

Audit Report

Beef Trim N60 Addendum

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

Audit Date: April 21, 2022 Auditor: Mark Sarratt



Audit Summary

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

| Contact Name: | Megan McLaughlin | |
|------------------------|------------------------|--|
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| Audit ID: | AO-003355 |
|---------------|----------------|
| Audit Date: | April 21, 2022 |
| Audit Type: | Annual audit |
| Audit Result: | Completed |

| Auditor Name: | Mark Sarratt |
|------------------------|-----------------------|
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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 used a 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? |
|---|---|
| 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 | Pre/Post reduction of generic 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, pSTECS monthly verification, 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. | |
| 2.4 | Written sampling program in place for box trim | No |
| Comment: | A boxed trim testing protocol was not written. | |
| 2.5 | Facility produces FTB, BLBT, LTB, AMR or similar material? | No |
| 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: | Other beef components were being produced. | | | |
| 2.8 | Written sampling program in place | for other raw beef components | | Yes |
| Comment: | A written program for sampling other | er beef components was in place. | | |
| 2.9 | Sampling program is demonstrated or better to the N=60 'best practice N=60, describe sampling process a | ' program for 95% or better statisti | | Yes |
| Comment: | The site used traditional N=60 exci | sion, and IEH N60+ sampling met | hods. | |
| 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.] | | | |
| Comment: | Traditional excision, and core samp | oling. | | |
| | 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, and IEH N60+ core sampling. | |
| 2.12 | If procedure is modified from traditi | onal excision, is there validation d | ocumentation? | Yes |
| Comment: | "Comparison of Organism Recovery Using Surface Excision Sampling and the IEH N60 Plus Sampler for Beef Trim 1/29/09". | | | |
| 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 daily. | | | |
| 2.14 | Facility verifies sample weights? Describe the process and list the frequency in Yes Comments. List sample weight minimum, maximum, and target. List how weight verification is documented. | | | |
| Comment: | Plant programs specified verification of sample weights daily. Sample target was 375 grams with a maximum of 400 grams and minimum of 360 grams. | | | |
| 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 Yes different trim pieces? | | | |
| 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. | Yes |
|----------|---|-----|
| 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: | Trim sampling was performed following aseptic procedures. The SOP for sampling was followed in all aspects observed. | |
| 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. | |
| | 1-10' | |

Lot Size

| Туре | 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. | |
| 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: 4/4/22, 3/2/22, 2/1/22, 1/13/22, 12/11/21, 11/30/21, 10/6/21, 9/3/21, and 8/2/21. 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 April, and the observation sample was tested at a third party laboratory. | |
| 3.7 | Aseptic technique being followed when performing verification testing. | Yes |
| Comment: | Aseptic procedures were followed. | |
| 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: | 182 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/ | | | | | |

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 but 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.

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 the previous two

quarters provided for review.

5 Lab Methods

4.6

| | | 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 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: | 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 <i>E. coli</i> 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: | Wet compositing was not performed. | |
| 5.7 | Presumptive positives are deemed positive if not culturally confirmed. | Yes |
| Comment: | 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: | 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. | Yes |
| Comment: | Product destined for raw ground use was accompanied with a COA indicating it was tested for <i>E. coli</i> 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, Mark Sarratt, do not have a conflict of interest with this auditee and the audit has been carried out independently, and impartially. | |