

## **EXECUTIVE SUMMARY**

### **REPORT OF THE AUDIT RESULTS BY THE AGRICULTURAL MARKETING SERVICE RELATED TO THE EXPORT VERIFICATION PROGRAM FOR JAPAN MAY 2006**

Export Verification (EV) programs were developed to meet specific product requirements established by importing countries that are not components of FSIS regulatory inspection activities. These EV programs work on the premise of establishments developing a system of process controls that are based off of the internationally accepted system developed by ISO (9001:2000).

AMS conducted trace-backs audits at 25 establishments, which had actually shipped product to Japan. The purpose of these audits was to prove that the traceability system established through the QSA/EV Program for Japan was robust and could be proven effective in case nonconforming product exists. Specifically, the scope of the trace-back included product that was shipped between December 13, 2005, and January 20, 2006. Using shipping and production records and the traceability systems in place, auditors were able to conduct trace-backs to verify that product was derived from acceptable carcasses or known-age animals for product shipped to Japan during those dates. All product names and product codes indicated that they were free of vertebral column and were either boneless or semi-boneless. The review of shipping records and production records verified that all products shipped were free of designated excluded materials, i.e., vertebral column, spinal cord, beef heads, and distal ileum.

QSA/EV audits were conducted beginning April 24, 2006, through May 4, 2006, for all 35 facilities listed in the EV Program for Japan. Although non-conformances were identified, they did not affect the acceptability or usability of the product. All establishments were effectively removing designated excluded materials and would have been able to meet the specific product requirements for the EV Program for Japan.

In conclusion, the United States places a high priority on meeting the Japanese standards for a supply of safe, high-quality beef. We understand these standards. The process control system employed by AMS is a coordinated system that enables the USDA to meet the high standards demanded by our trading partners around the world.

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RELATED TO THE EXPORT VERIFICATION PROGRAM FOR JAPAN  
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**BACKGROUND**

Export Verification (EV) programs were developed to meet specific product requirements established by importing countries that are not components of FSIS regulatory inspection activities. They provide a critical link between the Department of Agriculture (USDA) agencies, such as the Food Safety and Inspection Service (FSIS), and the Agricultural Marketing Service (AMS). These EV programs work on the premise of establishments developing a system of process controls that are based on the internationally accepted system developed by ISO (9001:2000). Consequently, these EV programs were all audited in accordance with ISO auditing guidelines ISO 19011:2002.

Following almost two years of banning the export of beef from the United States, Japan agreed to resume beef trade on December 12, 2005. In the agreement for resumption of trade with Japan, USDA's Agricultural Marketing Service (AMS) agreed to conduct audits to evaluate the systems in place to ensure that Japan's country specific requirements were met.

Once the official onsite audits for the EV Program for Japan began on December 12, 2005, establishments were audited against the ARC 1030J Procedure, *USDA Export Verification (EV) Program: Specified Product Requirements for Beef – Japan*, dated December 12, 2005, Rev 02. All establishments were audited by experienced USDA auditors, who as a part of their ongoing training, had successfully completed and passed the ISO 9001:2000 and ISO 14001:2000 Lead Auditor training class. Also, in addition to the extensive training and experience, the Program manager has reviewed hundreds of Quality System Assessment (QSA)/EV programs and is very knowledgeable of all the requirements of the EV Program for Japan along with all other EV programs for other countries.

## **METHODOLOGY OF AUDITS**

The auditors used the criteria outlined in Appendix I to conduct the audits for the EV Program for Japan and for the audits of other countries. As auditors proceed through the assessment, they sometimes identify areas where the system, its process, procedures, or the way they have implemented those procedures do not comply with the clauses of the QSA program. It is important to note that there are several degrees of findings. Typically, these findings are classified as one of the following: observations, minor non-conformances, or major non-conformances.

An observation is not a violation of the criteria but typically identifies that there may be a better way to monitor a process or document a process. It is not a problem but rather a potential for improvement and a way to avoid future problems.

A minor non-conformance (juuyou-do no hikui hi-tekigo jirei) is one that when taken by itself does not indicate a systemic problem with the quality management system. It is typically an isolated or random incident. An example would be that the most current version of a document is not available at the operator's station. The updated version exists, but a copy of it is not available for the operator's use. The operator is using an outdated procedure. Other examples include those instances where a form may not have a document control number on it and those instances when an internal audit has an overdue corrective action request.

A major non-conformance (juuyou-do no takai hi-tekigo jirei) occurs when one of the criteria of the standard (i.e., the QSA Program) is not addressed or has not been addressed adequately. Typically, these occur when an organization has not addressed all the requirements of the specific element or criterion. These also occur when an organization has put a process or procedure in place but has not implemented it or cannot yet demonstrate effective implementation.

As in all quality management systems, opportunities for continuous improvement exist. During the audits areas in need of improvement are identified and documented on the individual audit reports. These items are categorized by the auditor with complete and detailed descriptions. All non-conformances are required to be corrected in order for the establishment to continue to be listed as an EV-approved establishment. Non-conformances that affect the acceptability or usability of the product result in immediate suspension of production and shipping and possibly result in the delisting of the establishment.

In addition, corrective actions to address non-conformances are required in order for the establishments to continue to be approved for shipment. Once the corrective actions are completed, they are reviewed and verified.

Under the EV program, a major non-conformance must be addressed and corrected within 15 business days beginning with the date of the report to ensure the continued approval of the establishment. A minor non-conformance must be addressed and corrected within 30 business days to ensure the continued approval of the establishment. If the non-conformance affects product compliance, no products can be produced until the non-conformance is resolved.

As outlined in ISO guidelines, documented procedures are only required where the absence of a documented procedure would adversely effect the quality of the product being produced. Certain activities, by their nature, do not require a documented procedure. However, in order to satisfy the customer requests, and to provide AMS with a higher level of confidence, AMS has required companies to include in their QSA/EV manuals additional documented procedures and records. These required procedures and records are identified in the ARC 1002 Quality System Assessment Program Procedure. The absence of these procedures or records would be considered a major procedural non-conformance but in most cases would not directly translate to non-conforming product.

## **RESULTS OF RETROSPECTIVE AUDITS**

### Trace-back of Products Shipped to Japan

Following the suspension of trade with Japan on January 20, 2006, due to the discovery of the vertebral column in veal cuts, the USDA agreed to conduct a trace-back of all of the products that were shipped to Japan. The purpose of this trace-back was to prove that the traceability system established through the QSA/EV Program for Japan was robust and could be proven effective in the case non-conforming product exists. Specifically, the scope of the trace-back included product that was shipped between December 13, 2005 and January 20, 2006. A list of the establishments that shipped product to Japan (Appendix II) is attached.

AMS conducted trace-backs at 25 establishments. To facilitate trace-backs of products shipped to Japan, AMS requested all establishments approved in the EV Program for Japan provide production information specific to product produced for export to Japan between the dates of December 12, 2005 through January 20, 2006. USDA auditors reviewed all available production and shipping records for product shipped to Japan during those dates. Product was officially traced back in every establishment to ensure the product was derived from cattle that were 20 months of age or younger or met the A40 physiological maturity requirements. All establishments demonstrated that they had an effective traceability system in place for product shipped to Japan and that the product was produced from conforming carcasses and animals.

As indicated in Section 5.1 Specified Product Requirements of ARC 1030J Procedure the designated excluded materials that must be removed from product destined for shipment to Japan include the head, spinal cord, distal ileum and vertebral column.

During the trace-back of product auditors reviewed all records of product shipped. This included shipping records and production records. Auditors reviewed the product names and product codes to ensure that product shipped did not contain beef heads or intestines. The review concluded that the only offal products produced for and shipped to Japan

were tongues. Since there were no shipments of intestines to Japan, this information can be used to verify that the distal ileum was not included in any shipments to Japan.

The exported beef items included various bone-in, boneless beef items, outside skirt, diaphragm meat, and fresh chilled beef tongues. All product names and product codes indicated that they were free of vertebral column, and for the most part, product shipped to Japan was boneless. Product codes for boneless rib, short rib, boneless chuck flap meat, boneless short plates, outside skirt meat, boneless chuck short rib, and boneless rib eye roll were found. At some facilities, all of the product names and product codes were for boneless beef only. All products shipped to Japan were products free of vertebral column and were either boneless or semi-boneless. Beef items identified as items within close proximity of the vertebral column were identified as boneless products, e.g., boneless strip loins, boneless chuck short rib, boneless rib eyes, boneless sirloin. The review of shipping records and production records verified that all products shipped were free of designated excluded materials, i.e., vertebral column, spinal cord, beef heads, and distal ileum.

During the first round of audits conducted beginning December 12, 2005 each facility was audited and found to have sufficiently implemented their QSA programs. The process of removing the requested tissues in Section 5.1 was verified during these audits. Approved facilities are required to remove these tissues for other QSA/EV Programs and conduct this process as an ongoing normal business practice.

Also, during the April / May audits these processes were reviewed and verified. Audit results from both audits coupled with a review of documentation of product shipped to Japan, including product names and product codes, indicates that all product shipped to Japan was produced under an approved QSA program and meets the requirements set forth in the *ARC1030J Procedure, USDA Export Verification (EV) Program Specified Product Requirements for Beef – Japan*. The trace-back audits conducted verified the following two requirements:

## **5 Specified Product Requirements**

5.1 *Beef and beef offal that are eligible for export to Japan as listed on the Food Safety and Inspection Service (FSIS) website must be processed using the procedures as incorporated into the facility's HACCP or Sanitation SOP's, and must be produced in a manner that ensures the hygienic removal of the following materials and prevents the contamination of these tissues with meat products being produced for export to Japan:*

5.1.1 *Bovine heads (except for hygienically removed tongues and cheek meat, but including tonsils); spinal cords; distal ileum (two meters from connection to caecum); and vertebral column (excluding the transverse processes of the thoracic and lumbar vertebrae, the wings of the sacrum, and the vertebrae of the tail).*

5.2 *Eligible products must be derived from cattle that are 20 months of age or younger at the time of slaughter using either one of the following methods (5.2.1 or 5.2.2).*

## **RESULTS OF RECENT AUDITS**

### Audits Conducted April/May 2006

All establishments were audited for all requirements, including the new requirements that resulted from the USDA/GOJ Audit Exit meeting and the new requirements that were established after the January 20<sup>th</sup> suspension of trade with Japan. Establishments approved for Japan continued to operate their QSA/EV programs for all other countries for which they are approved to ship.

QSA/EV audits were conducted beginning April 24, 2006, and concluding May 4, 2006. All audits were conducted in accordance with ISO auditing guidelines ISO 19011:2002. Additionally, all auditors used the ARC 1002 Checklist that was developed with input from the GOJ. The AMS Lead auditors conducted the ARC 1030J (i.e., EV Program for Japan) audits in accordance with the criteria outlined in Appendix I.

AMS reviewed all QSA/EV Program manuals during these audits to verify compliance to the audit criteria. Although each establishment's QSA/EV Program manual was sufficient, AMS did identify some non-conformances due to a lack of detail in the

documented procedures. USDA auditors placed an emphasis on the review of documented procedures along with assessing the establishments' employees understanding of the EV Program procedures.

Following the delisting of the two veal facilities, there were 38 establishments listed on the AMS website as approved to export to Japan. AMS conducted audits of 35 of these establishments. The other three were not audited for the following reasons: one establishment that was originally approved under the EV Program for Japan requested to be removed from the program and two establishments have since closed. In 10 of the establishments that were audited, AMS did not find any non-conformances. In the other 25 establishments, procedural issues were identified. These will be resolved before the establishments will be eligible to produce product for Japan.

The following six major procedural non-conformances were identified. These non-conformances did not affect the acceptability or usability of the product.

*Major 1*

Requirement: The company must ensure that product purchased or received from outside establishments and used in the program conform to specified receiving requirements.

Finding: One lot of cattle slaughtered did not have a certificate in the establishment's records to verify the birth date of the cattle. This lot was received and included in the less than 20 month group of cattle and was identified as eligible for export to Japan. *However, these cattle were received from a designated supplier of 20-month of age or younger cattle. Further, records verified the birth date of the cattle to be less than 20 months of age.*



### *Major 2*

Requirement: EV Program's Additional Requirements requires that a company address specific items for the AMS Statement of Verification and the AMS Statement of Verification for Product Intended for Further Processing.

Finding: The company had fully addressed these requirements in an e-mail to the ARC Branch, but the requirements were only partially addressed in its EV Export Procedures.

### *Major 3*

Requirement: The company must conduct internal audits at planned intervals. The internal audits must determine whether the Quality Management System (QMS): a) conforms to the planned arrangements, to the requirements of this Procedure, and to the QMS requirements established by the company; and b) is effectively implemented and maintained. The company must have a documented procedure, which addresses: the audit criteria, scope, frequency, and methods; the selection criteria of the auditors and conduct of auditors which must ensure objectivity and impartiality of the audit process (Auditors must not audit their own work.); and the follow-up activities.

Finding: No internal audit has been performed to date. The procedure indicates that the Production Manager will be assigned the task of performing the internal audit. Other procedures in the Quality Manual indicate that this person has responsibilities over the Program activities. *However, during the USDA audit, it was determined that all process controls were in place and the system was fully functioning.*

#### *Major 4*

Requirement: The company must ensure that non-conforming product (raw material and/or finished product) is identified and controlled to prevent its unintended use.

Finding: The company's Quality Manual does not include a clearly defined documented procedure or identify the plant personnel who will be responsible for its implementation. *It should be noted that at the time of the audit this plant was not producing product for Japan.*

#### *Major 5*

Requirement: The EV Program's Additional Requirements, effective April 3, 2006, requires companies to provide a list of all products to be exported to each country for which they are approved. The product lists should have product codes that are specific to each country.

Finding: The current product lists use the North American Meat Processors (NAMP) Meat Buyers' Guide identification numbers as product codes for each product to be exported to each country. This does not allow for specific product codes for each country. *However, other previously approved controls were being used to ensure that product was shipped to the appropriate country.*

#### *Major 6*

Requirement: The company must have a documented procedure to identify product (i.e., raw materials and/or finished product) by suitable means throughout product realization, where appropriate. The documented procedure must describe the method for controlling and recording the unique identification of the product.

The company states that products from 20-months and younger carcasses for Japan will be packed in white boxes with red print.

Finding: A review of the submitted product code list indicated that, even the use of red and white boxes are unique for product to be exported to Japan, the product codes for the EV Japan Program are not unique to the Japan Program for the identification of Japan products. The same item codes are used for products from carcasses under 20 months and are used for the products fabricated from carcasses over 20 months but less than 30 months of age. *However, other previously approved controls were being used to ensure that product was shipped to the appropriate country.*

Provided below are examples of minor non-conformances identified during the audits. These procedural non-conformances did not affect the acceptability or usability of the product. They will be resolved before the establishments will be eligible to produce product for Japan.

*Minor 1*

Requirement: Control of records includes, at a minimum, that records must be stored in a manner so as to prevent loss, damage, or alteration.

Finding: The quality manual does not address this requirement. *Although not addressed in the quality manual, the records were properly maintained.*

*Minor 2*

Requirement: The company must conduct internal audits at planned intervals and must be effectively implemented and maintained. The company's Quality Manual states that internal audits will be done on a quarterly basis.

Finding: The company had conducted one internal audit but had not yet conducted the next scheduled quarterly audit. An audit checklist also was not included in this procedure to verify the effectiveness of the internal audit. *However, during the USDA audit, it was determined that all process controls were in place and the system was fully functioning.*

#### *Minor 3*

Requirement: The EV Program's Additional Requirements requires approved programs to include a company supplier listing if QSA/EV Program product is received from another supplier approved under the QSA/EV Program.

Finding: The company's supplier lists states that no EV product is received from outside suppliers. However, the company had not updated its Quality Manual and the EV Export Procedure to reflect this change. *The company has not received carcasses from outside suppliers since October 2005.*

#### *Minor 4*

Requirement: The QSA Program procedures require that QSA documents have a date or revision number in order to provide that only current documents are being utilized.

Finding: The Quality Manual review indicated several attachments were not dated nor did not contain a revision number for reference. Also multiple page documents did not contain page numbers.

Since establishments were not producing product for shipment to Japan during these audits, certain activities specific and unique to the EV Program for Japan were not available for observation. These specific activities related to the requirements that

products must be produced from animals 20 months of age or younger and/or produced from carcasses identified as meeting the A40 physiological maturity requirement.

Notwithstanding that the establishments were not specifically producing product for shipment to Japan, and notwithstanding the requirement that product for shipment to Japan must be produced from animals 20 months of age or younger; all establishments were effectively removing designated excluded materials, which would have been able to meet the specific product requirements for the EV Program for Japan.

These specific processes included, removal of all designated excluded materials, segregation of complying and non-complying product, labeling of product and documentation of program activities.

Particular attention was given to ensure that the documented procedures for activities involving the removal of designated excluded materials were in order. As in all audits, AMS conducted an extensive review of the actual production procedures in place at all locations throughout the establishment and visually verified conformance with EV Program requirements. In all instances, the establishments were found to be conducting these activities according to requirements. AMS did not find any incidence where the establishments produced nonconforming product.

Establishments will not be approved for the EV Program for Japan until such time as all outstanding procedural issues have been addressed. Corrective actions for some of the findings have already been received; however, all corrective actions for all findings are due to AMS by May 2006.

## **SUMMARY**

Through the continual review of the EV Program for Japan and EV programs for additional countries, the AMS QSA/EV programs have proven to be an effective link between USDA agencies. These QSA/EV systems are based off of internationally

recognized standards for process controls and for auditing that have been utilized by developed and developing nations for the last 50 years to ensure product quality and integrity.

In conclusion, the U.S. places a high priority on meeting the Japanese standards for a supply of safe, high quality beef. We understand these standards. The process control system employed by AMS is a coordinated system that enables the USDA to meet the high standards demanded by our trading partners around the world.

**APPENDIX I. LIST OF AUDIT CRITERIA USED BY THE AMS LEAD  
AUDITORS, TO AUDIT THE  
EXPORT VERIFICATION PROGRAM FOR JAPAN**

- The establishments' approved QSA/EV program
- ARC 1002 Procedure, *USDA Quality System Assessment (QSA) Program*, dated March 4, 2005
- *Use of Cattle Legally Imported from Canada, Mexico, or Other Third Free Countries within the EV Program for Japan*, dated December 12, 2005, Rev 01
- *EV Program for Japan – Clarification of Specified Requirements*, dated December 30, 2005
- *EV Programs Additional Requirements*, dated March 1, 2006, Revised and Effective April 3, 2006
- ARC 1030J Procedure, *USDA Export Verification (EV) Program: Specified Product Requirements for Beef – Japan*, dated December 12, 2005, Rev 02

**APPENDIX II. LIST OF ESTABLISHMENTS THAT SHIPPED PRODUCT TO JAPAN**

	<b>FSIS #</b>	<b>Plant Name and Location</b>
(1)	683	<b>PM Beef Holdings, in Windom, MN</b>
(2)	21488	<b>Brawley Beef, in Brawley, CA,</b>
(3)	27472	<b>Premium Protein Products, Hastings, NE</b>
(4)	86R	<b>Cargill Meat Solutions, in Ft. Morgan, CO,</b>
(5)	86M	<b>Cargill Meat Solutions, in Schuyler, NE</b>
(6)	562M	<b>Smithfield Beef Group, Packerland Packing Company, in Plainwell, MI</b>
(7)	969	<b>Swift Beef Company, in Greeley, CO</b>
(8)	410	<b>American Foods Group, in Green Bay, WI</b>
(9)	1311	<b>Moyer Packing Company, in Souderton, PA,</b>
(10)	245J	<b>Tyson Fresh Meats, in Geneseo, IL</b>
(11)	628	<b>Swift Beef Company, in Hyrum, UT</b>
(12)	969G	<b>Swift Beef Company, Grand Island, NE</b>
(13)	235	<b>Washington Beef, LLC dba AB Foods, in Toppenish, WA</b>
(14)	562	<b>Smithfield Beef Group – Packerland Packing Company, in Green Bay, WI</b>
(15)	267	<b>Sunland Beef Company, in Tolleson, AZ</b>
(16)	245E	<b>Tyson Fresh Meats, in Amarillo, TX</b>
(17)	208A	<b>National Beef Packing Company, in Liberal, KS</b>
(18)	262	<b>National Beef Packing Company, LLC, in Dodge City, KS</b>
(19)	19336	<b>Nebraska Beef Ltd., in Omaha, NE</b>
(20)	27	<b>Creekstone Farms Premium Beef, in Arkansas City, KS</b>
(21)	960/960A	<b>Greater Omaha Packing Company, in Omaha, NE</b>
(22)	245D	<b>Tyson Fresh Meats, in Emporia, KS</b>
(23)	6173	<b>Masami Foods, in Klamath Falls, OR</b>
(24)	86K	<b>Cargill Meat Solutions Corporation, Dodge City, KS</b>
(25)	783	<b>Harris Ranch Beef Company, in Selma, CA</b>