Audit Report

FSNS Beef Trim CCP Addendum

Caviness Packing Company - Hereford
3255 U.S. 60
Hereford, Texas 79045

Audit Date: November 12, 2021
Auditor: Michael Sanders

Audit Summary

Company Name:	Caviness Packing Company - Hereford	Company ID:	AUCAVHER
Address:	3255 U.S. 60 Hereford, Texas 79045		

Contact Name:	Jorge Aleman
Contact Phone Number:	806-357-2443
Contact Email Address:	jorge.aleman@cavinessbeef.com

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Auditor Name:	Michael Sanders
Auditor Phone Number:	210-744-3079
Auditor Email Address:	Michael.Sanders@FSNS.com

Definitions for the purpose of this Addendum:
Validation - Data that demonstrates there is a pathogen kill when an intervention is operating within specified parameters.
Verification - Demonstration of a microbiological reduction by an intervention when operating in validated parameter(s).
Monitoring - Checking / reading of intervention parameters / measurements (ex. Temperature, concentration, etc.).

PLEASE NOTE: A “NO” answer does not necessarily represent a deficiency in a facility’s programs or processes.

Beef Trim - CCP Addendum

1 HACCP

		Result
1.1	Adequacy of the HACCP plan is reassessed by the establishment on an annual basis or whenever changes occur that could affect the hazard analysis or alter the HACCP plan. Review the establishment's HACCP reassessment log to identify the last reassessment.	Yes
Comment:	HACCP plans were reassessed annually at a minimum or as required for process changes. The most recent reassessment occurred on 10/25/21.	
1.2	The establishment maintains records to demonstrate that responsible personnel have been trained in monitoring activities as described in their HACCP plan.	Yes
Comment:	CCP monitors received training annually and as needed; training records reviewed for 2021 evidenced program compliance.	
1.3	The establishment maintains records that confirm corrective actions are taken when there is a deviation from a critical limit.	Yes
Comment:	Corrective actions for CCP deviations met requirements of 9 CFR 417.3(a). Corrective actions from CCP zero tolerance deviations from 2021 were provided and met regulatory requirements.	

2 Interventions/Process Aids - Steam Vacuum

		Result
2.1	The establishment uses the steam vacuum intervention method.	Yes
Comment:	Steam vacuums were applied to hocks after skinning.	
2.2	The establishment identified this intervention as a CCP.	No
Comment:	Steam vacuums were not identified as a CCP.	
2.3	If the Steam Vacuum is a CCP, can the line run if this intervention is not operational or not in specification.	Not Applicable
Comment:	Steam vacuums were not identified as a CCP.	
2.4.1	None	Yes
Comment:	Validation was not provided.	
2.4.2	Validated Third Party Challenge Study or Validation Study	No
2.4.3	In-house Challenge Study or Validation Study	No
2.4.4	Third Party review of in-house challenge study or validation. List the name of the Third Party in Comments.	No
2.4.5	Resource white paper (Published Journal Article)	No
2.4.6	Resource white paper with third party review (peer reviewed paper - not published)	No

2.4.7	Other -- List in comments	No
2.5.1	A specific set of samples were chosen to support the validation hypothesis (objective).	Not Applicable
Comment:	Validation was not provided.	
2.5.2	Statistical parameters were used in the validation hypothesis and/or the analysis to support the conclusion.	Not Applicable
Comment:	Validation was not provided.	
2.5.3	Scientific support documentation.	Not Applicable
Comment:	Validation was not provided.	
2.5.4	Validation study was prepared by a third party. List the name of the third party in comments.	Not Applicable
Comment:	Validation was not provided.	
2.5.5	Other -- List in comments	Not Applicable
Comment:	Validation was not provided.	
2.6	The establishment has records demonstrating on-going verification activities for this intervention. List the Frequency in comments.	Yes
Comment:	One out of every 300 carcasses processed was swabbed for generic *E. coli* per regulatory requirements. Products intended for raw ground use were sampled and tested for *E. coli* O157:H7. Sampling and testing of finished products for non-O157 STEC, *Salmonella*, and indicator organisms including APC, coliforms, and generic *E. coli* was based on customer-specific requirements. Quarterly process validation swabs were collected on ten carcasses pre and post interventions; swabs were tested for APC, coliforms, and generic *E. coli*.	
2.7.1	The establishment has documented procedures that include the following: Operation of this intervention method	Yes
Comment:	Slaughter Job SOP - Hock Vacuum Hang Off defined requirements for steam vacuum operation.	
2.7.2	Temperature monitoring	Yes
Comment:	Temperature monitoring was conducted hourly per Sanitary Dressing Procedures.	
2.7.3	Vacuum monitoring	Yes
Comment:	Vacuum monitoring was conducted hourly per Sanitary Dressing Procedures.	
2.7.4	Steam pressure monitoring	Yes
Comment:	Steam pressure monitoring was conducted hourly per Sanitary Dressing Procedures.	
2.7.5	Removal of contamination (Must follow regulatory guidelines of 'less than one inch')	Yes
Comment:	Slaughter Job SOP - Legging defined knife trimming requirements to remove contamination in compliance with the less than one inch regulation.	
2.7.6	Maintenance of the intervention equipment	Yes
Comment:	Preventive maintenance instructions defined maintenance requirements for steam vacuums.	

2.7.7	Observation of the intervention in operation	Yes
Comment:	Observation of steam vacuum function and usage was conducted during hourly monitoring of sanitary dressing procedures.	
2.7.8	None of the above.	Not Applicable
2.8	Operators of the steam vacuum(s) are following documented procedures as written for this intervention. If no, list findings in comments.	Yes
Comment:	Steam vacuum operation was compliant with requirements defined in Slaughter Job SOPs.	
2.9	The establishment's intervention operating parameters fall within the validation supporting documentation parameters	Not Applicable
Comment:	Validation was not provided.	

3 Interventions/Process Aids - Thermal Intervention

		Result
3.1	The establishment uses the Thermal (hot water or steam pasteurization) intervention method.	Yes
Comment:	The site utilized 180F pre-evisceration and hot water pasteurization cabinet.	
3.2	The establishment identified this intervention as a CCP.	Yes
Comment:	The final pasteurization cabinet was identified as an either/or CCP with lactic acid.	
3.3	If the Thermal (hot water or steam pasteurization) intervention is a CCP, can the line run if this intervention is not operational or not in specification.	Yes
Comment:	The line could run without hot water pasteurization if lactic acid was operational. The line could not run without one of the interventions functioning properly.	
3.4.1	None	Not Applicable
3.4.2	Validated Third Party Challenge Study or Validation Study	No
3.4.3	In-house Challenge Study or Validation Study	Yes
Comment:	Hot Water Wash Cabinet Stand Alone Intervention Validation - 9/1/2021	
3.4.4	Third Party review of in-house challenge study or validation. List the name of the Third Party in Comments.	No
3.4.5	Resource white paper (Published Journal Article)	Yes

Comment: Effects of Steam-Vacuuming and Hot Water Spray Wash on the Microflora of Refrigerated Beef Carcass Surface Tissue Inoculated with *Escherichia coli* O157:H7, *Listeria* innocula and *Clostridium* sporogenes. Journal of Food Protection. Vol. 60, No. 2, Pages 114-119.

Use of Hot Water for Beef Carcass Decontamination. Journal of Food Protection. Vol. 60, Pages 19-25.

Treatment Using Hot Water Instead of Lactic Acid to Reduce Levels of Aerobic Bacteria and Enterobacteriaceae and Reduce the Prevalence of *Escherichia coli* O157:H7 on Pre-evisceration Beef Carcasses. Journal of Food Protection. Vol. 69, No.8. Pages 1808-1803.

Evaluation of Commonly Used Antimicrobial Interventions for Fresh Beef Innoculated with Shiga-Toxin Producing *Escherichia coli* Serotypes O26, O45, O103, O111, O121, O145, and O157:H7. Journal of Food Protection. Vol. 75, No. 7, 2012. Pages 1207-1212.

3.4.6	Resource white paper with third party review (peer reviewed paper - not published)	No
3.4.7	Other -- List in comments	No
3.5.1	A specific set of samples were chosen to support the validation hypothesis (objective).	Yes
Comment:	Specific sample sets were selected for the validation.	
3.5.2	Statistical parameters were used in the validation hypothesis and/or the analysis to support the conclusion.	Yes
Comment:	Log reduction of APC, coliforms, and generic *E. coli* supported the conclusion.	
3.5.3	Scientific support documentation.	Yes
Comment:	Microbiological testing data supported the conclusion.	
3.5.4	Validation study was prepared by a third party. List the name of the third party in comments.	No
Comment:	Validation study was prepared in-house.	
3.5.5	Other -- List in comments	Not Applicable
3.6	The establishment has records demonstrating on-going verification activities for this intervention. List the Frequency in comments.	Yes
Comment:	One out of every 300 carcasses processed was swabbed for generic *E. coli* per regulatory requirements. Products intended for raw ground use were sampled and tested for *E. coli* O157:H7. Sampling and testing of finished products for non-O157 STEC, Salmonella, and indicator organisms including APC, coliforms, and generic *E. coli* was based on customer-specific requirements. Quarterly process validation swabs were collected on ten carcasses pre and post interventions; swabs were tested for APC, coliforms, and generic *E. coli*.	
3.7.1	Operation of this intervention method.	Yes
Comment:	CHAD cabinet owner's manual defined operational requirements.	
3.7.2	Training records for the maintenance of this intervention equipment.	Yes
Comment:	Maintenance training records were maintained demonstrating training was conducted on operations and maintenance of the hot water wash cabinets.	

3.7.3	Checking the nozzles to ensure that they are not plugged and that they are all functioning.	Yes
Comment:	Nozzle function was verified during CCP monitoring.	
3.7.4	Checking the position of the arbors (are they moving correctly, or if stationary, are they aimed correctly).	Yes
Comment:	Arbor operation was verified during CCP monitoring.	
3.7.5	Start-up and shut-down procedures.	Yes
Comment:	Start up and shut down procedures were defined within maintenance PMs and the CHAD owner's manual.	
3.7.6	There is documentation of a monitoring process that assures that the water or steam is as least 160°F at the carcass surface.	Yes
Comment:	Carcass surface temperature was verified twice daily using a surface thermometer.	
3.7.7	The establishment monitors dwell time.	No
Comment:	Dwell time was not monitored.	
3.7.8	The establishment ensures that all areas and/or surfaces of the carcass are adequately covered by water or steam.	Yes
Comment:	Carcass coverage was visually verified during CCP monitoring.	
3.7.8	The establishment documents monitoring of start-up and shut-down.	Yes
Comment:	Start up and shut down procedures were documented through maintenance PMs.	
3.8	The establishment's intervention operating parameters fall within the validation supporting documentation parameters.	Yes
Comment:	Operating parameters fell within supporting validation documentation.	

4 Interventions / Process Aids -- Chemical Applications

		Result
4.1	The establishment uses Chemical Application(s) as an intervention method.	Yes
Comment:	The site utilized hypobromous acid, lactic acid, and ASC (acidified sodium chlorite) as chemical interventions.	
4.2	NOTE: Answer the following questions for each designated CCP. The establishment identified this intervention as a CCP. If YES, identify the location of the application (ex. Post-evis lactic acid).	Yes
Comment:	Final carcass and variety meats application of lactic acid were identified as CCPs.	
	List each intervention chemical (ex. Lactic acid, peracetic acid, chlorine, Sanova, SYNTRx) being utilized and the location of use. Verify that the establishment has FSIS Regulatory approval or other record of approval for the chemical(s) in use. Identify CCPs with parentheses.	

	Lactic acid (2-5%) was applied to applied to carcass mid-line at hide opening, bung area post hide removal and bunging, after hot water pasteurization (either/or CCP), on fabrication trim belts, and offline combo filling stations. Lactic acid was applied to heads, tongues, tails, hearts, kidneys, and livers (CCP). ASC (500-1200ppm) was applied to the neck area of the carcass post-hide removal, to the inside cavity and underneath the inside skirt post-evisceration, to railed-out carcasses prior to re-entry to the main rail, and through a pre-fabrication cabinet. Hypobromous acid (Bovibrom, 300-900ppm) was applied to carcasses through the spray chill system. Intervention chemicals were approved for use through FSIS Directive 7120.1.	
4.3	If the Chemical Application is a CCP, can the line run if this intervention is not operational or not in specification.	Yes
Comment:	The line could run if the hot water carcass final wash was operational and the ASC hand application spray for variety meat application was operational. Otherwise, the line could not run.	
4.4.1	None	Not Applicable
4.4.2	Validated Third Party Challenge Study or Validation Study	Yes
Comment:	Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Establishments - Penn State University 2005.	
4.4.3	In-house Challenge Study or Validation Study	Yes
Comment:	ASC Vs. Lactic Acid - July 2020 Lactic Acid Validation January 2020	
4.4.4	Third Party review of in-house challenge study or validation. List the name of the Third Party in Comments.	No
4.4.5	Resource white paper (Published Journal Article)	Not Applicable

Comment: Efficacy of Organic Acids Against *Escherichia coli* O157:H7 Attached to Beef Carcass Tissue Using a Pilot Scale Model Carcass Washer. Journal of Food Protection. Vol. 57, No. 2, Pages 97-103.

Evaluation of Various Antimicrobial Interventions for the Reduction of *Escherichia coli* O157:H7 on Bovine Heads During Processing. Journal of Food Protection. Vol. 71, No. 3, 2008. Pages 621-624.

Comparison of the Efficacy of a Sulfuric Acid Sodium Sulfate Blend and Lactic Acid for the Reduction of Salmonella on Pre-rigor Beef Carcass Surface Tissue. Journal of Food Protection. Vol. 80, No. 5, 2017. Pages 809-813.

Comparison of Water Wash, Trimming, and Combined Hot Water and Lactic Acid Treatments for Reducing Bacteria of Fecal Origin on Beef Carcasses. Journal of Food Protection. Vol. 61, No. 7, 1998. Pages 823-828.

Lactic Acid Sprays Reduce Bacterial Pathogens on Cold Beef Carcass Surfaces and in Subsequently Produced Ground Beef. Journal of Food Protection. Vol. 64, No. 1, 2001. Pages 58-62.

Effects of Cetylpyridinium Chloride, Acidified Sodium Chlorite and Potassium Sorbate on Populations of *Escherichia coli* O157:H7, *Listeria* monocytogenes, and *Staphylococcus* aureus on Fresh Beef. Journal of Food Protection. Vol. 67, No. 2, 2004. Pages 310-315.

Decreased Dosage of Acidified Sodium Chlorite Reduces Microbial Contamination and Maintains Organoleptic Qualities of Ground Beef Products. Journal of Food Protection. Vol. 67, No. 10, 2004. Pages 2248-2254.

Efficacy of Antimicrobial Compounds on Surface Decontamination of Seven Shiga Toxin-Producing *Escherichia coli* and *Salmonella* Inoculated onto Fresh Beef. Journal of Food Protection. Vol. 78, No. 3, 2015. Pages 503-510.

4.4.6	Resource white paper with third party review (peer reviewed paper - not published)	No
4.4.7	Other -- List in comments	Yes
Comment:	FSIS Directive 7120.1.	
1	A specific set of samples were chosen to support the validation hypothesis (objective).	Yes
Comment:	Specific sample sets were selected for the validation.	
2	Statistical parameters were used in the validation hypothesis and/or the analysis to support the conclusion.	Yes
Comment:	Log reduction of APC, coliforms, and generic *E. coli* supported the conclusion.	
3	Scientific support documentation.	Yes
Comment:	Microbiological testing data supported the conclusion.	
4	Validation study was prepared by a third party. List the name of the third party in comments.	No
Comment:	Validation study was prepared in-house.	
5	Other -- List in comments	Not Applicable

4.5.1	The establishment has records demonstrating on-going verification activities for this intervention. List the Frequency in comments.	Yes
Comment:	One out of every 300 carcasses processed was swabbed for generic *E. coli* per regulatory requirements. Products intended for raw ground use were sampled and tested for *E. coli* O157:H7. Sampling and testing of finished products for non-O157 STEC, Salmonella, and indicator organisms including APC, coliforms, and generic *E. coli* was based on customer-specific requirements. Quarterly process validation swabs were collected on ten carcasses pre and post interventions; swabs were tested for APC, coliforms, and generic *E. coli*.	
1	The establishment has documented procedures that include the following: Operation of this intervention method, including application of the treatment	Yes
Comment:	Maintenance PMs defined operation and application requirements.	
2	Preparation of the treatment solution(s)	Yes
Comment:	Maintenance PMs defined solution preparation requirements.	
3	Start up of the intervention equipment	Yes
Comment:	Maintenance PMs defined start up and shut down requirements.	
4	Shut down of the intervention equipment	Yes
Comment:	Maintenance PMs defined start up and shut down requirements.	
4.6.1	The establishment monitors and has set lower limits on the concentration of the treatment solution. Specify in the comments if TITRATION or CONDUCTIVITY is used to monitor the solution concentration.	Yes
Comment:	Concentration of chemical interventions was verified through titration. Lower limits were established as 300ppm for Bovibrom, 2% for lactic acid and 500ppm for ASC.	
4.6.2	The establishment monitors the temperature of the treatment solutions.	Yes
Comment:	Lactic acid temperature was verified through CCP monitoring. Temperature of other chemical interventions was not monitored.	
4.6.3	The establishment monitors the flow / volume	Yes
Comment:	Application (flow) of chemical interventions was verified through CCP and control point monitoring.	
4.6.4	The establishment monitors the nozzle pressure.	Yes
Comment:	Nozzle pressure was verified for lactic acid through CCP monitoring. Nozzle pressure of other chemical interventions was not monitored.	
4.6.5	The establishment ensures all areas and/or surfaces of the carcass are adequately covered by the chemical application.	Yes
Comment:	Visual verification of coverage application was conducted through CCP and control point monitoring.	
4.6.6	The intervention method is implemented as written in the documented procedure.	Yes
Comment:	Chemical interventions were operating within defined operational requirements.	
4.7	The establishment's intervention operating parameters fall within the validation supporting documentation parameters.	Yes

Comment:	Operating parameters fell were compliant with defined validation parameters.	
4.8.1	Is / Are there alternative intervention methods(s) being utilized other than those listed in the previous pages	No
Comment:	Alternative interventions were not utilized.	

5 Dressing Procedures / Critical Job Tasks

		Result
5.1	Is there an intervention or process aid utilized upon entering or exiting the out rail.	Yes
Comment:	ASC was applied to carcasses upon exiting the out-rail.	
5.2	The establishment designates and has documented descriptions of critical job tasks (i.e., skinning line, evisceration, etc.).	Yes
Comment:	Slaughter SOP Job Tasks defined requirements for critical job tasks.	
5.3	The establishment uses hot water or chemical solution to sanitize equipment (i.e., knife, steel, hook, etc.) during operations.	Yes
Comment:	Hot water or bleach water was used to sanitize equipment after trimming contamination.	
5.4.1	The establishment uses the following to ensure that knives are in the sanitizer dip long enough to sanitize: List which methods are utilized in which process i.e. multiple knife rotation on skinning line, 1-2 second dip post skinning, etc. Knife blade stays in the dip 1-2 seconds.	Yes
Comment:	A 2-3 second dip was utilized for sanitizing equipment following evisceration tasks and post-evisceration trimming. A multiple knife rotation was utilized for sanitizing equipment on the skinning line to the point of evisceration.	
5.4.2	Knife blade stays in the dip 2-3 seconds.	Yes
Comment:	A 2-3 second dip was utilized for sanitizing equipment following evisceration tasks and post-evisceration trimming.	
5.4.3	Knife blade stays in the dip for 4-6 seconds.	No
5.4.4	Multiple knife rotation.	Yes
Comment:	A multiple knife rotation was utilized for sanitizing equipment on the skinning line to the point of evisceration.	
5.5	The establishment sanitizes all equipment (hooks and knives) between each use to reduce cross contamination in the process when trimming visible contamination (i.e., fecal, hair, or dirt.).	Yes
Comment:	Equipment was sanitized between each use following trimming of contamination.	
5.6	There is an auditing / observation process for monitoring of critical job tasks	Yes
Comment:	Sanitary dressing processes were monitored hourly by QA technicians and continuously by supervisors.	

5.7.1	Type(s) of monitoring at the establishment: Auditor	Yes
Comment:	QA performed documented monitoring of sanitary dressing protocols hourly.	
5.7.2	Supervisor	Yes
Comment:	Supervisors performed continuous monitoring of sanitary dressing processes; monitoring was not documented.	
5.7.3	Video	No
5.7.4	Other -- List in Comments	Not Applicable
5.8	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, Michael Sanders, do not have a conflict of interest with this auditee.	