



Tyson Fresh Meats, Inc., Establishment 245L
Export of Box of Bone-in Product to Japan

November 6, 2009

EXECUTIVE SUMMARY

One shipment from Tyson Fresh Meats, Inc., Establishment 245L, 1500 Plum Creek Parkway, Lexington, Nebraska, to Japan containing a box of product, weighing 35.6 pounds, of ineligible Bone-in Beef Short Loin that was mis-packed as “Boneless Beef Skirt Diaphragm”, listed on Health Certificate No. MPH 124093, which was 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 bone-in beef product was incorrectly packaged as eligible “Boneless Beef Skirt Diaphragm” 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 was eligible for export to Japan. A Tyson Fresh Meats internal investigation identified that bone-in beef short loin is boxed at the same station as the beef diaphragm skirts and erroneously placed in a box labeled as “beef diaphragm skirts.” The establishment failed to identify the improperly 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, all plant employees labeling boxes will be retrained with regard to proper Japan export protocols. The box pack inspection and verification process was revised so that box inspectors/verifiers are present in the box sealing room and on the

production floor enabling a two-point inspection of all Japan eligible product codes and boxes.

PURPOSE

The United States Department of Agriculture (USDA) has conducted an inquiry into the operations of Tyson Fresh Meats, Inc., Establishment 245L in order to assess events surrounding its inclusion in a shipment to Japan of ineligible Bone-in Beef Short Loin 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.

AMS is responsible for developing 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 Tyson Fresh Meats, Inc., Establishment 245L complied with U.S. export certification requirements and the import requirements of Government of Japan.

Results are as follows:

- Tyson Fresh Meats failed to prevent the improper labeling of bone-in beef product which was incorrectly packaged as eligible “Boneless Beef Skirt Diaphragm” for Japan listed on Health Certificate No. MPH 124093.
- The probable root cause was employee errors which lead to the mis-packaging of ineligible Bone-in Beef Short Loin for Japan that was inadvertently mislabeled as eligible beef product, and placed on a pallet for shipment to Japan.
- There was no intention by Tyson Fresh Meats to package, label and ship ineligible product to Japan. Tyson Fresh Meats fully understands all the requirements of the EV program for Japan and fully intended to comply with those requirements.
- Bone-in beef short loin is boxed at the same station as the “beef diaphragm skirts” and was erroneously placed in a box labeled as “beef diaphragm skirts” during the production run in the Natural Beef Program. Boxes are devoid of product labels when presented to the boxing station. Appropriate labels are applied at this point. The employee designated to box boneless beef skirt diaphragm removed an empty box from the line, applied the “boneless beef skirt diaphragm” label to the box and placed the labeled box in the box fill station where boneless beef skirt diaphragm are packaged. At this point, an employee, untrained in

Japan export procedures, from an adjacent station provided assistance to the employee designated to box product for Japan due to product accumulating in the boneless beef skirt diaphragm/ short loin area. The “untrained” employee inadvertently placed the short loin product in a box labeled as “boneless beef skirt diaphragm” causing the error. The employee responsible for labeling product for export to Japan did not cause the mis-pack. The Natural Beef Program uses source and age verified animals less than twenty-one months with full trace backs of cattle and are fully eligible for export to Japan.

- An employee stationed at a point further along the conveyor line, failed to observe that the contents of the box in question did not match the product description on the box label. Previous inspection procedures involved a more thorough verification and inspection of all “insert boxes within a master container” type box arrangement. Boxed product with no “insert box” received less scrutiny of inspection. A “master container box” would be removed from the line, the insert box would be opened, and then both labels on the insert box and master container were compared to the contents for accuracy of identification of the boxed product. Any box that held “insert boxes” were more thoroughly inspected cross referencing product content to box label than boxes that did not have an “insert box”. When the employee on the line saw product in a box, he /she erroneously concluded that the contents within the box matched the label on the box. This inattentiveness to procedure and failure to verify content to label accuracy permitted the mis-pack to continue down the line toward the sealing step.

The “insert /master container” type inspection methodology was assessed to contain risk for potential errors and thus changed to the current system. The current methodology provides for 1) the same person will box and label product; 2) box inspectors/ verifiers were placed in the sealing department and on the production floor and 3) on a weekly basis, supervisors will review appropriate procedures for product destined for Japan with employees.

- 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 box contents 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

box of mis-packaged ineligible Bone-in Beef Short Loin, were conforming product and were verified during the export approval process.

CORRECTIVE ACTIONS

Tyson Fresh Meats has taken actions to correct conditions that caused or contributed to the export of non-conforming product to Japan.

Tyson Fresh Meats immediate corrective actions include the following:

- The procedure used for the labeling of boxes was changed so that the same person labeling the boxes will be boxing the product. The mis-pack incident at establishment 245L mis-pack involved vertebral bone-in product due to employee error by an untrained worker in the package area on Japan protocol. Corrective actions were modified to include that no vertebral bone-in product will be permitted to be present or packed at any box loading or pack-off area where Japan AV-A40 products are being packed or labeled. This will eliminate opportunity for vertebral product to be mis-packed as eligible product for Japan. A single “trained” worker may in fact be responsible for packaging of more than one type of eligible product. However, there will now be zero opportunity for future incidents of this kind as vertebral products will not be present in the packaging area where Japan eligible product is produced.
- All plant employees labeling boxes will be retrained with regard to proper Japan export protocols.
- The box pack inspection and verification process was revised so that box inspectors/verifiers are present in the box sealing room and on the production floor enabling a two-point inspection of all Japan eligible product codes and boxes. The two point inspection makes reference to two specific points in the box fill process prior to sealing of the boxes. The product labels are then compared to insure that the correct product is in the correct box.

Inspection point one is on the production floor. This area is located on each pack-off line where boxes are being transferred out of the production floor. Each area is capable of staging 1-2 pallets where boxes can be placed and reviewed. This will be performed by a trained hourly auditor for Japan run.

Inspection point two is in the case sealer room prior to box sealing. This area is located after the decline conveyor where trained hourly workers can see all boxes and labels. This is the location for which 100% inspection will occur and has two packing lines. Pack line one operates in an area of 6x30 feet for palletizing and stacking of product. Pack line two operates in an area of 15x20 feet for palletizing and stacking of product for inspection. Inspection point two will have one supervisor trained specifically for Japan export productions runs that will assist and monitor the operations.

- On a weekly basis, employees within the Japan product and boxing areas will be reeducated by the production supervisors of the proper packing and boxing protocols and procedures.

As of October 20, 2009, Tyson Fresh Meats has reassessed the Japan production process at all its beef facilities and did not find any systemic problems. The regrettable incident which occurred at establishment 245L was the result of an “untrained” production worker attempting to help a fellow employee during production of product bound for Japan. Though we are appreciative our dedicated employees’ work ethics to provide assistance to comrades, Tyson Fresh Meats believes that this unique incident occurred due to an “untrained employees good willed intentions. It is not our intention to dampen the cooperative nature of our employees; however, it was explained to the employee to always defer to employees trained in Japan export protocol procedures before proceeding with any packaging efforts. Tyson Fresh Meats also recognizes that system of prevention at other steps failed to achieve the desired outcome as designed. Plant corrective actions, as well as further proactive preventive measures implemented at all plants, serve to strengthen and fortify these procedures within all of our beef plants. As a preventative measure against further incidents and as a continuous improvement process, the firm will implement the following changes to Japan production runs in all beef plants by October 26, 2009:

- No vertebral bone-in product will be permitted to be present or packed off at any box loading or pack-off area where Japan AV-A40 products are being packed or labeled. This will eliminate opportunity for vertebral products to be mis-packed as eligible product for Japan. Packaging and boxing of bone-in products will be conducted at a different time and different location from Japan AV-A40 products.

- Label Cabinet Lock-Up – Only 1 key allowed for each label cabinet and keys are held and controlled by QA management.
- Additional mis-pack checks and rechecks procedures by Operations, Material Handling & QA team members in each plant are to be applied as necessary to prevent mis-pack occurrence.
- Rework was not identified as a source problem for the incident which occurred at establishment 245L. However, during a systems reassessment of all areas of production, Tyson Fresh Meats chose to make proactive changes to ensure that rework product would not be a source of problems for international production runs. We are affirming that no rework will be conducted during AV-A40 runs as part of the overall reassessment of the working system. Japan AV-A40 products requiring rework will be conducted when AV-A40 runs are not engaged and must be re-labeled as domestic product. In addition, no ‘rework’ boxes will be allowed back on to production floor during Japan AV-A40 production runs.
- Anomalous programming requirements must be fully engineered and validated to prevent any possibility of mis-packs from occurring in Japan product. This is to be assessed on a plant-specific case by case basis and will require written approval of the Senior Vice President of Operations of Tyson Foods.

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 ineligible “Bone-in Beef Short Loin” that was mis-packed as “Boneless Beef Shirt Diaphragm” 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.
- There was no intention by Tyson Fresh Meats to package, label and ship ineligible product to Japan. Tyson Fresh Meats fully understands all the

requirements of the EV program for Japan and fully intended to comply with those requirements.

- Tyson Fresh Meats has identified the probable root cause as employee error for the mis-packaging of Bone-in Beef Short Loin as eligible Boneless Beef Skirt Diaphragm for Japan listed on Health Certificate MPH 124093.
- Tyson Fresh Meats has taken effective actions to ensure that this problem will not reoccur.
- USDA verified the corrective actions taken by Tyson Fresh Meats.
- 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 box of mis-packaged ineligible Bone-in Beef Short Loin, were conforming product and were verified during the export approval process.
- USDA personnel followed all applicable regulations, directives and notices.