

**USDA REPORT  
AMS EXPORT VERIFICATION PROGRAM AUDIT  
DATED MAY 17, 2007**

**EXECUTIVE SUMMARY**

**PURPOSE**

The United States Department of Agriculture (USDA) conducted an Onsite Export Verification (EV) Program audit of Cargill Meat Solutions Establishment 86K, 3201 E HWY 154, Dodge City, KS, in order to: 1) assess the events surrounding its shipment to Japan on February 27, 2007 of four ineligible boxes within an otherwise fully eligible shipment of the 250 boxes of beef product were mistakenly included in the shipment covered by export certificate MPG- 416272, 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**

- The four boxes, which were not intended for export to Japan, could not be verified as complying with Japan's age verification requirements as defined in the Specified Product Requirements of the EV Program for Japan.
- USDA was able to verify that Cargill Est. 86K could satisfactorily trace finished eligible product – i.e., product in all other boxes in the shipment – back to age-verified animals as required by the Specified Product Requirements of the EV Program for beef to Japan.
- Cargill Est. 86K included ineligible product within an export shipment to Japan as a result of inadequate controls of pre-labeled boxes that allowed an establishment packaging personnel to mistakenly use these four Japan labeled box lids on product not intended for shipment to Japan. The pre-labeled box lids, which are the same size as lids for non Japan product, were not removed from the packaging area. The QSA manual did not specifically address the removal of pre-labeled lids, and does not specifically define the exact procedure of placing the lids on the boxes. The employee was not aware the boxes were labeled for Japan when they were placed on the boxes of non Japan tongues.
- Cargill Establishment 86K, Dodge City, Kansas, has proposed and taken several corrective and preventive actions to address this matter. Effective April 3, 2007, the pre-labeling of box lids with export eligible product codes is prohibited. The quality manual has been revised to strengthen the monitoring process for age-verified tongues. Cargill's Regulatory Affairs Superintendent conducted training on their corrective actions. In addition, Quality Assurance – Tech Services employees will more closely monitor the number of age verified cattle, the number of age verified tongues, the production times, and the number of finished boxes in order to better reconcile the final eligible product count.

**CONCLUSIONS**

Upon notification of this incident AMS took immediate action and suspended the issuing of Statements of Verification for the Cargill EST 86K Dodge City, KS plant. Since the AMS Statement of Verification is required prior to attaining the final signature for export by FSIS, this action prevented Cargill EST 86K from shipping any further product to Japan and in effect identified Cargill EST 86K, Dodge City, KS as ineligible from the EV Program for Japan.

The following was sent to Cargill Meat Solutions Corporate Headquarters on April 4, 2007:

*The ARC Branch is suspending issuances of AMS Statements of Verification for the EV Program for Japan immediately. This doesn't affect the facilities remaining approved EV Programs. The ARC Branch will reinstate issuance of AMS Statements of Verification when appropriate corrective actions are submitted to the ARC Branch and verified for implementation and effectiveness."*

Information provide to AMS by Cargill Meat Solutions on a Cargill "Non-Conforming BEV Product/Process Incident Report" indicates that a boxing employee mistakenly used four unused lids that were pre-labeled for product for export to Japan on product from cattle that were harvested after age-verified cattle. These four ineligible boxes were mistakenly included in the shipment to Japan. The four boxes of tongues were derived from animals that could not be verified as age-verified animals 20 months or younger but were harvested during the facilities Less Than 30 (LT30) month EV program and were properly trimmed according to FSIS requirements for removal of SRMs.

The USDA audit verified that four ineligible boxes within an otherwise fully eligible shipment of the 250 boxes of beef product were mistakenly included in the shipment covered by export certificate MPG- 416272. The audit confirmed that the ineligible product was inspected and passed by USDA for human consumption and was at the time of export a safe and wholesome product fit for consumption in the United States and eligible for export to most international markets.

Cargill Establishment 86K, Dodge City, Kansas, has proposed and taken several corrective and preventive actions to address this matter. USDA further concludes that Cargill Establishment 86K sufficiently identified the root cause of the error and has taken appropriate actions to ensure this isolated incident will not reoccur. During the normal AMS audit schedule particular care will be taken by the AMS auditors at of all other Cargill establishments to ensure that this incident is an isolated incident and not a company wide issue. It must be noted that no other Cargill plant has shipped nonconforming offal or exhibited lose of control or failure to follow their documented procedure in this area of the plant during processing of product for Japan. Upon reinstatement by the Government of Japan of Cargill Est. 86K, USDA, AMS will immediately begin issuing Statements of Verification for certificates for exports to Japan. USDA will continue to monitor the corrective actions taken by Cargill Establishment 86K and will exercise to the fullest extent their authority under U.S. law to ensure the import requirements of Japan are met.

All FSIS inspections and issuing of health certificates were conducted according to FSIS Directives and Regulations. No other nonconformances or issues were found in the offal area pertaining to the production of product for the Export Verification Program for Japan.

## **USDA REPORT**

### **PURPOSE**

The United States Department of Agriculture (USDA) conducted on May 10, 2007, an onsite Export Verification (EV) Audit of Cargill Meat Solutions Establishment 86K , 3201 E. HWY 154, Dodge City, KS, to: 1) evaluate the events surrounding a shipment of four ineligible boxes within an otherwise fully eligible shipment of the 250 boxes of beef product which were mistakenly included in the shipment covered by export certificate MPG- 416272 on February 27, 2007, and 2) verify the implementation and effectiveness of corrective and preventive action for ongoing compliance with requirements under all 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**

The AMS audit on May 10, 2007, was intended to 1) determine whether the practices and actions of Cargill Meat Solutions Est. 86K Dodge City, Kansas, complied with export verification requirements for Japan and 2) to verify the implementation and the effectiveness of corrective and preventive action taken to address the issue.

AMS found the following:

#### **1. The shipment of four boxes of ineligible beef tongues**

At the time of the incident, the Cargill Est. 86K approved QSA EV Program did not address the handling of pre-labeled boxes for export to Japan during production of ineligible products.

- A Cargill Est. 86K employee mistakenly placed four Japan pre-labeled box lids on product not intended for shipment to Japan. Four pre-labeled boxes intended for product produced from age-verified cattle for Japan remained in the packaging area after completion of the packaging of tongues from age-verified cattle. The Cargill Est. 86K employee mistakenly placed these four lids on product not intended for shipment to Japan. These four boxes were mistakenly included and shipped to Japan.

#### **2. Product traceability**

The results of an AMS trace-back analysis indicated that all other product identified and included on the export certificate was conforming product and verified during the export approval process.

It was also determined that **all** product included in the shipment meet the requirement for removal of all SRM's as defined in FSIS regulations and export verification requirements. The four boxes of tongues were derived from animals that could not be verified as age-verified animals 20 months or younger but were harvested during the facilities Less Than 30 (LT30) month EV program.

All FSIS inspections and issuing of health certificates were conducted according to FSIS Directives and Regulations. No other nonconformances or issues were found in the offal area pertaining to the production of product for the Export Verification Program for Japan.

### **CARGILL CORRECTIVE ACTIONS VERIFIED**

Effective April 3, 2007, the pre-labeling of box lids with export eligible product codes is prohibited. The new procedure on pre-labeling of boxes has been reviewed by all affected employees. Technical services will closely monitor the process for compliance when the next order is produced for Japan eligible tongues using the “Age-Verified Offal Monitoring Form.” The quality manual has been revised to strengthen the monitoring process for age-verified tongues to prevent this incident from happening again as follows:

- For Cargill Est. 86K, eligible tongues are vacuumed packaged in an area separate from the harvest floor. The packaging of eligible tongues is visually distinguishable from ineligible tongues and the pre-labeling of boxes with export eligible codes is prohibited.
- The monitoring of the process is documented on the Age-verified Offal Monitoring form. This record documents 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 tongues, the time product is placed into the offal chiller (to correlate to pack time), and the number of boxes produced.
- Final packaging of age verified tongues for Japan will be conducted in a specific area of the offal room.

AMS was able to verify that the Cargill Meat Solutions Est. 86K corrective actions for this incident were implemented and effective. Cargill’s Regulatory Affairs Superintendent conducted training on their corrective actions including all new procedures for production of age verified tongues for Japan.

The appropriate Slaughter, Offal, and Quality Assurance – Tech Services personnel were trained on the new procedures and training was documented. Cargill Est. 86K has designated a specific area of the offal room for final packaging of age verified tongues for Japan. “J” product code labels will only be applied to the box after the top is closed. Pre-labeling of boxes for age verified tongues for Japan is prohibited.

In addition, Quality Assurance – Tech Services employees will more closely monitor the number of age verified cattle, the number of age verified tongues, the production times, and the number of finished boxes in order to better reconcile the final eligible product count. A demonstration was conducted of the entire process from identification of the age verified cattle carcass/head/tongue to the final boxing and labeling of age verified tongues for Japan. Slaughter, Offal, and Quality Assurance – Tech Services personnel with responsibility affecting product integrity demonstrated their role in the process and interviews confirmed their understanding of the new procedures.

AMS has determined that during the onsite export verification audit AMS was able to verify the implementation and effectiveness of the corrective actions. These corrective actions, correctly followed should prevent a recurrence of this incident.