EAudit Report

Beef Trim N60 Addendum

CS Beef Packers, LLC
17365 South Cole Road
Kuna, Idaho 83634

Audit Date: July 16, 2024
Auditor: Rudy Hernandez

Audit Summary

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Beef Trim -- N60 Addendum

1 Interventions for Pathogen Reduction

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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 reasonable likely to occur in the 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 site used hot water pasteurization, lactic acid, peroxyacetic acid, and acidified sodium chlorite.	

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?
Peroxyacetic acid (CCP)	Concentration, temperature, pressure, and coverage
Acidified sodium chlorite	Concentration, temperature, pressure, and coverage
Lactic acid	Concentration, temperature, pressure, and coverage
Hypobromus acid	Concentration, temperature, pressure, and coverage
Hot water pasteurization (CCP)	Temperature, pressure, and coverage

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?
Acidified sodium chlorite	Concentration, temperature, pressure, 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	2023 Process Validation - CS Beef 5/15 - 5/17/2023

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

Ongoing verifications included sampling one out of every 300 head harvested for generic *E. coli*, quarterly process validations, which consisted of sampling carcasses pre- and post-intervention, and CCP/pre-requisite program monitoring of operating parameters.

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: ASC was applied to trimmings prior to combo fill and sampling.

2 Sampling Programs for Products Destined for Raw, Ground

2 Note: A minimum of N=60 testing per lot for *E. coli* O157:H7 is performed on beef trim and other raw beef components [i.e., head meat, hearts, etc.] produced in the plant that are 'intended for raw ground use'. Sampling programs must be written and supported with validation data and documentation. Related documents shall be available for review upon request.

2.1 Facility produces combo trim? — Yes

Comment: Combo trim was produced.

2.2 Written sampling program in place for combo trim — Yes

Comment: CP 12 MSD Micro Tally Cloth Sampling

2.3 Facility produces box trim? — Yes

Comment: Boxed trim was produced.

2.4 Written sampling program in place for box trim — Yes

Comment: CP1 N60 and N60 Plus Procedure was implemented.

2.5 Facility produces FTB, BLBT, LTB, AMR or similar material? — No

Comment: Such were not produced.

2.6	Written sampling program in place for FTB, BLBT, LTB, AMR or similar material	Not Applicable
Comment:	Such were not produced.	

2.7	Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc.)?	Yes
Comment:	The site produced and tested head meat, hearts, salivary glands, and cheek meat.	

2.8	Written sampling program in place for other raw beef components	Yes
Comment:	CP1 N60 and N60 Plus Procedure.	

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 excision sampling was used for a variety meat products and boxed trim. Trim samples were collected using the manual cloth method. Cloth Sampling Validation—4/17/2018.	

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:	Box trim and variety meat samples were collected by traditional N60 excision sampling. Combo trimming samples were collected by MSD (manual sampling device) using the cloth method.	

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.]	Modified Excision	Box trim and variety meat samples were collected by traditional N60 excision sampling. Combo trimming samples were collected by MSD (manual sampling device) using the cloth method.

2.12	If procedure is modified from traditional excision, is there validation documentation?	Yes
Comment:	Cloth Sampling Validation - 4/17/2018 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?	No
Comment:	Sample counts were not verified for variety meats and such was not applicable to cloth sampling.	

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 for variety meats were verified once per period and recorded on the Variety Meats Sampling Checks form and boxed trim when produced. Sample weight minimum was 375g, maximum was 400g, and target was 400g.

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

Comment: External tissue was targeted.

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

Comment: Excision samples were required to be collected from distinctly different pieces. Cloth samples were collected from the entire surface of the top 1/3 of the combo bin.

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: Larger pieces of product were not product. The site cut larger pieces in to manageable sizes to accommodate sampling.

2.18 Is there a program in place to address the handling of lotting for slow fill versus fast fill combos? Yes

Comment: Combo fill start and stop times were recorded on each combo bin. There were no combo fill stations that required longer than one production period to fill.

2.19 OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP. Yes

Comment: Samples were collected according to written protocols. The employee collecting the sample sanitized their plastic gloves and sleeves. Sample technique and collection time were consistent with the sampling 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: Employees conducting sampling were trained initially and annually. Records of the most recent training conducted from YTD 2024 were available. Verification of sampling technique occurred during initial qualification and during annual refresher training. Reviews were documented within the training.

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 lot
Boxed trim	Pallets	Up to five pallets

Variety meats	Other	Per production period

3 Verification Testing / Check Sample Program

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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 conducted quarterly.	
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 of trim, and VM was collected from product sampled using traditional N60 methods with results reported as negative. If reports were non-negative, a new verification sample would be taken.	
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 sample was ground prior to sample collection.	
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 quarterly. Testing for the past three quarters was conducted on 1/5/2024, 4/1/2024, 7/2/2024.	
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 a third party annually. Laboratory testing was conducted by a third party.	
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 samples occurred annually in August. Samples were sent to a third party laboratory.	
3.7	Aseptic technique being followed when performing verification testing.	Yes

Comment: Verification samples were collected aseptically. The offline grinder and collection tubs were clean and sanitized. The employee collecting the sample sanitized plastic gloves and sleeves.

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. Not Applicable

Comment: The sample was collected by grab sample and ground in an offline grinder.

3.10 List piece count of the final sample if applicable. Not Applicable

Comment: Final sample was from ground product.

3.11 List weight of the final sample. Comment Only

Comment: The final sample weight was 416 grams.

4 Testing Laboratory

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Laboratory Information

Lab Name	Lab Location
FSNS	Boise, Idaho

List Accreditation and/or Third Party Audit & date.

The laboratory was ISO 17025:2005 accredited through A2LA with a certificate valid until 7/31/2025. The laboratory participated in proficiency testing three times per year.

4.2 If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas. Not Applicable

Comment: Laboratory testing conducted offsite.

4.3 Controls to prevent pathogen contamination are in place. Not Applicable

Comment: Laboratory testing conducted offsite.

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

Comment: Positive controls were run 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 participated in proficiency testing through LGC. Records were available for review.

5 Lab Methods

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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 not utilized.	
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 not utilized.	
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 screening method was utilized.	

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	PCR-BAX RT Exact	8-10 hours @ 42C (+/-2C) and a 1:5 dilution factor (meat), 200ml (cloth)
Method 2		
Method 3		

5.6	If method includes "wet" compositing, is the method validated?	Not Applicable
Comment:	Wet compositing not utilized.	
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.	Not Applicable
Comment:	Cultural confirmation not conducted.	
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:	CP 21 High Event Period explained procedures for managing event days.	

6 Certificate of Analysis

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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 each shipment of trimming destined for raw ground use.	
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 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 was noted in the 'remarks' section of the report, with a reference to the original COA report number.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	Yes
Comment:	Analytical Results was printed across the top of the report.	
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 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.	