

**USDA REPORT
AMS EXPORT VERIFICATION PROGRAM AUDIT
DATED JUNE 6, 2007**

EXECUTIVE SUMMARY

PURPOSE

The United States Department of Agriculture (USDA) conducted an Onsite Export Verification (EV) Program audit on May 24, 2007 of Cargill Meat Solutions Establishment 86R, 1505 E. Burlington Ave. Ft. Morgan, CO in order to: 1) assess the events surrounding its shipment to Japan of a mislabeled box of beef omasum within an otherwise fully eligible shipment of the 2899 boxes of beef products in the shipment covered by export certificate MPG-403561, and 2) verify the implementation and effectiveness of corrective and preventive action to ensure ongoing compliance with requirements under USDA's EV Program for Japan.

FINDINGS

- One box of beef omasum was shipped to Japan from Cargill 86R, Ft. Morgan, CO, in a box contained two labels: one for beef liver (product code J90501) and another for beef omasum (product code 20638).
- A plant employee, using a previously labeled box lid, affixed a second label. The employee did not know that the box lid had already been labeled for beef omasum. The lid was removed and placed on a box of beef omasum, still labeled with the beef liver label. When the box arrived in the cold storage staging area the box was stacked with beef livers for export to Japan instead of the beef omasum.
- Although beef omasum is an eligible beef item to ship to Japan, at the time of production Cargill 86R had not been evaluated by AMS to produce beef omasum for export to Japan.
- The most likely explanation is the omasum came from age-verified cattle but this can not be confirmed because beef omasum is not intended for export to Japan. Beef omasum is harvested from age verified cattle; however, there was no separation of this product from potentially nonconforming product. Beef omasum produced under product code 20638 at 86R is not specifically designated as age verified.

CONCLUSIONS

One box of beef omasum was shipped to Japan in a box contained two labels: one for beef liver (product code J90501) and another for beef omasum (product code 20638). Although beef omasum is an eligible beef item to ship to Japan, at the time of production Cargill 86R had not been evaluated by AMS to produce beef omasum for export to Japan.

Cargill 86R made a decision on April 3, 2007 to stop pre-labeling any boxes for Japan product. This was reflected in the training records for May 18th, 2007. Appropriate Slaughter, Offal and Quality Assurance-Tech Services personnel were trained to this new requirement and records reflect this. USDA considers this an isolated incident, which should not affect product previously produced. Along with training of appropriate employees, the following corrective action has been taken:

- For Cargill Est. 86R, livers are packaged in an area separate from the harvest floor. The packaging of livers is visually distinguishable from other offal products and the pre-labeling of boxes with export eligible codes is prohibited.

- The monitoring of the process is documented on an offal monitoring form. This record will document the start/stop time in offal harvest (to trace back to age-verified carcasses), the number of pieces harvested and received back from packaging to offal in order to account for age-verified livers and the number of boxes produced.
- Final packaging of age verified livers for Japan will be conducted in a specific area of the offal room.

In addition, Quality Assurance – Tech Services employees will more closely monitor the number of age verified cattle, the number of age verified livers, the production times, and the number of finished boxes in order to better reconcile the final eligible product count.

USDA REPORT

PURPOSE

The United States Department of Agriculture (USDA) conducted an Onsite Export Verification (EV) Program audit of Cargill Meat Solutions Establishment 86R, 1505 E. Burlington Ave. Ft. Morgan, CO in order to: 1) assess the events surrounding its shipment to Japan of a mislabeled box of beef omasum within an otherwise fully eligible shipment of the 2859 boxes of beef products in the shipment covered by export certificate MPG-403561, and 2) verify the implementation and effectiveness of corrective and preventive action to ensure ongoing compliance with requirements under USDA's EV Program for Japan.

BACKGROUND

The export of U.S. meat products to other countries is facilitated by the activities of three separate but interdependent entities: the U.S. meat and poultry industry, USDA's Food Safety and Inspection Service (FSIS), and 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 Programs standards to ensure that establishments certified for export can meet the 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.

AMS EV Program

The AMS Audit, Review, and Compliance (ARC) Branch is responsible for reviewing and approving companies as eligible suppliers of meat and meat products under the USDA EV Programs, which outline the specified product requirements for individual countries.

Establishments that export product to countries with EV Programs must first apply for EV certification. This application identifies the products to be included in the EV program and the production practices necessary to meet that requirement.

In order to be eligible for EV certification, establishments must have in place an approved USDA Quality System Assessment (QSA) Program. The QSA Program provides establishments with a method to meet specified product requirements and the opportunity to assure customers of their ability to provide consistent quality products.

As one of the requirements for getting a QSA Program approved, establishments applying for EV certification must submit a documented quality management system (QMS). The QMS must include a quality manual, documented specified product requirements, documented QMS procedures, procedures for the control of all QMS documents, and procedures for controlling related establishment records.

In addition, before getting QSA Program approval, the establishment must demonstrate that personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills, and/or experience. All training must be documented and records maintained.

AMS ARC Branch personnel conduct regular audits of EV certified suppliers. These announced audits are conducted at least twice per fiscal year (October 1 to September 30). However, more frequent announced audits may be conducted for any of the following reasons: (1) if either numerous major or minor non-conformances are identified during an audit; (2) if customer complaints indicate an ongoing problem; (3) to satisfy specific requests as declared by customers, trading partners, or other financially interested parties; or (4) as directed by the ARC Branch Chief.

Eligible suppliers are posted on the AMS website for the USDA EV Programs. Only eligible suppliers listed in the Official Listing for a country may supply product identified as meeting the requirements of that country's EV Program. Eligible product must be produced under an approved EV Program and be identified by the establishment as meeting the requirements of the EV Program. Only eligible products may be issued a FSIS Export certificate as listed in the FSIS Library of Export Requirements.

EV Program for Japan

The EV Program for Japan mandates that fresh/frozen beef and beef offal and veal and veal offal are derived from animals 20 months or age or younger.

The establishment must establish and maintain records to provide evidence of conformity to program requirements, to specify product requirements, and to provide evidence of the effective operation of the QMS.

As part of the EV Program, the establishment, before it can forward the FSIS Export Certificate to an FSIS certifying official for signature, must receive a letter from AMS confirming that the EV Program requirements have been met and the products are eligible for export. This AMS Statement of Verification (SOV) is based on AMS' verification of the approved products list and export document review.

Shipping documentation (bills of lading, etc.) must have the statement "Product Meets EV Program Requirements for Japan" and must clearly identify the product and product quantity. Eligible products produced by eligible establishments and identified as meeting the requirements of the EV Program for Japan shall receive a FSIS Export Certificate with the statement "Product Meets EV Program Requirements for Japan."

FSIS Re-inspection and Certification

FSIS Directive 9000.1, Revision 1, directs inspection program personnel to perform a sensory evaluation of the product to determine its eligibility for export, with personnel being particularly alert for signs that product is or may become adulterated or unwholesome. If inspection program personnel find no signs of poor product handling or storage, re-inspection is not required, and inspection program personnel can proceed with signing FSIS Form 9060-6, Application for Export Certificate, and issuing the FSIS Form 9060-5, Export Certificate. If inspection program personnel do find signs of poor product handling or storage while conducting the organoleptic examination of the shipping cartons, they are to randomly select up to five percent of the boxes or containers and inspect the contents for soundness and wholesomeness.

RESULTS OF AMS AUDIT

During import inspection into Japan it was found that one box labeled beef liver product code J90501 was in fact a box of beef omasum. Upon further inspection, it was found that the box was also labeled as beef omasum. Although beef omasum is an eligible beef item to ship to Japan, at the time of production Cargill EST 86R had not been evaluated by AMS to produce beef omasum for export to Japan.

Results of Investigation into the Cause of Non Complying Shipment

Beef livers are packed in two piece boxes consisting of a full bottom and full top. A plant employee used a previously labeled box lid on a bottom box of conforming beef livers. It is believed that this box lid, which was not used during the day shift packaging of beef omasum was removed from the offal processing floor during shift cleanup and placed in the dry storage area where all boxes are stored in order to keep them dry and clean. At this time the box lid was commingled with other lids of the same size which are used for beef livers. This lid was brought back out to the floor for the nightshift packaging and was inadvertently used to pack livers.

The box containing beef livers was weighted and a scale generated label was printed out and affixed to the lid not knowing that the lid had already been labeled for beef omasum. The box was sent to the strapping machine. At the time of strapping, the plant employee noticed that the lid displayed both labels and removed the lid from the box. A new lid was placed on the bottom box of conforming beef livers and the plant employee followed the same procedure for weighing and labeling the box. The employee did not remove the scale generated beef liver label from the box lid prior to handing it to the employee packaging beef omasum.

The top that was originally removed from the liver box was handed to the beef omasum packer (within arms reach) and the "liver weight label" was not removed. It must be noted that the beef omasum boxes also get a printed label with the weight, date and sequence number. The employee did not see the liver label that had been previously affixed by another plant employee, or thought it was the printed label for beef omasum.

The lid was placed on the bottom box containing beef omasum, once this was done the box was moved to a strapping machine to seal the box and it proceeded on to freezer stacking. This strapping machine is a common machine used for both omasum and beef livers. Further down the line, the plant employee stacking boxes on pallets for freezing seeing the beef liver label and not the beef omasum label placed the box on the same pallet as the other beef livers destined for shipment to Japan. All boxes on the pallet displayed beef liver labels facing out which were scanned and shipped to Japan. The box containing beef omasum was positioned such that no one could see the beef omasum label on the box during the shipping process.

- 1) During the production and labeling of the beef livers and omasum the plant was harvesting approximately 700 age verified cattle 20 months or younger. Age verified cattle were harvested beginning at approximately 21:30 until the end of the night shift.
- 2) It takes beef omasum 20 minutes from the time of cattle stunning to arrive in the offal department. This would put age-verified product in the offal department at 21:50.
- 3) The time to process beef omasum and for product to arrive at the strapping machine is 45 minutes after arriving in the offal area.
- 4) The box in question was produced and strapped off at 22:49 allowing 45 minutes for processing would mean the omasum in the box began processing at 22:04, 14 minutes after age verified product first arrived in the offal department.
- 5) Based on this USDA speculates that the beef omasum was derived from age verified cattle.

	<i>Age verified product available for processing in the offal department</i>			
21:30	21:50	22:04	22:49	24:00
Harvest of Age Verified Cattle Begins	First offal items arrive in offal department, liver and omasum	Omasum from box in question begins processing	Lid with both labels placed on omasum box.	Approximate time of end of shift
<i>Age Verified cattle processed</i>				

Beef omasum is harvested from age verified cattle but is not intended for export to Japan, there is no separation of this product from nonconforming product. Beef omasum produced under product code 20638 at this facility is not specifically designated as age verified for Japan or has it been ensured they are derived from animals 20 months of age and younger. Est. 86R management officials indicated that no start or end time was recorded in the offal department that would have identified specifically when the first and last carton of beef omasum was packaged on March 1, 2007.

There is no segregation activity for beef omasum. Beef omasum is processed on both shifts of production. The product is produced as commercial product during processing and since the product was not intended for or produced for export to Japan, Est. 86R could not provide any offal production records that show the box of beef omasum in question was derived from animals 20 months of age or younger.

Corrective Actions

Cargill 86R made a decision on April 3, 2007 to stop pre-labeling any boxes for Japan product. Cargill 86R wrote into the scope of the training records for May 18th, 2007 “There will be no pre-labeling of boxes with Japan J codes. The appropriate Slaughter, Offal, and Quality Assurance – Tech Services personnel were trained on the new procedures and training was documented. Along with training of appropriate employees, the following corrective action has been taken:

- For Cargill Est. 86R, livers are packaged in an area separate from the harvest floor. The packaging of livers is visually distinguishable from other offal products and the pre-labeling of boxes with export eligible codes is prohibited.
- The monitoring of the process is documented on an offal monitoring form. This record will document the start/stop time in offal harvest (to trace back to age-verified carcasses), the number of pieces harvested and received back from packaging to offal in order to account for age-verified livers and the number of boxes produced.
- Final packaging of age verified livers for Japan will be conducted in a specific area of the offal room.

In addition, Quality Assurance – Tech Services employees will more closely monitor the number of age verified cattle, the number of age verified livers, the production times, and the number of finished boxes in order to better reconcile the final eligible product count.

We would stress that the product, beef omasum is an eligible beef item that can be shipped to Japan and that the beef omasum most likely was produced from age-verified cattle 20 months or younger. Products produced from age-verified cattle do not require a special process such as those for A40 offal items, only a starting time and ending time. Beef items produced from 9:30 PM until the end of the shift would be eligible to ship to Japan as long as all SRMs were properly removed. This incident was a single box out of a shipment of over 2600 boxes, which did not contain any SRM material or is identified as an ineligible beef item for shipment to Japan.

It is USDA's assessment that had the no-pre-labeling procedure been implemented and the associated training taken place at the time the omasum was produced, its inclusion in the liver shipment would have been precluded, as there would not have been omasum and liver labels on the box lid in question. USDA considers this an isolated incident, further validated during 100% inspection of other product exported by Cargill 86R which should not affect product previously produced. AMS is prepared to begin issuing Statements of Verifications for shipments to Japan.