



Creekstone Farms Premium Beef LLC, Establishment 27
Export of Ineligible Beef to Japan

NOVEMBER 5, 2009

EXECUTIVE SUMMARY

One shipment from Creekstone Farms Premium Beef, LLC, Establishment 27, 604 Goff Industrial Park Road, Arkansas City, Kansas to Japan containing two cartons, weighing 107 pounds, of ineligible Beef Neck Bones that were not produced under the Export Verification program for Japan, not listed on Health Certificate No. MPH 473713, were erroneously shipped from the United States. Consequently, Japan suspended import procedures for products originating in this establishment and requested a report from the United States Department of Agriculture (USDA) resulting from a detailed inquiry of this incident.

The USDA inquiry concluded that beef neck bones were incorrectly labeled as eligible "Chilled Beef Short Plate Boneless" and included in a shipment of product exported to Japan. The inquiry revealed that the establishment's management controls were inadequate to prevent non-conforming product from being labeled as products that were eligible for export to Japan. The inquiry revealed that the establishment's management controls were inadequate to prevent non-conforming product from being labeled as product that was eligible for export to Japan. A Creekstone Farms internal investigation identified that the employee packing the product failed to apply the correct label. The establishment failed to identify the improperly boxed and labeled product. The plant failed to prevent and detect employee errors that resulted in nonconforming product commingled with conforming product for export to Japan.

As corrective actions, the Export Verification program was revised to prevent the scheduling of bone in beef products during the Japan runs with a follow up review of records by Quality Assurance (QA) personnel. All plant employees labeling boxes will be retrained with regard to proper Japan export protocols. Modification of the pack off department in the fabrication area included extensions to the product conveyor belts and the addition several packing stations.

PURPOSE

The United States Department of Agriculture (USDA) has conducted an inquiry into the operations of Creekstone Farms Premium Beef, Establishment 27 in order to assess events surrounding its inclusion in a shipment to Japan of 107 pounds of ineligible Beef Neck Bones not listed on the export certificate and was not produced under the Export Verification program for export to Japan.

BACKGROUND

The export of U.S. meat products to other countries is facilitated by the activities of three separate but interdependent entities:

- 1) the U.S. meat and poultry industry,
- 2) USDA's Food Safety and Inspection Service (FSIS), and
- 3) USDA's Agricultural Marketing Service (AMS).

The U.S. meat industry is responsible for the slaughter of healthy animals and preparation of food products that are wholesome, properly labeled, and not adulterated. In addition to meeting U.S. food safety standards, the industry must meet all requirements imposed by importing countries. Both U.S. food safety requirements and the trade requirements of importing countries must be met before a product can be certified by USDA for export from the United States.

FSIS is responsible for the inspection of meat and poultry products and the certification of products for export to other countries. FSIS Directive 9000.1, Revision 1, "Export Certification," published March 1, 2006, provides an in-depth description of these responsibilities. The primary regulatory role of FSIS is to make critical determinations that meat and poultry products are not adulterated and meet all U.S. food safety standards for sale in domestic or international commerce. This regulatory activity is complete when FSIS applies the USDA mark of inspection. However, additional verifications are necessary after inspection is complete in order for FSIS officials to execute certifications of product for export.

The Agricultural Marketing Service (AMS) is responsible for developing Export Verification (EV) Program standards to ensure that establishments certified for export can meet the additional requirements of importing countries. These programs are approved and monitored by AMS for a fee, which is paid by participating establishments.

The combination of a USDA mark of inspection and an AMS EV Program provide assurance that U.S. meat and poultry products offered for export may be certified as meeting all U.S. food safety standards and importing country trade requirements.

RESULTS OF INQUIRY

USDA conducted an inquiry to determine whether the procedures and actions of Creekstone Farms Premium Beef, Establishment 27 complied with U.S. export certification requirements and the import requirements of Government of Japan.

Results are as follows:

- Creekstone Farms Premium Beef failed to prevent the inclusion of Edible Beef Neck Bones not produced under the Export Verification (EV) program for Japan as eligible “Chilled Beef Short Plate Boneless” listed on Health Certificate No. MPH 473713.
- There are three conveyors in the pack off fabrication department. Both white and brown boxes are used for varying grades of eligible beef products bound for export to Japan as well as product not exported to Japan. The positioning of the packaging station for Japan product boxes is at the end of the second pack off conveyor.
- The probable root cause was employee errors which lead to the inclusion of beef neck bones not produced under the EV program for Japan that were inadvertently mislabeled as eligible beef product, and placed on a pallet for shipment to Japan.
- There are no specific procedures indicated for the packaging stations in the EV Manual. On the day of the production run for Japan, an employee in charge of packing “Beef Short Plates” was also in charge of packing “Beef Neck Bones” running on the various conveyor belts moving both colored boxes. Inattentiveness by the employee responsible for packing the boxes to maintain appropriate separation of eligible product bound for Japan lead to the mislabeling of “Neck Bone” boxes being labeled as “Short Plate” boxes. This error was further exacerbated when the QA inspector on duty responsible for 100% inspection failed to identify that the box content did not match the box label and take appropriate inspection actions to prevent the inclusion of the mis-packaged and mislabeled product bound for export to Japan prior to the box sealing step. Compounded negligence at multiple steps by employees during implementation of production resulted in the regrettable transaction of events that followed. The boxes were subsequently sealed which prevented detection of the error. All boxes labeled as “beef short plates” were palletized though two boxes contained the wrong product. Specific changes have been made to prevent the packaging of products with vertebral column during subsequent EV QSA or A40 production runs for Japan as a result of this incident.
- All products are inventoried by computer using a “Bizerba” scaling and inventory system. When the shipment for Japan was being prepared, an electronic search was made using the bar codes and weight range verification check. The system identified the two packages of mislabeled beef neck bones as conforming product because they were labeled with the approved Japan export code and within the weight range for eligible product packaged that day. Correct coding and labeling of the outer boxes, regardless of color, did not trigger an error by the computerized system. The Quality Assurance employee failed to identify that the box content did not match the box label and take appropriate inspection actions

to prevent the inclusion of the mis-packed and mislabeled product bound for export to Japan.

- Specifically, on June 25, 2009, Beef Short Plate Boneless and Beef Neck Bones were being boxed at the same pack off line station by the same employee. The Beef Neck Bones were improperly labeled as “Beef Short Plate Boneless, product code 53962.” The product in question was within the set weight range of 40 to 100 pounds which did not trigger a weight rejection by the Bizerba system for code label rejection. At the time of the incident, the plants’ visual monitoring procedures failed to identify non-conforming product and verify proper product labeling at the packaging station.
- Quality Assurance (QA) Technician failed to identify the improperly boxed and labeled product during the staging for shipment. The employee scanning each box failed to identify the improperly packaged and labeled product and palletized the beef product.
- Once the mislabeled box was sealed and palletized, the error could no longer be detected until reopened on arrival in Japan.
- It was determined through investigation and review of photographs of the product involved in this incident that the box label and the product inside the box did not match.
- USDA trace-back analysis confirmed all cartons in the shipment were produced from age verified cattle 20 months of age or younger and, with the exception the two boxes of ineligible mis-labeled Beef Neck Bones, were conforming product and were verified during the export approval process.

CORRECTIVE ACTIONS

Creekstone Farms Premium Beef has taken actions to correct conditions that caused or contributed to the export of non-conforming product to Japan.

Creekstone Farms Premium Beef corrective actions include the following:

- On July 22, 2009, AMS reviewed the corrective actions submitted as well as additions made to the EV QSA program.
- The corrective actions are delineated in the EV QSA Program revised on July 24, 2009, to include an operation and scheduling procedure change to ensure that no product with vertebral column is scheduled during EV QSA or A40 production runs. Training of scheduling team members was accomplished on July 24, 2009. Only personnel specifically trained in EV procedures will be permitted to package product for Japan and will be identified by specially marked helmets with “EV- Export Qualified” sticker for ease of identification. In addition, QA SOG 78 was added to the scheduling procedures listing products that are prohibited from being packaged during EV QSA or A40 production runs. This addendum was added to the EV Program.

- All packers and QA Technicians involved with the EV QSA production have been retrained in the QSA methodology as of July 28, 2009. An “EV- Export Qualified” sticker will be applied to the helmets of QSA trained personnel.
- Two QA Technicians will be present at all times to monitor the EV QSA Production lines.
- Packaging Team members and QA Technicians involved in the initial incident have either been reassigned other duties not involved in the EV QSA Program or terminated. A new Packing Supervisor was hired and trained in the new methodology.
- Employees will only be issued the number of labels needed for Japan product. The labels will be designed of a different background to facilitate ease of recognition of Japan product for packers and inspectors. All personnel have been trained in appropriate EV procedures. Personnel in charge of packaging product bound for Japan are qualified and indicated with an “EV Export Qualified” sticker on their helmets. Personnel may be assigned to packaging both domestic and export products. However, only personnel specifically trained in EV procedures and displaying the “EV Export Qualified” sticker on his / her helmet will be permitted to package product for Japan.
- During future EV QSA production runs the QA Fabrication Supervisor will perform an audit of every schedule and production run per written procedures outlined. Additionally, during Grade Change (SOG48), a trained QA Technician, QA Supervisor or Export Coordinator will check packaging to assure that no product with vertebral columns is being run during the EV QSA or A40 production runs.
- A record review of the monitoring form will be conducted after each production prior to export to Japan. The results of the verification will be documented on the BEV 02 Audit Form and signed by Creekstone Farms Quality Assurance personnel at the actual time the reviewed occurred.
- On July 29 USDA/AMS audit personnel conducted a follow up review of the EV QSA Program (revised on July 24, 2009) and verified that the written procedural changes had been implemented.
- Several additions were made to the pack off department in fabrication which includes an extension of conveyor belts along with additional packaging stations. A seventeen foot section of packaging conveyor / box conveyor was added in 2008. This extended the pack off line from thirty-three feet to fifty feet, allowing an addition of nine more packaging stations. The extension of the conveyor lines will facilitate separation of the specified “EV Export Qualified” employees handling product for Japan. There are twenty to twenty-five people working in the packaging boxing station during various production operations. All personnel packaging product bound for Japan have been trained and have the “EV Export Qualified” sticker on their helmets as identification of Japan product handlers during production runs.
- Once the establishment is re-listed USDA will verify the implementation of all corrective actions for compliance through the performance of applicable inspection procedures.

CONCLUSIONS

USDA conclusions from this inquiry are as follows:

- The ineligible products were inspected and passed by USDA for human consumption and were at the time of export safe and wholesome products fit for consumption in the United States.
- The inclusion of Beef Neck Bones not produced under the EV program and incorrectly labeled as eligible Beef Short Plate Boneless for export to Japan revealed that the establishment's management controls were inadequate to prevent non-conforming product from being labeled as products that were eligible for export to Japan.
- Creekstone Farms Premium Beef has identified the probable root cause as employee error for the inclusion of beef neck bones not produced under the EV program for Japan as eligible "Chilled Beef Short Plate Boneless" listed on Health Certificate MPH 473713.
- Creekstone Farms Premium Beef has taken effective actions to ensure that this problem will not reoccur.
- USDA verified the revisional changes to the EV QSA Program.
- Once the establishment is re-listed USDA will verify the implementation of all corrective actions for compliance through the performance of applicable inspection procedures.
- USDA trace-back analysis confirmed all cartons in the shipment were produced from age verified cattle 20 months of age or younger and, with the exception the two boxes of ineligible mis-labeled Beef Neck Bones, were conforming product and were verified during the export approval process.
- USDA personnel followed all applicable regulations, directives and notices.