Audit Report

Beef Trim N60 Addendum

National Beef Packing Co., LLC. - Liberal
1501 East 8th Avenue
Liberal, Kansas 67905

Audit Date: October 10, 2023
Auditor: Rudy Hernandez

Audit Summary

Company Name:	National Beef Packing Co., LLC. - Liberal	Company ID:	AUNATLIB
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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 a biological hazard identified as reasonably likely to occur in facility 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:	Caustic acid, hot water, lactic acid, and peracetic acid were utilized as antimicrobial interventions.	

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?
Caustic acid applied through the hide on carcass wash	Caustic acid applied through the hide on carcass wash
Lactic acid on hide opening and post final hot water wash	Concentration, coverage, and temperature
Hot water pre-evisceration wash	Temperature, pressure, and application coverage
Peracetic acid applied to carcasses post evisceration and to heads, hearts, boneless beef, livers, and weasand (CCP)	Concentration and nozzle function (CCP)
Hot water applied to carcasses through CHAD cabinets 1 and 2 (CCP) and to heads through the head wash	Temperature, pressure, and nozzle function (CCP)
PAA applied to carcasses through the transfer cabinet from the hot box to the sales cooler	Concentration and coverage

Bacteriophage applied to live cattle during warmer months	Monthly viability sample

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?
PAA applied through the pre-fabrication cabinet, chuck cabinet, trim belts, and primal belts	Concentration and 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	Whizzard Lactic Acid Application Est. 208A Liberal Plant Microbial Validation 9/10/23 Carcass Pre Fabrication Peracetic Wash Est. 208A Liberal Plant Microbial Validation 10/5/23. Final Carcass Wash Lactic Acid Wash Est. 208A Liberal Plant Microbial Validation 9/10/23. Final Carcass Peracetic Acid Wash Est. 208A Liberal Plant Microbial Validation 9/10/23. Heart Peracetic Wash Est. 208A Liberal Plant Microbial Validation 7/13/2023 Boneless Beef Est. 208A Microbial Validation 4/9/23 Head Wash Peracetic Acid Est. 208A Liberal Plant Microbial Validation 9/10/23 Transfer Hallway Peracetic Wash Est. 208A Liberal Plant Microbial Validation 10/5/23 Primal Peracetic Treatment Est. 208A Liberal Plant Microbial Validation 7/33/23 Trim Peracetic Treatment Est. 208A Liberal Plant Microbial Validation 7/13/23 Carcass Pre Fabrication Neck Peracetic Wash Est. 208A Liberal Plant Microbial Validation 7/13/23

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

Generic *E. coli* swabs were collected from one out of every 300 carcasses processed. Carcass mapping swabs were collected at hide-on, before the pre-evisceration cabinet, before the final wash, after the final wash, before the transfer cabinet, after the transfer cabinet, and after the pre-fabrication cabinet for TPC, coliforms, and generic *E. coli*. Swabs were collected three times per shift from three carcasses; carcasses were swabbed on the round, chuck, and midline. Products for raw ground use were sampled and tested per identified lot for *E. coli* O157:H7. Process Assessment sampling of such products for pSTEC was conducted monthly for both variety meats and boneless trim.

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: PAA was applied to trim belts prior to 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:	Sampling and Testing Procedures MCT Combo Individual Combo Sub Samples MicroTally Swab Combo Sampling and Testing Procedure and Beef *E. coli* O157:H7 and STEC Testing program defined combo sampling requirements.	
2.3	Facility produces box trim?	no
Comment:	Boxed trim was not produced.	
2.4	Written sampling program in place for box trim	Not Applicable
Comment:	Boxed trim was not produced.	
2.5	Facility produces FTB, BLBT, LTB, AMR or similar material?	yes
Comment:	AMR was produced.	
2.6	Written sampling program in place for FTB, BLBT, LTB, AMR or similar material	yes
Comment:	National Beef Packing Co. LLC Intermediate Lean Sampling Procedures *E. coli* O157:H7, Iron, Calcium was implemented for sampling of AMR.	
2.7	Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc.)?	yes
Comment:	Head meat, cheek meat, boneless trim, and hearts were produced.	
2.8	Written sampling program in place for other raw beef components	yes
Comment:	The Process Assessment Testing Procedures for Offal Products Intended for Use as Non-Intact SOP was implemented for offal testing.	
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:	N60 sampling, and manual cloth sampling were performed.	
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:	Trim samples were collected through manual cloth sampling, or traditional excision. Offal samples were collected via traditional excision. AMR samples were collected using N60 grab sample.	

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	Variety meats were sampled via traditional excision. Trim was sampled via microtally cloth. AMR was N60 grab sample.

2.12	If procedure is modified from traditional excision, is there validation documentation?	yes
Comment:	Validation for the manual cloth sampling method was through the MARC MSD Validation Study. "Novel Continuous and Manual Sampling Methods for Beef Trim Microbiological Testing. Wheeler, T.L. and Arthur, T.M. 2018".	
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:	The laboratory did not verify sample counts. Weekly verifications of sample counts by QA management, of samples collected through traditional excision, were documented on the National Beef Verification of *E. coli* O157:H7 Sampling for Trimmings/Naked in Combo Primals and Verification of *E. coli* O157:H7 Sampling for Offal sheets. Verification of time required for use of the Micro Tally cloth sampling was also documented once per week on these forms. Records from the week of 4/26/23 evidenced program 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:	Weights were verified on each sample collected by the laboratory and QA technicians if excision sampling was performed. Sample weights were also verified weekly by QA management, with verifications documented on the National Beef Verification of *E. coli* O157:H7 Sampling for Trimmings/Naked in Combo Primals/AMR and Verification of *E. coli* O157:H7 Sampling for Offal sheets. Target sample weights were 375g to 450g with a target of 375g for each sample type. This question was not applicable to samples collected with the Micro Tally cloth.	
2.15	Does sampling program target – where possible - surface tissue over internal tissue?	yes
Comment:	Sampling protocols targeted surface tissue when performing excision sampling.	
2.16	Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces?	yes
Comment:	Samples were collected from distinctly different trim pieces when excision was performed.	
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:	Cloth sampling was utilized for sampling large pieces.	
2.18	Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	yes
Comment:	Protocols required that these combos were sampled when 3/4 full and full. Slow fill combos did not remain on the floor for more than two hours. Combos were identified by lot number, product code, and identification number. Combo fill times were documented.	
2.19	OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	yes

Comment: The sampling of trim combos observed was performed following procedures defined in the documented sampling protocol. Sampling equipment, sleeves, and gloves were sanitized using hot alcohol-based sanitizer before sampling and allowed to dry. Gloves and sleeves were changed between samples collected. Care was taken with the cloth to ensure cross-contamination did not occur, and the sample was massaged for the required amount of time.

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: Weekly verifications of procedures used for excision sampling, Micro Tally Cloth sampling, and grab sampling were performed by QA management, with results documented on the verification documents. Records from the week of 4/26/23 were presented and supported program compliance. Annual training was conducted for employees performing sample collection. Training records from YTD 2023 were presented as verification.

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 method support was defined within sampling programs.

Lot Size

Type	Lot Size	Comment
Combo Trim	Combos	A single combo was identified as one lot.
Head meat, hearts, cheek meat, tongue root muscle	Production Day	A production day was considered a lot.
AMR	Production Day	A production day was considered a lot.

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: Process Assessment verification samples were collected monthly. Samples for *E. coli* O157:H7 and pSTEC were collected at the same time, with the pSTEC sample held until initial *E. coli* O157:H7 test results were received. If a non-negative result was received, a new product was selected for Process Assessment testing.

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: Process Assessment verification samples were collected monthly. Samples for *E. coli* O157:H7 and pSTEC were collected at the same time, with the pSTEC sample held until initial *E. coli* O157:H7 test results were received. If a non-negative result was received, a new product was selected for Process Assessment testing.

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:	Process Assessment verification samples were collected from ground product.	
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 samples were collected monthly. Testing results from the following dates were reviewed and returned negative results. Trim - 10/26/2022, 11/15/2022, 12/20/2022, 1/18/2022, 2/7/2023, 3/21/2023, 4/12/2023, 5/2/2023, 6/13/2023, 7/18/2023, 8/8/2023. and 9/12/2023. Offal - 10/26/2022, 11/15/2022, 12/10/2022, 1/18/2023, 2/7/2023, 3/21/2023, 4/13/2023, 5/2/2023, 6/13/2023, 7/18/2023, 8/8/2023, and 9/12/2023. AMR was not subjected to verification testing.	
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 observations by a third party typically occurred twice per year. Most recent verification observation occurred in October 2023. Verification samples were sent to a third party laboratory for 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:	Observations occurred between April and October of the calendar year. A third party laboratory was used for verification testing.	
3.7	Aseptic technique being followed when performing verification testing.	yes
Comment:	Aseptic technique was followed. The observed combo was sampled using a core drill inserted into multiple locations that covered the entirety of the combo. Samples were ground twice through a floor grinder prior to selection. Sampling drill, collection container, and grinder were sanitized prior to starting the process.	
3.8	Where possible, surface tissue being targeted over internal tissue.	Not Applicable
Comment:	Samples were collected via core drill.	
3.9	Excision sub-samples are being collected from distinctly different pieces.	Not Applicable
Comment:	Samples were collected via core drill.	
3.10	List piece count of the final sample if applicable.	Not Applicable
Comment:	Samples were collected via core drill.	
3.11	List weight of the final sample.	Comment Only
Comment:	392 grams	

4 Testing Laboratory

Result

Laboratory Information

Lab Name	Lab Location
National Beef Food Safety Center	Liberal, Kansas

List Accreditation and/or Third Party Audit & date.

ISO 17025:2017 certificate through A2LA with a certificate valid until 6/30/24.

4.2 If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas. — yes

Comment: The Food Safety Center laboratory was physically segregated from the plant and was housed in a secured building with limited access. Employees delivering samples did not enter the lab. Only laboratory employees entered the facility unless otherwise granted permission.

4.3 Controls to prevent pathogen contamination are in place. — yes

Comment: Food Safety Center Microbiology Laboratory Quality Control Manual defined sanitation and contamination prevention protocols. Areas within the lab were segregated with dedicated employees.

4.5 There is a program for running positive controls/cultures with documented records for all analyses. — yes

Comment: The site ran a positive control with each batch of samples tested. Results were maintained electronically and were graphed each quarter.

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 participated in quarterly proficiency testing through AOAC. Records presented included verification of the previous three proficiency tests conducted through AOAC dated 10/10/22, 1/30/23, 4/24/23, and 7/24/23.

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 as intact slices if excision was performed. The cloth was enriched as an intact material.

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 *E. coli* O157:H7 [including Cluster A strains].	yes
Comment:	PCR DNA amplification was used for detection of *E. coli* O157:H7.	

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	Hygenia BAX (AOAC PTM 102.003)	Sample enrichment was 1:5 dilution, 8-18 hours, at 42 C.
Method 2		
Method 3		

5.6	If method includes “wet” compositing, is the method validated?	no
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 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 on the entire enrichment.	

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:	The Justification for High Event Period Program defined requirements for handling 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:	Product intended for raw ground use was accompanied by a certificate of analysis including negative *E. coli* O157:H7 results for each tested 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 and documented on COAs and Sample Requirement Sheets.	
6.3	Each Certificate of Analysis has its own unique number or identifier.	yes
Comment:	The report number served as the unique identifier for each COA.	
6.4	COA's that are revised indicate a revision date, revision reason and are traceable to the original COA.	yes
Comment:	The superseding process was utilized to trace revised COAs back to the original COA. The original report was referenced and included the revision date and reason for revisions. Each report number and revised label were listed. An example from August 2023 was reviewed and demonstrated compliance.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	yes
Comment:	Test results were labeled as a Certificate of Analysis.	
6.6	The type of test and testing method used are listed on the Certificate of Analysis.	yes
Comment:	Test type and method 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, Rudy Hernandez, do not have a conflict of interest with this auditee	