

USDA Findings and Actions Report

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I. EXECUTIVE SUMMARY

On December 12, 2005, after nearly two years of banning the export of beef from the United States, Japan resumed beef trade with the United States. On January 20, 2006, Japan government officials discovered 3 boxes of veal with vertebral column shipped from the United States. Vertebral column is not allowed under the specific trade agreement with Japan. The United States acknowledges this was unacceptable because it did not meet the terms of our agreement with Japan, but emphasized that the product did not present a health risk to the public.

Once the United States government was made aware of this ineligible shipment, the U.S. Secretary of Agriculture ordered a thorough investigation. The Office of Program Evaluation, Enforcement and Review, the office within the Food Safety and Inspection Service (FSIS) responsible for audits and evaluations, immediately began an investigation into what happened in this particular incident that allowed ineligible product to reach Japan. FSIS also partnered with the investigative branch of the Office of the Inspector General (OIG) to conduct its investigation. This investigation was completed on February 2, 2006. (See Section II of this Report.)

The investigation revealed this incident was the result of inadequate familiarity on the part of the exporter and USDA inspector with the specific products that were eligible for shipment to Japan. By agreement with the Government of Japan, no vertebral column is to be shipped. Vertebral column was shipped in 1 box labeled Hotel Rack and 2 boxes labeled Trimmed Loin. In addition, the investigation revealed that FSIS inspection program personnel at the establishment involved were not sufficiently aware of the AMS EV program and should not have certified/approved shipment of ineligible product for export to Japan. Because this was the first and only shipment of veal to Japan under the EV program, we are confident in our assessment that the circumstances surrounding this ineligible shipment were unique. (See Section III of this Report.)

U.S. Secretary of Agriculture Mike Johanns initially announced 12 actions steps in response to this ineligible shipment of veal to prevent the repeat occurrence of this incident. These 12 action steps included delisting of the establishments in question that had exported ineligible veal products to Japan. Additionally, within 3 days of notification of the ineligible shipment, FSIS held interactive web-based training for its responsible inspection program personnel at all EV approved establishments. Within 4 days, USDA officials held a meeting at USDA headquarters in Washington, D.C., with Chief Executive Officers and other senior management for establishments exporting beef under EV programs to ensure industry understood critical issues for compliance with EV export requirements. U.S. Secretary of Agriculture Mike Johanns personally addressed the group and articulated very clearly the importance of compliance with all requirements to maintain the high standard of excellence associated with the U.S. farm and food product export programs. (See Section IV of this Report.)

Following the investigation, USDA determined appropriate additional action steps to address the findings of the investigation. For example, to be certain that FSIS inspection program personnel are fully aware of specific products approved for export to each country participating in EV programs, the Agricultural Marketing Service (AMS) will maintain a list of specific products approved for export to each country on an internal web site accessible to FSIS trained inspection program personnel. Additionally, AMS will notify FSIS each time establishments are audited, listed, or delisted for EV programs. (See Section IV of this Report.)

On January 27, 2006, the U.S. Secretary of Agriculture also asked that the OIG, the independent investigative arm of the USDA accountable to the American public through the U.S. Congress, perform an audit to evaluate the adequacy of USDA's coordination and control process for the beef export verification program to Japan. This investigation concluded with the completion of an OIG audit report on February 10, 2006, and is also included in this report (see Section III). The findings and corresponding USDA actions presented in this report (see Section IV) are the result of the FSIS *Japan Export Investigation Report, Golden Veal Corp., and Atlantic Veal and Lamb, Inc.*, and OIG *Assessment of USDA's Controls for the Beef Export Verification Program for Japan*. The findings, facts, and actions are very similar for each investigation.

The United States places a high priority on meeting Japanese standards for imported beef. We understand the Japanese requirements. They are very clear and our system is designed to meet these requirements. As a result of our thorough investigations, we are confident that this detection of ineligible product in a single veal shipment does not indicate weakness in the overall U.S. beef processing or inspection or export systems. Through our investigations and our response to this incident, we have incorporated additional protections into the U.S. system to prevent a similar incident from occurring.



UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF PROGRAM EVALUATION, ENFORCEMENT AND REVIEW
Compliance and Investigations Division

Japan Export Investigation Report
Golden Veal Corp. & Atlantic Veal and Lamb, Inc.

February 14, 2006

Approved By:

William C. Smith
Assistant Administrator, OPEER

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Japan Export Investigation Report

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Purpose

The purpose of this document is to detail an investigation, conducted by the United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS), Office of Program Evaluation, Enforcement and Review (OPEER), Compliance and Investigations Division, to determine if Atlantic Veal and Lamb, Inc. (Atlantic), (Est. 1509A), 275 Morgan Avenue, Brooklyn, New York, 11211, and Golden Veal Corp. (Golden), (Est. 1915), 2416 East West Salem Road, Creston, Ohio, 44217, slaughtered, fabricated, shipped, and exported veal products to Japan which did not comply with USDA's Agricultural Marketing Service (AMS) Export Verification (EV) Program for Japan. Atlantic's and Golden's records document that some select veal cuts and all offal shipped to Japan did not meet EV Program requirements for export to Japan.

Background

The export of U.S. meat and poultry products to other countries is facilitated by the activities of three separate but interdependent entities: the U.S. meat and poultry industry, the USDA Food Safety and Inspection Service (FSIS), and the USDA Agricultural Marketing Service (AMS).

The U.S. meat and poultry 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. For example, Japan requires the removal of certain beef tissues that neither the U.S. nor international standard setting organizations, such as the International Epizootic Office (OIE), have specified as risk materials. 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, "Export Certification," published September 9, 1999, 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.

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AMS is responsible for developing EV Programs 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 Export Verification (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 Export Verification (EV) Programs. The EV Programs 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 certified 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

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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.

As part of the agreement, spinal cord and spinal column (excluding the transverse process of the thoracic and lumbar vertebrae, the wings of the sacrum, and the vertebrae of the tail) must be removed from any product destined for export to Japan.

The agreement to use EV Programs to meet Japan Export requirements resulted from the following activities.

Timeline of Japan's Acceptance of U. S. Beef

April 24, 2004: Under Secretary Penn for Farm and Foreign Agricultural Services led an interagency team to discuss the resumption of beef trade with the Government of Japan (GOJ). As a result of the meetings, GOJ and the U.S. Government (USG) agreed to actively engage in consultations, including a series of working group meetings of experts and technical staff to discuss issues surrounding Bovine Spongiform Encephalopathy (BSE) control and food safety. The two sides also agreed to a process that would lead to a resumption of trade by "around summer" 2004 for both U.S. and Japanese beef.

Joint Working Group meetings—May 18-19; June 28-30; and July 21-22, 2004: The working group, comprising technical and academic experts from both Japan and the United States, discussed specific issues raised at the policy-level meetings, including: definition of BSE and the method of testing; definition of SRMs and the method of removal; appropriate surveillance; appropriate feed ban implementation; risk categorization/status of countries; and cattle month-age identification. These meetings resulted in a productive exchange of the best scientific information available on BSE. In particular, the Japanese experts acknowledged that 100-percent testing of all slaughter cattle 20 months of age (MOA) and younger could cease.

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October 4-5, 2004: Another technical session was held in Colorado to discuss some remaining technical issues and allow the Japanese technical experts an opportunity to get a firsthand view of the U.S. cattle and beef production system.

October 15, 2004: As a result of the findings of the FSC related to the efficacy of testing of all cattle at slaughter, GOJ presented to the FSC its proposed regulation to set the mandatory testing of cattle at 20 MOA and older. The Prion committee began its review of the proposed regulations.

October 23, 2004: Under Secretary Penn led an interagency team to review the conclusions of the Joint Working Group and to discuss specific requirements for the resumption of trade. These requirements were captured in a shared understanding. Methods of age verification also were established, which included individual or herd identification through documentation and A-Maturity grading. These discussions established the parameters for USDA's Agricultural Marketing Service (AMS) to begin drafting a Beef Export Verification (BEV) Program for Japan.

November 3, 2004: AMS posts a draft EV program for Japan on its website to help industry begin its preparations for audits. Establishments were eligible to begin submitting their program documentation. Note: Any changes in the draft EV program could require establishments to provide supplemental documentation.

December 2-3, 2004: A GOJ delegation travelled to Kansas to discuss technical issues related to age verification of animals younger than 20 MOA and SRM removal consistent with the October 23 shared understanding. This technical delegation visited a packing plant, a feedlot, and a ranch to again gain firsthand knowledge about our cattle and beef production system and USDA Process Verified Systems.

December 16-17, 2004: Deputy Under Secretary Lambert led a USDA delegation to Japan to discuss technical details of the EV Program for known-age animals and to present the results of the study correlating physiological maturity with chronological age.

January 19, 2005: Deputy Under Secretary Lambert for Marketing and Regulatory Programs led a delegation to Japan to present to the Japanese expert panel the report on the relationship between physiological maturity and chronological age. The study demonstrated that use of A40 grading would eliminate beef from cattle older than 20 MOA from being exported to Japan.

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February 8, 2005: The Japanese Expert Panel, in a public meeting, accepted the U.S. study that demonstrated the A40 grading level was effective in eliminating meat from animals 21 MOA or older from export to Japan.

February 10, 2005: Deputy Under Secretary Lambert met with his counterparts via a digital video conference (DVC) to continue discussions on the final details of the EV for Japan.

February 18, 2005: Japanese Embassy officials informed Under Secretary Penn that the Government of Japan would like USDA to provide test results for another 200 carcasses for cattle older than 20 MOA in order to strengthen their defense of A40 physiological maturity to serve to ensure that the age of imported U.S. beef is 20 MOA or younger, and also wants to send another Japanese team to the United States to evaluate the U.S. meat grading system.

March 28, 2005: Japan's (FSC) Prion Committee approved the GOJ regulations allowing exemption from 100-percent testing at slaughter cattle 20 MOA and younger. Note: Shortly thereafter, the Diet approved subsidies for all prefectures to continue testing animals 20 MOA and younger on a voluntary basis. All slaughter plants are currently participating in the subsidy program, which is valid for 3 years.

March 31, 2005: The FSC approved its Prion committees March 28 review of the GOJ regulations exempting from testing cattle 20 MOA and younger.

April 25-27, 2005: Delegation of United States Government and academic experts visited Japan to hold technical meeting with GOJ counterparts as well as participate in a variety of public events to explain the safety and quality of U.S. beef. The draft EV Program for Japan was provisionally finalized, with the understanding that it may be subject to future revisions depending on the outcome of the anticipated FSC assessment of its equivalency to Japan's BSE measures. AMS pre-on-site audits for EV programs for Japan could begin.

May 6, 2005: Following close of the public comment period the FSC issued its final report which formalized the Prion committee's review of GOJ regulations to exempt cattle 20 MOA and younger from mandatory BSE testing at slaughter.

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May 8-11, 2005: Two GOJ technical teams visited the United States to conduct further site visits to address additional questions related to U.S. feeding practices as well as further evaluate the U.S. ability to verify age on the basis of physiological maturity as well as the SRM-removal practices in U.S. establishments.

May 24, 2005: GOJ submitted to the FSC its request for the FSC to evaluate “The equivalency of the BSE risk level between the ingestion of beef and bovine organs which are imported from the U.S. under the management of the current U.S. domestic regulations and the exportation program to Japan and ingestion of those slaughtered, processed and distributed in Japan”. A final assessment of equivalency of the terms of the EV program would be the basis of Japan’s lifting of its ban on U.S. beef.

August 8, 2005: USG assessed a draft import health protocol qualifying that nothing could be finalized until after the FSC issued a final determination that the proposed measures under the EV Program for Japan were equivalent to Japan’s domestic measures. As such, any aspects of the protocol provisionally agreed upon during this stage would be subject to revision depending on the FSC outcome.

October 31, 2005: The FSC Prion Committee issued a draft report, which concluded that the risk differential between U.S. beef shipped under the requirements of the provisional EV Program and Japanese beef produced under Japan’s domestic BSE measures is extremely small.

November 2, 2005: The FSC met and accepted the Prion Committee’s draft report, initiating a four-week comment period scheduled to end on November 29, 2005.

November 4, 2005: USDA delegation, led by Deputy Under Secretary Lambert, met with Ministry of Agriculture, Forestry and Fisheries Officials and Ministry of Health, Labor and Welfare Officials to continue discussions on the draft health protocol and the upcoming audits by GOJ of U.S. plants establishments to export beef to Japan.

December 8, 2005: Following the close of the public comment period, the FSC issued its final report, which formalized the Prion Committee’s conclusion that U.S. measures under the proposed export program for Japan were effectively equivalent to those measures in place in Japan. With this determination, no regulatory barriers to resuming imports remained.

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December 9, 2005: On the basis of the terms of the FSC final report, GOJ finalized the animal health protocol. Japan's Chief Veterinary officer (CVO), formally conveyed it to the U.S. CVO. U.S. CVO accepted its provisions.

December 12, 2005: GOJ accepted the certificates and announced that the ban on U.S. beef was formally lifted. With this announcement, AMS finalized the provisional EV program which were unchanged from the April draft as a consequence of the final FSC findings and final terms of the protocol. AMS posted it to its website and commenced onsite audits of U.S. plants desiring to export U.S. beef to Japan.

December 14-23, 2005: GOJ conducted audits of 11 U.S. plants. AMS audited all of these establishments in advance of GOJ officials visit in order for them to observe actual production of product for Japan (as establishments were not producing under the Japan-specific requirements before that time). GOJ's audits essentially were a second audit, and thus, any noncompliant processes found during these audits were subject to corrective actions.

January 23-29, 2006: GOJ officials were scheduled to conduct the second set of audits of 10 establishments eligible to export U.S. beef to Japan. These were postponed due to the veal shipment to Japan, which contained unauthorized vertebral column.

USDA requested that veal be an eligible product to ship to Japan. On December 8, 2005, USDA Foreign Agricultural Services was informed by Japan that veal must conform to the requirements of the export verification program for Japan. A Japanese audit team visited the U.S. in mid-December, at which time the addition of veal was discussed. As it had done with beef products, Japan required all veal products to be approved under the USDA Export Verification (EV) Program for Japan.

Veal generally is recognized as the meat from a calf or immature beef animal of either sex that is no more that approximately 16 to 18 weeks of age, weighing up to 450 pounds. Other distinguishing features of a veal calf is that it generally is recognized as being fed special formula rations that excluded fibrous forages or coarse dry grains, and is lacking a functional rumen. At the time of slaughter, a veal calf always would be younger than 20 months of age. Although veal meat differs from beef meat in color, texture, and other organoleptic characteristics, many of the primal and sub-primal cuts of veal are prepared similarly to those from beef. A helpful reference for commonly traded veal and beef cuts is the institutional Meat Purchase Specifications (IMPS) Series 300 (for fresh veal and calf) and Series 100 (for fresh beef products). The IMPS are available on the Agricultural Marketing Service, USDA, website (see <http://www.ams.usda.gov/lsg/stand/imps.htm>).

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The Japanese team offered general recommendations related to the export verification program on December 22, 2005, and those recommendations were implemented in full on December 30, 2005.

Atlantic Veal and Lamb, Inc. shipped the first and only shipment of veal to Japan in response to a custom order from Japan.

The EV Program for Japan mandates the removal of the spinal cord and vertebral column. Hygienically removed tongue and cheek meat are eligible if produced under an approved EV Program. The establishment must monitor the characteristics of the product to verify that product requirements have been met before product release and service delivery with records maintained accordingly.

Under the EV Program for Japan, the establishment can use one of three methods of age determination (individual animal age verification, group age verification, or age verification through carcass evaluation). The establishment must also have a unique documented procedure to identify product by suitable means throughout production process.

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. 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."

Specifics of Atlantic Veal and Lamb, Inc. Shipment

Two plants requested certification to export veal, a slaughter plant, Golden Veal, and a fabricating plant, Atlantic Veal and Lamb, Inc. Atlantic shipped the first and only shipment of veal to Japan in response to a custom order from Nobuo Shiraiwa, Nihon Siber Hegner K.K. of Japan on December 27, 2005. Golden shipped 21 EV approved veal carcasses and 14 various other veal products to Atlantic on January 11, 2006. Atlantic assembled and fabricated various veal products from this shipment and sent these products to Japan on January 18, 2005.

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On January 19, 2006, the veal products arrived in Japan under Export Certificate MPF-455144. Upon arrival in Japan, an inspection revealed that three of the 41 boxes contained vertebral columns (Hotel Racks and Trimmed Loin), which were prohibited from entering Japan from the United States under Japan's EV Program.

On January 20, 2006, FSIS received notification that the country of Japan had suspended importation of all beef products from the United States. This decision resulted because of Japan receiving an export shipment of veal, originating from Atlantic, which contained three (3) boxes of product that included portions of the vertebral columns (Hotel Rack and Trimmed Loin), and was in violation of their EV Program requirements.

Investigative Facts

Requirements

On December 12, 2005, USDA announced that the Japanese market had been reopened to U.S. beef products. Under this export agreement, the United States can export to Japan fresh/frozen beef and beef offal and veal and veal offal derived from animals 20 months of age or younger. As part of the agreement, spinal cord and spinal column (excluding the transverse process of the thoracic and lumbar vertebrae, the wings of the sacrum, and the vertebrae of the tail) must be removed from any product destined for export to Japan. Eligible beef and beef offal and veal and veal offal must be produced under an approved AMS EV Program for beef to Japan.

Order for Veal Products from Japan

On December 12, 2005, Mr. Yoshimitsu Ichii, representative of the company that placed an order for various veal products with Atlantic, emailed Mr. Peerless, President of Atlantic stating Mr. Peerless could not export his current stocks to Japan without a EV Program for Japan.

December 12, 2005 7:56pm Email

To: Philip Peerless

From: Yoshimitsu Ichii

"As you might know well, USDA AMS say that, (<http://www.ams.usda/ARC1030J.pdf>><http://www.ams.usda.gov/lsg/arc/ARC1030J.pdg>), only companies with an approved QSA Program for the EV Program for Japan may label and sell