Beef Trim -- N60 Addendum

Company:	Iowa Premium, LLC	**Audit Date:**	February 9, 2017
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Est #, and/or FDA #:	M8	**FSNS Evaluator:**	Alyssa McMahan
Audit Number:	5170045		

PLEASE NOTE: A "NO" answer does not necessarily represent a deficiency in a facility's programs or processes.

Beef Trim -- N60 Addendum
Interventions for Pathogen Reduction

Description / Question	Response	Comments
E. coli O157:H7 is a hazard likely to occur in the facility's HACCP plan(s)?	Yes	*E.coli* O157:H7 was identified in the facility's HACCP plans.
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	The facility implemented pre-evisceration lactic acid cabinet, hot water carcass wash, pre-chill lactic acid spray, peracetic acid in chill water, and lactic acid spray entering fabrication area.
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 (CCP identified by ***bold italics***).	Slaughter	1. Pre-evisceration lactic acid spray
		2. Hot water carcass wash
		3. Pre-chill lactic acid
		4.
		5.
		6.
		7.
	Fabrication	1. Lactic acid spray entering fabrication
		2. Peracetic acid on trim lines
		3. Peracetic acid in spray chiller
		4.
		5.

Beef Trim -- N60 Addendum
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Description / Question	Response	Comments
Document what the facility is monitoring (Ex. concentration, temperature, dwell time, etc.) for each intervention **and** identify which interventions are CCPs (CCP identified by ***bold italics***).	Slaughter	1. Mixing temperature and concentration
		2. Temperature, pressure, nozzle function
		3. Concentration and mixing temperature
		4.
		5.
		6.
		7.
	Fabrication	1.Concentration and mixing temperature
		2. Concentration
		3. Concentration
		4.
		5.
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.]	In-house Validation	Data Analysis of Hot Water Cabinet Iowa Premium Beef. 1/12/17
	Journal Article	Treatments using Hot Water Instead of Lactic Acid Reduce Levels of Aerobic Bacteria and Enterobacteriaceae and Reduce the Prevalence of *Escherichia coli* O157:H7 on pre-evisceration Beef Carcass. Journal of Food Protection Vol 69, No. 8, 2006. Pages 1803-1813.

Beef Trim -- N60 Addendum
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Description / Question	Response	Comments
List all on-going verification programs for microbiological interventions and pathogen reduction processing aids.	Carcass swabs were taken by the facility as verification of interventions. Harvest Monitoring Swabs were taken once per hour swabs at hide-on, hide-off, prior to pre-evisceration wash and post final carcass lactic acid wash.	
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	Trim was sprayed with PAA prior to being comboed.

Beef Trim -- N60 Addendum
Sampling Programs for Products Destined for Raw, Ground

Description / Question	Response	Comments
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.		
Facility produces combo trim?	Yes	The facility produced combo trim.
Written sampling program in place for combo trim?	Yes	The Beef *E.coli* O157:H7 and STEC Testing program was implemented for testing of combo trim.
Facility produces box trim?	No	The facility did not produce box trim.
Written sampling program in place for box trim?	No	The facility did not produce box trim.
Facility produces FTB, BLBT, LTB, AMR?	No	The facility did not produce FTB, BLBT, LTB, or AMR.
Written sampling program in place for FTB, BLBT, LTB, AMR?	No	The facility did not produce FTB, BLBT, LTB, or AMR.
Facility produces other raw beef components (head meat, cheek meat, hearts, tongue root, etc.)?	Yes	The facility produced hearts, head meat, cheek meat and weasand.
Written sampling program in place for other raw beef components?	Yes	The Variety Meats Sampling program was implemented.

Beef Trim -- N60 Addendum
Sampling Programs for Products Destined for Raw, Ground

Description / Question	Response	Comments
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 Other	The facility used the IEH N60 plus sampling methods which was validated on June 16, 2015.
Sampling program specifics [Note – Auditor should distinguish differences – where applicable - in sampling programs. For example, combo trim programs may differ from FTB programs]:		
How are the samples collected? [For example, traditional excision, modified excision or mechanical. NOTE – Traditional excision is defined as the USDA sampling method.]	Mechanical	Samples were collected via drill and blunt nose fluted sampling device.
If procedure is modified from traditional excision, is there validation documentation?	Yes	The facility used the IEH N60 plus sampling methods which was validated on June 16, 2015.
Does the facility verify sample counts? List the frequency in Comments (ex. X times by plant per week, X times by lab per week). *Note if sample count verification is documented.*	N/A	The sampling method did not require piece counts.
Does the facility check sample weights? Describe the process and list the frequency in Comments. List sample weight minimum, maximum, and target. *Note if weight checks are documented.*	Yes	The facility documented sample weights for every sample obtained. Weights were documented on the Fat and N60 Sampling Log. Target weight was 0.47lbs, maximum weight was 0.8lbs and minimum weight was 0.40lbs.
Does sampling program target – where possible - surface tissue over internal tissue?	Yes	The sampling program targeted surface tissue.

Beef Trim -- N60 Addendum
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Description / Question	Response	Comments
Does sampling program require each excision sub-sample to be collected from distinctly different trim pieces?	N/A	The sampling method was not designated to collect sub-samples from different trim pieces.
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	The sampling program included procedures for sampling of large pieces of trim such as two piece chucks.
Is there a program in place to address the handling of lotting for slow fill versus fast fill combos?	Yes	Start and stop times were tracked on combos.
OBSERVATION OF TRIM SAMPLING – Auditor should observe sample collection and report accuracy against specified method and SOP.	Employee conducting sampling was following sampling procedures.	
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	Employees conducting sampling were trained annually on the sampling program and techniques. Training records from 2016 were reviewed. Direct observation of employee sampling was conducted once per production period and documented.

Beef Trim -- N60 Addendum
Sampling Programs for Products Destined for Raw, Ground

Description / Question	Response	Comments
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	Lotting methods and sizes were outlined in the sampling program.
List lot size(s) for the following [lot size may be in pounds, combos, pallets, boxes, etc., list most accurate description]:		
Combo trim	Combos	Single combo was considered a lot.
Box trim	Combos	Box trim was produced from combos which was previously tested.
FTB, BLBT, LT		Not produced.
Other raw beef components	Production Day	A production day was considered a lot.

Beef Trim -- N60 Addendum
Verification Testing / Check Sample Program

Description / Question	Response	Comments
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	Ongoing verification checks were conducted monthly by the facility. Verification samples were collected at the same time as initial testing. In event of the initial test being positive, a new lot would be sampled for verification purposes.
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. Is the facility doing this?	Yes	Verification samples were taken at the same time as initial samples. Verification samples were not tested until initial sample results were obtained and negative.
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. Is the verification sample taken from finished (ground) product?	No	Verification samples were taken with N60 Plus methods.
Verification/check sampling and testing are increased to a monthly frequency for 2nd and 3rd quarters (April – September). *Auditor is to list the dates of the last **3 quarters** verification/check samples in the comments section.*	Yes	Verification testing was conducted monthly by the facility. Verification results from 2/15/16, 3/23/16, 4/15/16, 5/31/16, 6/6/16, 7/12/16, 8/16/16, 9/6/16, 10/6/16, 11/8/16, 12/31/16 and 1/25/17 were reviewed.
OBSERVATION OF VERIFICATION / CHECK SAMPLING - N60 verification/check samples shall be observed by an independent 3rd party auditor minimally 1x/year, and lab testing shall be conducted at a 3rd party lab minimally 1x/year.	Yes	Verification sampling was observed by a third party, FSNS C&A, most recently on 1/15/16. The sample was sent to a third party laboratory. This observation occurred on 2/9/17.

Beef Trim -- N60 Addendum
Verification Testing / Check Sample Program

Description / Question	Response	Comments
At least one of the 3rd 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 3rd party lab, the observation sample does not need to go to a different lab.	Yes	One verification sample was observed by a third party per year. The last observed verification sample was conducted on 1/15/16. Samples were sent to a third party laboratory.
Aseptic technique being followed when performing verification testing.	Yes	Aseptic techniques were being followed during testing.
Where possible, surface tissue being targeted over internal tissue.	Yes	Target tissue was surface tissue.
Excision sub-samples are being collected from distinctly different pieces	N/A	Verification samples were taken with N60 Plus methods.
List piece count of the final sample if applicable.	Piece counts were obtained using the N60 Plus sampling method.	
List weight of the final sample.	The final sample weight was 0.60 lbs.	

Beef Trim -- N60 Addendum
Testing Laboratory

Description / Question	Response	Comments
The laboratory must be operated under a Quality System that supports the chosen ECH7 method, which, at a minimum includes validation of employee training, sample traceability, timely transmission of COA's, and recordkeeping. Evidence of compliance is either accreditation or auditing by an independent 3rd party. A Quality System that meets ISO 17025 is acceptable. Validation documents shall be provided upon request.		
List Lab Name & Location.	Name	IEH Laboratories
	Location	Tama, IA
List Accreditation and/or 3rd Party Audit & date.	The laboratory was accredited through ANAB with a certificate valid through 1/31/19.	
If the testing for *E. coli* O157:H7 is on-site, the laboratory is physically isolated from production areas.	Yes	Tha laboratory where *E.coli* O157:H7 testing was located onsite but in a totally segregated building from the facility.
Controls to prevent pathogen contamination are in place.	N/A	Samples were collected by QA technicians and delivered to the door of the laboratory in a cooler.
There is a program for running positive controls/cultures with documented records for all analyses.	Yes	Positive controls were ran with each set of samples.
Laboratory participates in a proficiency testing program to assure accuracy of its results. Records are available for review. List proficiency program.	Yes	The laboratory participated in proficeincy testing as part of the accreditation process. The most recent accreditation was valid through 1/31/19.

Beef Trim -- N60 Addendum
Lab Methods

Description / Question	Response	Comments
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	Samples were enriched intact.
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).	Wet compositing was not being used.	
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).	Wet compositing was not being used.	
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].	PCR DNA	The laboratory used AOAC 100701 testing methods.
For the following, please note if methodologies differ based on product types (ex. trim testing has different enrich time versus ground product).		
Document all methods being used by facility.	Method 1	AOAC 100701
	Method 2	
	Method 3	

Beef Trim -- N60 Addendum
Lab Methods

Description / Question	Response	Comments
Document incubation time, temperature and dilution factor.	Method 1	9 hours, 42C, 1:1 dilution factor
	Method 2	
	Method 3	
If method includes "wet" compositing, is the method validated?	N/A	Wet compositing was not used.
Product Disposition		
Presumptive positives are deemed positive if not culturally confirmed.	Yes	Disposition of presumptive positive was determined as positive.
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	Product disposition was based on presumptive results.
Confirmation capability of the lab is validated.	Yes	The laboratory used USDA MLG 5 testing methods for confirmation.
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	Event day procedures were outlined in the Iowa Premium High Event Period SOP.

Beef Trim -- N60 Addendum
Certificate of Analysis

Description / Question		Response	Comments
[Note - Auditor shall review a Certificate of Analysis to confirm the presence, or record the absence, of the items listed below. This document may also be identified under a different name – Certificate of Conformance, Analytical Results, Laboratory Report, Testing Declaration, etc.]			
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	The COAs generated were for trim which was intended for raw ground use.
All laboratory results are subject to a minimum of a dual review and approval process.		Yes	COAs were subject to dual review approval processes.
Each Certificate of Analysis has its own unique number or identifier.		Yes	COAs were identified by a Report Number which was unique to each COA.
COA's that are revised indicate a revision date, revision reason and are traceable to the original COA.		Yes	Revised COAs were marked with the revision date and "Amended" to identified revised COA.
The document clearly identifies that it is a Certificate of Analysis. List identifier.		Yes	COAs were identified on the top of the page with "Certificate of Analysis".
The type of test and testing method used are listed on the Certificate of Analysis.		Yes	Testing methods were identified on the bottom of the COA.
Conflict of Interest Declaration	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.		I, Alyssa McMahan, do not have a conflict of interest with this auditee.