Audit Report

Beef Trim N60 Addendum

Upper Iowa Beef, LLC
4614 Highway 63
Lime Springs, Iowa 52155

Audit Date: June 24, 2025
Auditor: Danielle Massukado

Audit Summary

Company Name:	Upper Iowa Beef, LLC	Company ID:	AUUPPLIM
Address:	4614 Highway 63 Lime Springs, Iowa 52155		

Contact Name:	Annette Kime
Contact Phone Number:	563-566-2202
Contact Email Address:	akime@upperiowabeef.com

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Auditor Name:	Danielle Massukado
Auditor Phone Number:	
Auditor Email Address:	danielle.massukado@fsns.com

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 hazard in the HACCP plan covering slaughter and fabrication.	
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 bromine (DBDMH), lactic acid, and peroxyacetic acid 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?
Bromine ((DBDMH - BoviBrom) post-evisceration carcass wash (optional) and variety meats and head products (CCP)	Concentration, temperature, and coverage
Lactic acid application carcasses post carcass wash (CCP)	Concentration, temperature, and coverage

Fabrication Interventions

Fabrication Interventions	What parameters are monitored?
Peroxyacetic acid on the primal lines	Concentration, application
Peroxyacetic acid on trim belts	Concentration, application

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	Slaughter HACCP Validation 01/20/20
Other	Investigation of the Uses of 1,3 Dibromo 5,5 Dimethyl hydantoin (DBDMH) in beef harvest interventions. Colorado State University. 02/15/18.
In-house Validation	In-Plant Validation of Anti-Microbial Interventions Used for Reduction of *Escherichia coli* O157:H7 on Beef Carcasses, FSNS, Alex Brandt, PhD 07/13/22

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

Ongoing verifications included carcass swabbing of one out of every 300 head for generic *E. coli* and sampling for *E. coli* O157:H7 on materials intended for raw ground use. One swab from the rump and brisket was collected pre- and post-bromine (DBDMH - BoviBrom) carcass wash and lactic cabinet (CCP) monthly, which was tested for EB and APC.

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: The facility used peracetic acid on trim belts in fabrication.

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: The site produced combo trim.

2.2 Written sampling program in place for combo trim Yes

Comment: The Pathogen Testing and Sampling Procedure detailed 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:	Such was not produced.	
2.5	Facility produces FTB, BLBT, LTB, AMR or similar material?	No
Comment:	Such was not produced.	
2.6	Written sampling program in place for FTB, BLBT, LTB, AMRor similar material	Not Applicable
Comment:	Such was not produced.	
2.7	Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc.)?	No
Comment:	Such was not intended for grinding.	
2.8	Written sampling program in place for other raw beef components	Not Applicable
Comment:	Such was not intended for grinding.	
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:	Evaluation of Continuous and Manual Sampling Devices as Sample Collection Methods for Upper Iowa Beef by Terry Arthur and Tommy Wheeler at the Meat Safety and Quality Research Unit, U.S. Meat Animal Research Center, Clay Center, NE, November 10, 2020, evidenced that the sampling methods were equivalent or better than N=60.	
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 currently sampled using the MSD MicroTally manual 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.]	Other	The site used the microtally cloth method on combo product.

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

Comment:	Evaluation of Continuous and Manual Sampling Devices as Sample Collection Methods for Upper Iowa Beef by Terry Arthur and Tommy Wheeler at the Meat Safety and Quality Research Unit, U.S. Meat Animal Research Center, Clay Center, NE, November 10, 2020, evidenced that the Micro Tally sampling methods were equivalent or better than N=60.	
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?	Not Applicable
Comment:	Sample counts for combo trim were not required due to use of Micro Tally method used.	
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.	Not Applicable
Comment:	Sample weights were not required due to use of Micro Tally Cloth method.	
2.15	Does sampling program target – where possible - surface tissue over internal tissue?	Not Applicable
Comment:	Cloth method was utilized.	
2.16	Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces?	Not Applicable
Comment:	Cloth method was utilized.	
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.	Not Applicable
Comment:	Large trim pieces were not produced.	
2.18	Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	Yes
Comment:	Combos of 85% trim were considered slow fill and were single combo lots that took roughly 1.5 hours to fill. Combos were numbered and time-stamped when sampled, which was completed at the time the combo was filled. Combo fill times were documented on the Sampling Single Combo Trim Lots sheet.	
2.19	OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	Yes
Comment:	Microtally cloth sampling was observed on a combo of beef trimmings. Sample collection was compliant with the 90-second requirement defined in the sampling protocol. Gloves and sleeves were sprayed with an alcohol-based sanitizer and allowed to dry prior to handling of the microtally cloth and prior to collection of the verification trim sample. The sample was collected in an aseptic manner.	
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: Daily direct observations were conducted and documented on the Sampling Single Combo Trim Lots form. Training was conducted upon hire and as needed. Current training from FY25 was available for review for all QA employees.

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: Lots were single combo and were supported in sampling protocols.

Lot Size

Type	Lot Size	Comment
Combo trim	Combos	Single combo lot

3 Verification Testing / Check Sample Program

3

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: The Pathogen Testing and Sampling Procedure required verification samples to be collected quarterly in the first and fourth quarter, and monthly in the second and third quarter.

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 concurrently with the initial *E. coli* O157:H7 sample. If either sample was non-negative, a new verification sample was selected for 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: The initial verification sample was collected through traditional excision and then ground in a benchtop grinder.

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 results were reviewed for: 2024 – 04/22/24, 05/23/24, 06/05/24, 07/10/24, 08/27/24, 09/18/24, 10/21/24; and 2025 – 02/04/25, 04/28/25, 05/19/25, 06/11/25. Results were negative.

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:	Samples were tested through a third-party laboratory. Observation occurred annually, most recently during 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.	Yes
Comment:	The previous observation was completed on 07/09/24. The most current observation occurred during this assessment on 06/26/25. Samples were tested through a third-party laboratory.	
3.7	Aseptic technique being followed when performing verification testing.	Yes
Comment:	Aseptic technique, including the use of alcohol-based sanitizer, allowing drying, and disposable gloves, was observed.	
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.	Yes
Comment:	Samples were collected from distinctly different pieces of trim on the trim belt filling a single combo.	
3.10	List piece count of the final sample if applicable.	Comment Only
Comment:	The final piece count was 60 pieces.	
3.11	List weight of the final sample.	Comment Only
Comment:	The final ground sample was 376 grams.	

4 Testing Laboratory

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Laboratory Information

Lab Name	Lab Location
FSNS	Plymouth, MN

List Accreditation and/or Third Party Audit & date.

ISO 17025:2017 accreditation through A2LA with a certificate valid until 04/30/26.

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

Comment:	Testing was outsourced to an off-site third-party laboratory.	
4.3	Controls to prevent pathogen contamination are in place.	Not Applicable
Comment:	Testing was outsourced to an off-site third-party laboratory.	
4.5	There is a program for running positive controls/cultures with documented records for all analyses.	Yes
Comment:	Positive controls were ran with each set of samples. Records were maintained in the LIMS system.	
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:	Laboratory completed proficiency testing per accreditation requirements through both LGC and A2LA throughout the year. Results 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 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 utilized for *E. coli* O157:H7 testing.	

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-AOAC RI 031002	Meat: 10-24 hours, 42C +/ 1C, 1:4 dilution. Cloth: 9-15 hours, 42C +/ 1C, 200mL
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: Presumptive positives were treated as positives and shipped for cooking only. Cultural confirmation for *E. coli* O157:H7 only was utilized to determine requirements for handling of shoulder combos and associated sub-primals. The site did not culturally confirm for non-O157 STEC. If positive then product was labeled for lethality cooking If negative, the product was still handled as a positive and was either rendered or was sold as for cooking only.

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: Presumptive positives were treated as positives and shipped for cooking only. Cultural confirmation for *E. coli* O157:H7 only was utilized to determine requirements for handling of shoulder combos and associated sub-primals. The site did not culturally confirm for non-O157 STEC. If positive then product was labeled for lethality cooking If negative, the product was still handled as a positive and was either rendered or was sold as for cooking only.

5.9 Confirmation capability of the lab is validated. Yes

Comment: Cultural confirmation was performed utilizing USDA MLG Chapter 5C. The site was only performing a confirmation for *E. coli* O157:H7 and was not performing a non-O157 STEC confirmation when a sample tested presumptive positive.

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 High Event Period Program detailed the requirements if multiple presumptive positives were detected on a single production day.

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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:	The Analytical Report from the third party laboratory was provided and showed Shiga Toxin Escherichia coli producer results as "not detected per Micro Tally Sheet" for each lot covered by the COA.	
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 laboratory used for routine sampling titled the document Analytical Results with a unique report number.	
6.4	COA's that are revised indicate a revision date, revision reason and are traceable to the original COA.	Yes
Comment:	Revised documents included revised notation in the remarks and included the date and reasons for revisions.	
6.5	The document clearly identifies that it is a Certificate of Analysis. List identifier.	Yes
Comment:	The laboratory used for routine sampling titled the document Analytical Results with a unique report number.	
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 document.	
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, Danielle Massukado, do not have a conflict of interest with this auditee.	