



Audit Report

FSNS Beef Trim CCP Addendum

Harris Ranch Beef Company
16277 South McCall Avenue
Selma, California 93662

Audit Date: September 30, 2022
Auditor: Scott Devitt



Audit Summary

Company Name:	Harris Ranch Beef Company	Company ID:	AUHARRIS
Address:	16277 South McCall Avenue Selma, California 93662		

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Audit ID:	AO-004480
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Audit Type:	Annual audit
Audit Result:	Completed

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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 product, equipment, or process changes. The most recent reassessments were completed between 6/9/22 and 9/23/22.		
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 monitor training was refreshed annually. CCP training records were available for QA Technicians performing CCP monitoring during this assessment and were current.		
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 were required to meet 9 CFR 417.3 requirements. Corrective actions reviewed from the week of 6/27/22 demonstrated compliance.		

2 Interventions/Process Aids - Steam Vacuum

		Result
2.1	The establishment uses the steam vacuum intervention method.	Not Applicable
Comment: Steam vacuums were not utilized.		
2.2	The establishment identified this intervention as a CCP.	Not Applicable
Comment: Steam vacuums were not utilized.		
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 utilized.		
2.4.1	None	Not Applicable
Comment: Steam vacuums were not utilized.		
2.4.2	Validated Third Party Challenge Study or Validation Study	Not Applicable
Comment: Steam vacuums were not utilized.		
2.4.3	In-house Challenge Study or Validation Study	Not Applicable
Comment: Steam vacuums were not utilized.		
2.4.4	Third Party review of in-house challenge study or validation. List the name of the Third Party in Comments.	Not Applicable

Comment: Steam vacuums were not utilized.		
2.4.5	Resource white paper (Published Journal Article)	Not Applicable
Comment: Steam vacuums were not utilized.		
2.4.6	Resource white paper with third party review (peer reviewed paper - not published)	Not Applicable
Comment: Steam vacuums were not utilized.		
2.4.7	Other -- List in comments	Not Applicable
Comment: Steam vacuums were not utilized.		
2.5.1	A specific set of samples were chosen to support the validation hypothesis (objective).	Not Applicable
Comment: Steam vacuums were not utilized.		
2.5.2	Statistical parameters were used in the validation hypothesis and/or the analysis to support the conclusion.	Not Applicable
Comment: Steam vacuums were not utilized.		
2.5.3	Scientific support documentation.	Not Applicable
Comment: Steam vacuums were not utilized.		
2.5.4	Validation study was prepared by a third party. List the name of the third party in comments.	Not Applicable
Comment: Steam vacuums were not utilized.		
2.5.5	Other -- List in comments	Not Applicable
Comment: Steam vacuums were not utilized.		
2.6	The establishment has records demonstrating on-going verification activities for this intervention. List the Frequency in comments.	Not Applicable
Comment: Steam vacuums were not utilized.		
2.7.1	The establishment has documented procedures that include the following: Operation of this intervention method	Not Applicable
Comment: Steam vacuums were not utilized.		
2.7.2	Temperature monitoring	Not Applicable
Comment: Steam vacuums were not utilized.		
2.7.3	Vacuum monitoring	Not Applicable
Comment: Steam vacuums were not utilized.		
2.7.4	Steam pressure monitoring	Not Applicable
Comment: Steam vacuums were not utilized.		
2.7.5	Removal of contamination (Must follow regulatory guidelines of 'less than one inch')	Not Applicable
Comment: Steam vacuums were not utilized.		
2.7.6	Maintenance of the intervention equipment	Not Applicable

Comment: Steam vacuums were not utilized.		
2.7.7	Observation of the intervention in operation	Not Applicable
Comment: Steam vacuums were not utilized.		
2.7.8	None of the above.	Not Applicable
Comment: Steam vacuums were not utilized.		
2.8	Operators of the steam vacuum(s) are following documented procedures as written for this intervention. If no, list findings in comments.	Not Applicable
Comment: Steam vacuums were not utilized.		
2.9	The establishment's intervention operating parameters fall within the validation supporting documentation parameters	Not Applicable
Comment: Steam vacuums were not utilized.		

3 Interventions/Process Aids - Thermal Intervention

		Result
3.1	The establishment uses the Thermal (hot water or steam pasteurization) intervention method.	Yes
Comment: The facility used a 180°F hot water pre-evisceration carcass wash, and a hot water pasteurization cabinet.		
3.2	The establishment identified this intervention as a CCP.	Yes
Comment: Hot water pasteurization was a CCP.		
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.	No
Comment: The line could not operate without hot water pasteurization.		
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: In house Study -Scott et al., 2014 Bullard et al., 2018 Validation of Changes to HACCP CCP-S-1 Operating Parameters Due to Facility and Equipment Improvements.		
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: 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.		
3.4.6	Resource white paper with third party review (peer reviewed paper - not published)	No
3.4.7	Other -- List in comments	Yes

Comment: Castillo et al., 1998
 Kochevar et al., 1997
 Scott et al., 2015
 Kalahayand et al., 2006 Bosilevac et al., 2006
 USDA-FSIS Inspection Procedures 6350.1, 1996
 Manufacturer's Calculations

3.5.1	A specific set of samples were chosen to support the validation hypothesis (objective).	Yes
Comment:	Specific sample sets were utilized.	
3.5.2	Statistical parameters were used in the validation hypothesis and/or the analysis to support the conclusion.	Yes
Comment:	Log reduction of <i>Salmonella typhimurium</i> , <i>Escherichia coli</i> , O157:H7, aerobic plate counts, <i>Enterobacteriaceae</i> , total coliforms, thermotolerant coliforms, and generic <i>E. coli</i> supported the conclusion.	
3.5.3	Scientific support documentation.	Yes
Comment:	Microbiological test results supported the conclusion.	
3.5.4	Validation study was prepared by a third party. List the name of the third party in comments.	No
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:	Ongoing verification included CCP monitoring, shaving cream tests, ink tests, temperature data recording device attached to a carcass passed through the cabinet minimally twice daily, temperature decals attached to carcasses passed through the cabinet randomly, daily carcass mapping (sampling of carcasses post hide removal, pre and post evisceration, and post interventions) for APC, generic <i>E. coli</i> , and coliforms, and sampling of one out of every 300 carcasses for generic <i>E. coli</i> .	
3.7.1	Operation of this intervention method.	Yes
Comment:	Preventive maintenance instructions documented operation methods.	
3.7.2	Training records for the maintenance of this intervention equipment.	Yes
Comment:	Training records were available for the maintenance of the pre-evisceration and hot carcass washes.	
3.7.3	Checking the nozzles to ensure that they are not plugged and that they are all functioning.	Yes
Comment:	Nozzle function was observed 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:	Nozzle position was observed during CCP monitoring.	
3.7.5	Start-up and shut-down procedures.	Yes
Comment:	Preventive maintenance instructions documented start-up and shut-down procedures.	
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: A temperature data recording device attached to a carcass was passed through the cabinet minimally twice daily to verify minimum 160°F water temperature for 14 seconds and 170°F for 10 seconds. Temperature decals attached to carcasses were passed through the cabinet randomly to verify 170°F at the carcass surface.

3.7.7	The establishment monitors dwell time.	Yes
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Comment: Dwell time was monitored.

3.7.8	The establishment ensures that all areas and/or surfaces of the carcass are adequately covered by water or steam.	Yes
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Comment: Carcass coverage was verified during shaving cream tests and CCP monitoring

3.7.8	The establishment documents monitoring of start-up and shut-down.	Yes
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Comment: Start up and shut down were monitored during preventive maintenance.

3.8	The establishment's intervention operating parameters fall within the validation supporting documentation parameters.	Yes
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Comment: Hot water temperature was 204°F during the assessment with nozzles functioning properly.

4 Interventions / Process Aids -- Chemical Applications

		Result
4.1	The establishment uses Chemical Application(s) as an intervention method.	Yes

Comment: The facility used lauric arginate, lactic acid and hypobromous acid

4.2	NOTE: Answer the following questions for each designated CCP.	Yes
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The establishment identified this intervention as a CCP.
If YES, identify the location of the application (ex. Post-evis lactic acid).

Comment: Lactic acid on carcasses post hot water pasteurization was a CCP.

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.

1. Lactic acid was applied to carcasses pre-evisceration, on hide opening patterns, (post hot water pasteurization), on whole heads, tongues, and hearts, and on primals, sub-primals, and trimmings. Approved per FSIS Directive 7120.1.
2. Hypobromous acid was applied to carcasses in the final cold wash cabinet and in the spray chill, and (on whole heads and tongues in the head wash). Approved per FSIS Directive 7120.1.
3. Lauric Arginate (LAE20) was applied to RTE product during packaging. Approved per 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.	No
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Comment: The line could not run without the carcass lactic acid application.

4.4.1	None	Not Applicable
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4.4.2	Validated Third Party Challenge Study or Validation Study	No
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4.4.3	In-house Challenge Study or Validation Study	No
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) Comment: Antimicrobial Efficacy of a Lactic Acid and Citric Acid Blend Against Shiga Toxin-Producing <i>Escherichia coli</i> , <i>Salmonella</i> , and Nonpathogenic <i>Escherichia coli</i> Biotype I on inoculated Prerigor Beef Carcass Surface Tissue - Journal of Food Protection, Vol 78, No 12, 2015, pages 2136-2142	Yes
4.4.6	Resource white paper with third party review (peer reviewed paper - not published)	No
4.4.7	Other -- List in comments	Not Applicable
1	A specific set of samples were chosen to support the validation hypothesis (objective). Comment: Specific sample sets were chosen for the study.	Yes
2	Statistical parameters were used in the validation hypothesis and/or the analysis to support the conclusion. Comment: Statistical parameters were used in the validation to demonstrate a log reduction of pathogenic strains of <i>E.coli</i> .	Yes
3	Scientific support documentation. Comment: APC and EB test results supported the study.	Yes
4	Validation study was prepared by a third party. List the name of the third party in comments.	No
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. Comment: Ongoing verification included CCP monitoring, shaving cream tests, ink tests, temperature data recording device attached to a carcass passed through the cabinet minimally twice daily, temperature decals attached to carcasses passed through the cabinet randomly, daily carcass mapping (sampling of carcasses post hide removal, pre and post evisceration, and post interventions) for APC, generic <i>E. coli</i> , and coliforms, and sampling of one out of every 300 carcasses for generic <i>E. coli</i> .	Yes
1	The establishment has documented procedures that include the following: Operation of this intervention method, including application of the treatment Comment: Preventive maintenance records documented operational parameters for the intervention including preparation of solutions, start up, and shut down tasks.	Yes
2	Preparation of the treatment solution(s) Comment: Preventive maintenance records documented operational parameters for the intervention including preparation of solutions, start up, and shut down tasks.	Yes
3	Start up of the intervention equipment Comment: Preventive maintenance records documented operational parameters for the intervention including preparation of solutions, start up, and shut down tasks.	Yes
4	Shut down of the intervention equipment	Yes

Comment: Preventive maintenance records documented operational parameters for the intervention including preparation of solutions, start up, and shut down tasks.		
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: Chemical contractions were verified by titration. Lower and upper limits were established and monitored by FSQA.		
4.6.2	The establishment monitors the temperature of the treatment solutions.	Yes
Comment: Temperature monitoring was a part of CCP monitoring.		
4.6.3	The establishment monitors the flow / volume	No
Comment: Such was not monitored.		
4.6.4	The establishment monitors the nozzle pressure.	Yes
Comment: Nozzle pressure was included in CCP monitoring.		
4.6.5	The establishment ensures all areas and/or surfaces of the carcass are adequately covered by the chemical application.	Yes
Comment: Coverage was included in CCP monitoring.		
4.6.6	The intervention method is implemented as written in the documented procedure.	Yes
Comment: Lactic acid concentration, pressure, and temperature were within acceptable limits at the time of this assessment.		
4.7	The establishment's intervention operating parameters fall within the validation supporting documentation parameters.	Yes
Comment: Operating parameters were within validated limits.		
4.8.1	Is / Are there alternative intervention methods(s) being utilized other than those listed in the previous pages	No
Comment: Novel 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: Lactic acid was applied to carcass railed back in off the outtrail.		
5.2	The establishment designates and has documented descriptions of critical job tasks (i.e., skinning line, evisceration, etc.).	Yes
Comment: Job specific standard operating procedure identified 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: 180°F hot water sterilizers were used to sanitize equipment during operations.		



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.	No
5.4.2	Knife blade stays in the dip 2-3 seconds.	No
5.4.3	Knife blade stays in the dip for 4-6 seconds.	No
5.4.4	Multiple knife rotation. Comment: Dual knife rotation was used from initial sticking through final carcass trim out.	Yes
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.). Comment: Knives were rotated between each carcass and were sanitized after trimming visible contamination.	Yes
5.6	There is an auditing / observation process for monitoring of critical job tasks Comment: Sanitary Dressing Audits were conducted for hide on tasks each period. AQL audits were conducted on hide off carcasses hourly.	Yes
5.7.1	Type(s) of monitoring at the establishment: Auditor Comment: Dressing audits were completed on each dressing position minimal daily and recorded on the Job Performance Training Checklist. In practice, audits were completed every period of production. Weekly audits were completed on critical dressing tasks. Records reviewed demonstrated compliance.	Yes
5.7.2	Supervisor Comment: Supervisor audits were not conducted.	No
5.7.3	Video Comment: Job performance audits using cameras were completed on each position minimally daily and recorded on the Job Performance Training Checklist. Records reviewed from the week of 6/27/22 demonstrated compliance.	Yes
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. Comment: I, Scott Devitt, do not have conflict of interest with this auditee.	Yes