date: March 21, 2023
Auditor: Tamara DeFord

Audit Summary

Company Name:	Missouri Prime Beef Packers	Company ID:	AUMISPRI
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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:	Missouri Prime Beef employed multiple hurdle interventions to carcasses, primal, and trimmings. Including lactic acid in the pre-evisceration cabinet, PAA in the post-evisceration wash cabinet, steam vacuum, lactic acid in the anti-microbial intervention cabinet (CCP), and PAA on trim lines.	

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 Post Evisceration	Concentration <600 ppm measured through titration
Lactic Acid Application Carcass Final Cabinet (CCP), and pre-evisceration	Concentration > 2% < 5% measured through titration, temperature < 131 F, pressure (CCP and pre-evisceration cabinet)
Lactic Acid Application Offal Products (CCP)	Concentration > 2% < 5% measured through titration, temperature < 131 F, pressure (CCP)
Steam vacuums on hide opening patterns	Temperature and pressure

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?

Application of organic acid to trimmings.	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	Validation of the Antimicrobial Efficacy of Steam Vacuum, Lactic Acid, and Peroxyacetic Acid During Slaughter and Fabrication final on May 16, 2022.

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, pSTECS monthly verification sampling, 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?	Yes
Comment:	Combo trim was 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 not routinely produced, however if produced, boxed trim was made from previously tested combos.	
2.4	Written sampling program in place for box trim	Yes

Comment:	Box trim was not routinely produced, however if produced, boxed trim was made from previously tested combos.	
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, AMR or 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:	Head, cheek, heart, and 85/15 trim, 90/10 trim, 93/7 trim were produced intended for raw ground use.	
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. The Pathogen Sampling SOP (9/08/2022) outlined N60 excision and N60+ sampling of head, cheek, heart, and trim.	
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 and IEH N60+ sampling 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 and core sampling was utilized.	

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, and IEH N60+ core sampling.

2.12	If procedure is modified from traditional excision, is there validation documentation?	Yes
Comment:	Validation Data for Pathogen Sampling Surface Excision Sampling and the IEH N60 Plus Sampler for Beef Trim 12/29/2021 was provided.	
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 for traditional excision samples daily by visual confirmation recorded on the sample form. Third party laboratory verified piece counts for each sample received and documented counts within their programs. Piece counts were not applicable to the N60+ sampling methods.	

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 and documentation of sample weights daily on sample forms. Sample target was 375 grams with a maximum of 400 grams and minimum of 360 grams for samples collected via traditional excision. N60 plus target weight was 104 grams. Sampling was not allowed after sample collection.	
2.15	Does sampling program target – where possible - surface tissue over internal tissue?	Yes
Comment:	Sampling program specified selection of external tissue if excision sampling was performed.	
2.16	Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces?	Yes
Comment:	Sampling program specified sampling from 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 documentation of slow fill times.	
2.19	OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	Yes
Comment:	Trim sampling was performed following aseptic procedures. The SOP for sampling were observed in compliance with company procedures.	
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 was conducted annually for sampling personnel. Visual verification for competency was conducted daily with records from the week of 11/28/2022 available for review.	
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
Trimmings	Combos	Lotting was single combos.
Offal products	Production Day	Products were segregated by 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 sampling was performed monthly. By program, verification was conducted concurrently with testing for ECH7. A positive result for ECH7 resulted in taking of a new verification sample.	
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:	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	Yes
Comment:	Grinding of verification samples was performed.	
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 monthly through the calendar year on trimmings. Offal products were not subject to verification sampling at the time of this assessment. Samples were selected on: 7/30/2022, 8/02/2022, 9/01/2022, 10/27/2022, 11/15/2022, 12/01/2022, 1/04/2023, 2/13/2023, and 3/01/2023. All samples returned a negative result.	
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:	Observation of sampling and check samples was performed during this audit. Verification 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.	Yes
Comment:	The third party verification occurred during 10/27/2022, and the observation sample was tested at a third party laboratory.	
3.7	Aseptic technique being followed when performing verification testing.	Yes
Comment:	Sampling equipment was observed sanitized in 180F water, and offline grinder was cleaned and sanitized by third party sanitation personnel. Sterile whirl-pak style bags were used.	
3.8	Where possible, surface tissue being targeted over internal tissue.	Yes

Comment:	Sampling was with the IEH N60+ core sampler which negated the ability to target surface tissue, but was validated as equivalent to excision sampling.	
3.9	Excision sub-samples are being collected from distinctly different pieces.	Yes
Comment:	Sampling was with the IEH N60+ core sampler which negated the ability to target surface tissue, but was validated as equivalent to excision sampling.	
3.10	List piece count of the final sample if applicable.	Not Applicable
Comment:	Samples were taken through core method.	
3.11	List weight of the final sample.	Comment Only
Comment:	186 grams	

4 Testing Laboratory

Result

Laboratory Information

Lab Name	Lab Location
IEH	Meta, MO, performed onsite at plant location.

List Accreditation and/or Third Party Audit & date.

ISO/IEC 17025:2017 accredited through ANAB with a certificate valid through 2/3/24.

4.2	If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas.	Yes
Comment:	The testing laboratory was onsite in a secure and segregated area. The laboratory was operated by a contracted service provider.	
4.3	Controls to prevent pathogen contamination are in place.	Yes
Comment:	The laboratory used dedicated and secured bins for laboratory waste and used a traffic pattern that did not enter production areas.	
4.5	There is a program for running positive controls/cultures with documented records for all analyses.	Yes
Comment:	Test kits were verified prior to use and a blank (negative control) was run with each analysis. Results were documented.	
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 underwent proficiency testing quarterly with results from 11/14/2022 were reviewed. The most recent quarter result (3/20/2023) was pending.	

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).	Yes
Comment:	The third-party laboratory enriched samples intact (one combo) and composited five of the combos for the test. Retain sample of the original combo sample was stored by the lab for confirmation testing if required by customer.	
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).	Yes
Comment:	The third-party laboratory enriched samples intact (one combo) and composited five of the combos for the test. Retain sample of the original combo sample was stored by the lab for confirmation testing if required by customer.	
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 PCR	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 validated method was AOAC RI 100701 PCR NB 217.01	
5.7	Presumptive positives are deemed positive if not culturally confirmed.	Yes
Comment:	Product disposition was based on initial test results though customer could request culture confirmation.	
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 test results though customer could request culture confirmation.	
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.	Yes
Comment:	Product destined for raw ground use was accompanied with a COA indicating it was tested for *E. coli* O157:H7 and found negative.	
6.2	All laboratory results are subject to a minimum of a dual review and approval process.	Yes
Comment:	The testing protocol specified that results were subjected to secondary review.	
6.3	Each Certificate of Analysis has its own unique number or identifier.	Yes
Comment:	COAs were identified by report number that correlated to product lot number.	
6.4	COA's that are revised indicate a revision date, revision reason and are traceable to the original COA.	Yes
Comment:	Revised COAs referenced a revision date, reason for revision, and were traceable to the original COA.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	Yes
Comment:	The document was headed Certificate of Analysis.	
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 at the bottom of the report.	
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, Tamara Deford, do not have a conflict of interest with this auditee and the audit has been carried out independently, and impartially.	