



February 21, 2012

Dear Valued Customer:

Harris Ranch Beef Company (HRBC; Est. #783) is a functionally-integrated beef company committed to producing safe, wholesome beef products of the highest quality. We are a federally inspected establishment that operates under the principles and procedures outlined in our written HACCP and SSOP programs that simultaneously assure compliance with all relevant USDA-FSIS regulatory requirements. This includes the reassessments performed in reference to FSIS Notice 44-02 identifying *E. coli* O157:H7 as a hazard that is reasonably likely to occur and 65-07 Notice of Reassessment of *E. coli* O157:H7 Control and Completion of Checklist for all beef operations. Additionally, we perform routine annual reassessments as required, to further assure adequacy of our HACCP plans.

Harris Ranch's unique production model affords us direct control over our raw materials (i.e., cattle), not commonly experienced in the beef industry. Our sister company, Harris Feeding Company (HFC) employs several technologies designed to reduce the prevalence and spread of *Escherichia coli* O157:H7 in live cattle. All cattle, while at HFC, are fed Bovamine[®], a direct-fed antimicrobial, which has demonstrated a propensity to reduce the fecal shedding of *E. coli* O157:H7. Furthermore, all cattle trucks are washed with a state-of-the-art truck wash between each load of cattle transported to HRBC thereby reducing the possibility of cross-contamination across loads of cattle. In totality, all of these pre-harvest pathogen mitigation strategies reduce the pathogenic burden entering HRBC's facility subsequently enhancing our ability to preclude the occurrence of pathogenic organisms on our beef products.

Within the animal-to-carass conversion process, Harris Ranch incorporates Multiple Hurdle Technology which directs the application of multiple-sequential, broad spectrum antimicrobial interventions consequently providing synergistic microbial reduction. All antimicrobial interventions employed at HRBC have demonstrated efficacy against enteric pathogens, including *E. coli* O157:H7 and *Salmonella*. The foundation of our antimicrobial intervention strategy is reducing the transfer of microbial contamination, as outlined by our sanitary carcass dressing procedures. In addition, carcasses are subjected to knife trimming of visual contamination, numerous pattern-focused steam vacuums, pattern-focused lactic acid application, carcass hot water pasteurization, carcass organic acid spray and rapid carcass chilling. Our hot water pasteurization and organic acid spray are validated pathogen interventions and thus, classified as Critical Control Point in our HACCP Plan which are monitored for temperature and acid concentration, respectively. These interventions are recognized as having the capacity of reducing *E. coli* O157:H7 to an undetectable level. Our CCP justification is based on the following research:

1. Castillo, A., L. M. Lucia, K. J. Goodson, J. W. Savell, and G. R. Acuff. 1998a. Use of hot water for beef carcass decontamination. *J. Food Prot.* 61:19-65.



2. Castillo, A., L. M. Lucia, K. J. Goodson, J. W. Savell, and G. R. Acuff. 1998b. Comparison of water wash, trimming, and combined hot water and lactic acid treatments for reducing bacteria of fecal origin on beef carcasses. *J. Food Prot.* 61:823-828.

Our carcass chill process is also identified as a Critical Control Point considering the significance of temperature's influence on mesophilic pathogen growth. Carcass surface temperatures are also monitored before Fabrication to ensure temperature maintenance. A cold chain management protocol is utilized throughout the entire storage, handling and shipping process. Facility temperatures are monitored real-time with a 24-7, electronic monitoring system complete with temperature threshold alert notifications sent to all appropriate departments upon temperatures exceeding pre-set thresholds. Facility temperatures are also manually verified six times daily, to assure appropriate temperature control.

Harris Ranch's antimicrobial intervention system is continuously validated, on a daily basis, through qualitative and quantitative data collection, analysis and trending. Harris Ranch objectively monitors its sanitary dressing procedures and harvest floor CCP (i.e., thermal pasteurization and organic acid) efficacy through carcass swabbing and subsequent analysis for APC, coliforms and generic *E. coli* populations. Additional carcass testing includes generic *E. coli*, in accordance with regulatory requirements as stated in 9 CFR 310.25(a), as well as, compliance with the *Salmonella* Performance Standards. Validation is further substantiated through HRBC's intensive Raw Ground Beef Component *E. coli* O157:H7 testing program. Harris Ranch can confidently provide daily evidence demonstrating the efficacy of our antimicrobial intervention strategies.

All raw ground beef component testing for *E. coli* O157:H7 presence is facilitated utilizing the N60 sample collection methodology that results in a 375 gram analytical unit. Harris Ranch's microbiological lotting scheme directs the combination of up to three combos of trim or three pallets of boxed beef for every *E. coli* O157:H7 analysis. Microbiological subplot integrity is maintained regardless if tested products are consumed within HRBC's internal grinding operation or shipped to outside customers. Variety meat items, commonly utilized in ground beef manufacturing (i.e., head meat, cheek meat, heart and weasand meat), are also tested for the presence of *E. coli* O157:H7 utilizing N60 methodology. However, N60 sample collection is extended over an entire day's production where the day's production, for each specific item, is considered a microbiological subplot. All HRBC *E. coli* O157:H7 samples are sent to an accredited 3rd party laboratory where they are screened for the presence of the organism with Strategic Diagnostics Inc. AOAC approved RapidChek[®] *E. coli* O157 immunoassay following 10 hour enrichment, unless required otherwise per customer testing specifications (reported in customer's COA document). All products tested for *E. coli* O157:H7 remain on hold and are not ground or shipped until receipt of written confirmation of negative results. In the event the initial screen results in a "potential" result, the respective result is molecularly confirmed with either Dupont's BAX[®] *E. coli* O157:H7 MP or Biocontrol's



Assurance *E. coli* O157:H7 GDS™ PCR detection platforms. Upon “presumptive” PCR results, HRBC may elect to proceed with cultural confirmation utilizing USDA-FSIS’ MLG methodology. For HRBC customers who request *E. coli* O157:H7 testing, a Certificate of Analysis (COA) will be provided depicting negative results and the corresponding testing methodology.

Harris Ranch intends to fully comply with USDA-FSIS’ proposed rule (Docket No. FSIS-2010-0023) **Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products** where raw, ground beef components will be tested for *Escherichia coli* serotypes O26, O45, O103, O111, O121 and O145 (pSTEC) once the rule is implemented by the agency. Accordingly, HRBC will reassess all HACCP plans to include pSTEC as a hazard reasonably likely to occur and test all raw, ground beef components for pSTEC presence. Harris Ranch will utilize a molecular detection platform optimized to simultaneously screen for the seven pertinent *E. coli* serotypes. All COAs corresponding to product derived from cattle harvested after the agency’s implementation date will reflect negative results for *E. coli* O157:H7, O26, O45, O103, O111, O121 and O145. An updated HRBC HACCP letter, documenting all of the appropriate revisions, will be sent out to all HRBC customers.

Harris Ranch employs the industry’s most conservative “Event Day” protocol. Harris Ranch considers anymore than a single *E. coli* O157:H7 positive, occurring during a single day’s production, to be indicative of potential system failure and warrants initiation of appropriate system investigation. During an Event Day, HRBC will direct the positive microbiological subplot, as well as, the microbiological sublots of similar products produced immediately before and after the positive subplot to a full-lethality process or landfill. This protocol is justified by HRBC’s historical microbiological performance.

Quarterly verification testing is also performed for *E. coli* O157:H7 sampling and analysis. The testing includes performing one verification during the first and fourth quarters and three during the second and third quarters. The quarters are defined as: January – March (1 sampling); April – June (3 samplings); July – September (3 samplings); October – December (1 sampling). The samples are collected using N60 methodology and are analyzed by an outside laboratory utilizing Dupont’s BAX® *E. coli* O157:H7 MP or Biocontrol’s Assurance *E. coli* O157:H7 GDS™ PCR technology.

Harris Ranch utilizes in-house sanitation at the completion of each day’s production to facilitate the clean-up and sanitation of all food manufacturing equipment and processing areas. Sanitation efficacy is verified every day through pre-operational inspection to assure the absence of previous day’s product debris. Additionally, bioluminescence and APC swabs are collected from random equipment in all processing areas, on a weekly basis, to quantify equipment hygiene. Results are analyzed to identify any problematic equipment and/or areas. Sanitizers, with differing modes of action, are rotated within a week to discourage the development of



microbial resistance. A Sanitation Master Schedule (SMS) is utilized to all equipment and facilities that do not garner daily attention. The SMS is verified on a weekly basis.

In the event of an emergency, written Recall Procedures are in place to provide prompt identification and tracking all affected products while assuring proper notification to customers, government agencies, news media, etc. The program includes a listing of team members with assigned responsibilities to assure prompt action. Mock recalls are performed at least twice annually. The company also has a written Food Defense program to assure systems are in place to prevent the risk of intentional food contamination. The facility is fenced in and access is controlled 24-7 by a security service.

Other pre-requisite programs in place include but are not limited to:

- Pest Control: Licensed Technician
- Allergen Control: Written procedures to assure allergens are controlled within our facility
- Employee training: Upon hire and ongoing training is accomplished through monthly line meetings. This includes but is not limited to: HACCP, SSOP, GMP's, Product Handling, Employee Hygiene, etc.
- Metal Detection: Utilized on boneless beef trimmings, ground product, fully cooked products and portion control products

Harris Farms Inc. (HRBC's parent company) has long recognized the value of training its' employees to treat the animals in the most respectful and humane way possible. Harris Ranch Beef Company and HFC incorporate the latest technology and professional consultations in our efforts to continue to lead the industry in these initiatives. Proper handling of livestock is extremely important to all in the meat production continuum, both ethically and economically. Harris Ranch maintains a comprehensive written Animal Welfare program which is in compliance with all USDA-FSIS regulatory requirements and is based on AMI's Recommended Animal Handling Guide, 2010 Edition. Harris Ranch employs all of the recommended weekly welfare and transportation audits to assure the best possible treatment of our animals.

Specified Risk Materials (SRM's) are handled in accordance with all USDA-FSIS regulatory requirements, including the SRM Final Rule, "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle (and subsequently published "Requirements for the Disposition of Cattle that Become Non-Ambulatory Disabled Following Ante-Mortem Inspection on March 18, 2009 to augment the previous rule); "Disposition of Non-Ambulatory Disabled Cattle, FSIS Notice 74-10 Issued 12/22/10"; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter" issued in the Federal Register July 13, 2007; effective on October 1, 2007 specifically listed as:



1. *Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle*
 - a. *Non-ambulatory disabled animals are unfit for human food:*

HRBC does not accept or harvest non-ambulatory animals.
 - b. *All cattle – tonsils and distal ileum are inedible:*

The tonsils are removed from all carcasses.
Eighty inches of the small intestine including the distal ileum, as measured from the ileocecal junction is discarded to inedible rendering.
 - c. *Cattle 30 months and older – the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column are inedible (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum):*

HRBC relies on cattle birth records and/or dentition to determine the age of all cattle and segregates those identified as 30 months and older. Our segregation procedures assure that the SRM's have been removed and properly disposed of as inedible. Bone-in products (that include the vertebral column) are produced from animals that are under 30 months of age. If it is necessary to produce bone-in product from animals that are 30 months of age and older, specific written procedures are followed to control the SRM (vertebral column) as required by USDA-FSIS regulatory requirements, including proper documentation with customer order. In addition to meeting USDA-FSIS regulatory requirements for SRM, some customers consider the spinal cord, dura and dorsal root ganglia as an SRM in cattle of all ages, therefore, HRBC also removes the spinal cord, sheath (dura) and dorsal root ganglia (DRG) that extends from the spinal channel on all carcasses.
2. *Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems:*

HRBC does not produce AMR product.
3. *Prohibition of the Use of Certain Stunning Devices to Immobilize Cattle During Stunning:*

HRBC does not utilize air injected stunning equipment.

As required under 9 CFR 417.4(a)(3), HRBC has reassessed its HACCP Plan for the SRM Final Rule effective October 1, 2007.

Meat offered for sale is derived from cattle that have been fed materials in compliance with the FDA regulation 21 CFR 589.2000. This regulation prohibits the feeding of ruminant meat and bone meal to ruminant animals. Documentation is maintained to substantiate this claim and verify compliance.

Harris Ranch Beef Company is audited at least annually by a 3rd party which includes GMP's, Food Safety, Animal Welfare, SRM's and Verification/Validation of *E. coli* O157:H7 testing (N60).



Harris Ranch Beef Company is committed to producing the safest and highest quality products possible. All programs are available for review onsite. If you have any questions or need clarification pertaining to the aforementioned, please, do not hesitate contacting me.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Carlson", with a stylized, cursive script.

Brandon Carlson, Ph.D.
Director, Food Safety & Quality Assurance