

JANUARY 4, 2023

To Whom It May Concern,

We continue to be committed to providing our customers with the highest quality products possible. As a part of this commitment, we continuously look at ways to improve our food safety program.

DemKota Ranch Beef is assuring we have addressed the following regulatory requirements:

- All sources of cattle comply with Title 21, Chapter 1, subchapter E, part 589 of the CFR, which prohibits the feeding of ruminant meat and bone meat to ruminant animals.
- Compliance with all BSE and SRM final rule requirements as set forth in the FSIS Notice 26-16, dated 04/26/2016.

New Angus LLC, DemKota Ranch Beef, Est. 45471 implemented an approved Hazard Analysis and Critical Control Point (HACCP) food safety system in November of 2015, which conforms to all applicable requirements set for in 9 CFR Part 417. Since its inception, we continuously reassess the program to improve the overall system and comply with all FSIS Notices and Regulations. Reassessments occur annually and on an as needed basis. Our food safety program also consists of Standard Operating Procedures (SOP's), Good Manufacturing Practices (GMP's), and Sanitation Standard Operating Procedures (SSOP's), 9 CFR 416.

We utilize a multiple hurdle approach to food safety including these intervention strategies:

- Throughout the slaughter process we inspect and trim carcasses
- Steam vacuums – placed in strategic locations on the slaughter floor
- Pre-Evisceration wash and intervention
- Thermal Pasteurization (Hot Water Wash System)
- PAA and/or Lactic Acid Application
- Variety Meat – PAA and/or Lactic Acid Application
- Intervention in Carcass Chill Spray - PAA
- Fabrication Intervention – Incoming carcasses are treated with an antimicrobial spray in the Carcass Cabinet and primal and sub-primal products are subject to an antimicrobial spray prior to bagging-PAA (Sub-primal and Trimming Sprays)
- Temperature Management

**HACCP Interventions (CCP – Critical Control Points):** *CCP's are designed and validated, with both scientific literature and in-house microbial data, to eliminate or reduce pathogenic microbial (E.coli 0157:H7) to below detectable limits.*

- Hot Water Wash – Monitored and validated on a daily basis
- Zero Tolerance for fecal, ingesta and milk contamination (Directive 6420.2)
- Carcass and Variety Meat Chilling

These intervention strategies are designed to reduce the risk of pathogenic bacteria contamination (*E.coli* 0157:H7).

In addition to the above interventions we test for generic *E. coli* Biotype I (9 CFR Part 310, §310.25), Aerobic Plate Count (APC), and coliforms. Our facility is also in compliance with FSIS regulated Salmonella testing on carcasses in accordance with §310.25.

DemKota Ranch Beef is in compliance with the FDA Bioterrorism Act. DemKota Ranch Beef requires all cattle suppliers to have a current signed affidavit on file attesting to compliance with all FDA feed and drug regulations. The signed affidavit is updated on a yearly basis and cattle suppliers without an updated affidavit will not be eligible for marketing livestock to DemKota Ranch Beef.

In connection with the October 7, 2002, USDA FSIS notice on *E. coli 0157:H7* we have identified *E.coli* 0157:H7 in our HACCP Program as a “hazard reasonably likely” to occur. In addition, we have included interventions as critical control points in our HACCP Program (see list above) and have intensified our verification and validation procedures.

DemKota Ranch Beef has a recall plan on file that includes notification to affected customers as well as a written and monitored Pest Control Program which uses USDA approved chemicals.

DemKota Ranch Beef has reassessed its HACCP Plan and implemented the appropriate programs/policies to ensure compliance with FSIS Notice 56-07. DemKota Ranch Beef has implemented the following programs to assure our customers that our company does not produce products that contain “AMR” (Advanced Meat Recovery), downer cattle or any bone-in products that contain the spinal column in cattle age 30 months and older, and/or any other SRM material as identified in 9CFR part 309 and part 310.22.

- FSIS approved age verification and segregation of cattle programs through documentation and dentition of cattle. All carcasses identified as 30 months and over, will be marked on the complete vertebrae with blue ink (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), segregated and ran separate from carcasses less than 30 months of age. All carcasses identified 30 months and over will have the marked vertebral column removed on the fabrication floor;
- FSIS approved downer policy that prohibits the use of non-ambulatory cattle from our edible process;
- Our company does not produce “AMR”;
- Our company does not use an “air-injected” stun gun; and

- All SRM's are removed from the edible food chain (tonsils and small intestines of all cattle and from cattle 30 months of age and older the head – skull, eyes, brain, and trigeminal ganglia; and the vertebral column – spinal cord and dorsal root ganglia).

DemKota Ranch Beef is a Federally Inspected Establishment that is required to meet the requirements of 9CFR 416 and 417. These regulations ensure that our facility has verified and validated their HACCP Programs and associated CCPs. This is continually monitored by FSIS personnel who are required to do so in order for product to contain the FSIS Mark of Inspection.

DemKota Ranch Beef has addressed the following regulatory requirements:

#### **HACCP/Pathogen Reduction Regulation Compliance**

- Testing of carcasses for *E. coli* Biotype I (9 CFR Part 310, §310.25), effective June 1997. (Slaughter plants)
- Implementation of SSOP (Sanitation Standard Operating Procedures, 9 CFR, Part 416, §416.11 - §416.17), effective January 26, 1997.
- Implementation of HACCP Systems (9 CFR, Part 417, §417.1 - §417.8), effective January 27, 1998 for plants with greater than 500 employees.
- Testing of carcasses and/or ground beef for Salmonella as conducted by USDA in accordance with §310.25.

#### **Directive 6420.2 – Issued 12/19/19**

##### **Federal Register Docket 00-022N, dated 10/7/02 (*E.coli* 0157:H7 Reassessment)**

Specific to addressing regulatory requirements regarding *E. coli* 0157:H7, please be advised of the following actions:

- Reassessment of HACCP plans for *E. coli* 0157:H7 in accordance with the Federal Register Docket 00-022N, dated 10/7/02.
- Completion of annual reassessment of HACCP plans in accordance with 9CFR 417.4(a)(3) effective January 26, 2004.
- CCP's in place and effect for zero tolerance requirements for head meat, cheek meat and weasand.  
\*\*DemKota Ranch Beef does not produce weasand meat at this time. (Effective 5/17/04).

#### **Directive 10,010.1 – revised 08/20/15**

#### **Directives 6100.2 – revised 10/24/16 and 6100.4 – Revised 10/24/17**

#### **FSIS Notice 65-07 – 10/12/07 - HACCP Plans Reassessed Annually or As Needed**

#### **Labeling**

- USDA approval for the following label disclaimer/instructional statements are available at DemKota Ranch Beef
  - ***For Cooking Only***

## ***E.coli* 0157:H7 CONTROLS AND TESTING**

### **Disposition of Tested Product**

- All material destined for grinding operation is placed in DemKota Ranch Beef's Test & Hold Program using the N=60 Robust and/or N=60Plus Single Lot Combo testing methods. All tested lots are analyzed by a 3<sup>rd</sup> party accredited laboratory using an AOAC approved methodology that has been validated to meet USDA Criteria  $\geq 98\%$  Sensitivity and  $\geq 90\%$  Specificity. The items may include boneless trimmings, boneless trimming components, and/or sub-primals. All negative lots will be accompanied with a Certificate of Analysis (COA). If product is shipped prior to receiving Negative results, an agreement with the customer not to break the seal until results are received is put in place.
- One combo will be considered a lot.
- Sample will be collected using either N=60 Robust and/or N=60Plus Single Lot Combo testing methods. Samples will be tested in accordance with AOAC Official Method 996.09 through IEH.
- All materials that are tested for *E.coli* 0157:H7 that are not found to have negative results are addressed within the HACCP plans.
  - These lots are controlled, relabeled (when applicable) with the statement "For Cooking Only" and are cooked or otherwise disposed by rendering or sold as inedible.
  - Records reflect appropriate disposition of affected material.

***\*Vacuum packaged beef sub-primals sold in a box are not intended for use in ground products, unless the label specifies tested product. If a COA is not received, the product has not been tested.***

### **Verification Tests for *E.coli* 0157:H7**

- Trim – Quarterly verification testing for *E.coli* 0157:H7 and non-0157 STECs are conducted during the first and fourth quarters with increased testing conducted on a monthly basis during the second and third quarters
- Variety Meats - Quarterly verification testing for *E.coli* 0157:H7 and non-0157 STECs are conducted during the first and fourth quarters with increased testing conducted on a monthly basis during the second and third quarters
- DemKota Ranch Beef has a Verification and Validation microbial testing program in place. This program is an ongoing continuous testing program that specifically targets high risk areas for indicator organisms to ensure our systems are operating accurately and in a sanitary manner. This V & V program includes testing protocols that include hide on to finished product tests that demonstrate a continuous reduction in microbial presence as the carcasses move through the entire flow diagram.

### **Event Day Investigation**

- DemKota Ranch Beef has implemented a formal risk assessment program that will evaluate plant processes, programs, and procedures immediately following an "Event Day" incident. "Event Days" are identified by statistical data compiled on daily *E.coli* 0157:H7 incidence rates. All product from the "Event Day" will be assessed for disposition.

### **Non-0157 Shiga Toxin producing *E.coli* (STEC)**

- DemKota Ranch Beef has reassessed our HACCP plans for the Non-0157 STECs using internal testing data, scientific research (Kalchayanand, N. et al., 2012) and FSIS guidance and Notices and have determined that our current food safety systems controls that are in place at DemKota Ranch Beef addressing *E.coli* 0157:H7 are also effective in controlling the presence of Non-0157 STECs.

### **Allergens**

- DemKota Ranch Beef, a USDA inspected facility, establishment number M-45471, does not use any allergens in any of its processes. We produce only beef products, with no additional ingredients.
- There is a potential for allergens to be in the plant due to vending machines and employee lunches, however we control these allergens through Good Manufacturing Practices, wherein no food or drink is allowed in production areas and all employees are required to wash their hands prior to entry of production areas.

DemKota Ranch Beef is committed to build a work environment that is free from human trafficking, forced labor, and unlawful child labor (“human trafficking and slavery”). We strongly believe that we are responsible for promoting ethical and lawful employment practices. These practices are also strongly recommended to be followed by our suppliers, subcontractors, and business partners.

We are continuously striving to improve our food safety systems through the implementation of new technologies and systems as they become available. However, there is no technology available today that can guarantee fresh meat products are “free of pathogens”. Therefore, we want to stress the importance of proper product handling and cooking procedures by you and your customers.



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