

対日牛肉輸出証明プログラムに関する調査結果・対策報告書（要旨）
（在日米国大使館ホームページより）

* 下記の日本語文書は参考のための仮翻訳で、正文は英文です。

米国農務省

2006 年 2 月 17 日

2005 年 12 月 12 日、日本はほぼ 2 年間の米国産牛肉輸入禁止を解除し、米国産牛肉の輸入を再開した。2006 年 1 月 20 日、日本政府担当官は脊（せき）柱が付いた米国産子牛肉（ヴィール）3 箱を発見した。日本との個別な貿易合意の下では、脊柱の混入は認められていない。米国は、これが日本との合意条件に沿うものではなく、日本にとって受け入れられないことを認めたが、その製品が国民の健康を害するものではないと強調した。

米国政府はこの不適格な出荷の報告を受けて、即座に農務長官は徹底的な調査を命じた。食品安全検査局 (FSIS) 内の監査、評価を担当するプログラム評価、実施、レビュー室は直ちに、どのような経緯でこの不適格な牛肉が日本に輸出されたのかについて調査を始めた。さらに食品安全検査局は農務省監査室 (OIG) と連携して調査を行った。この調査は 2006 年 2 月 2 日に完了した。（本報告書第 2 章参照）

調査により、本件は輸出業者および農務省検査官が日本へ輸出可能な特定の製品を熟知していなかったためであると判明した。日本政府との合意により脊柱は輸出できないこととなっている。その脊柱を含む「ホテルラック（子牛の部位）」というラベルが貼られた箱が 1 つ、「（子牛の）整形したロース肉」のラベルの貼られたものが 2 箱出荷された。さらに、問題の施設を担当した食品安全検査局の検査官が農業マーケティング局（AMS）の輸出証明プログラム（BEV）について十分認識しておらず、日本向け輸出に不適格な製品の出荷を認可および承認すべきではなかった、ということも明らかになった。輸出証明プログラムの下で今回が最初で唯一の子牛肉の出荷であることから、不適格な出荷の経緯は例外的なケースであるという判断に確信をもっている。（本報告書第 3 章参照）

ジョハンズ農務長官はまず、不適格な子牛肉の出荷に対応し、12 の再発防止策を発表した。その中には、不適格な子牛肉を日本に輸出した問題の施設を認定業者のリストから除くことも含まれている。さらに不適格な出荷の連

絡を受けて、食品安全検査局は3日以内に、輸出プログラムの承認を受けたすべての施設にいる検査責任者に対して、ウェブサイトを利用した双方向の研修を行った。4日以内に、農務省職員は業界側が輸出証明プログラムの求める輸出条件を順守するために重要な問題を確実に理解するために、ワシントンの農務省本省において、輸出証明プログラムの下で牛肉を輸出する施設の最高経営責任者およびその他の幹部役員との会合を開催した。ジョハンズ農務長官は出席者に対し、直接そして非常に明確に、米国の農業製品および食品輸出プログラムに関し、非常に高いレベルでの基準を維持するため、すべての必要条件を満たすことの重要性を述べた。(本報告書第4章参照)

調査終了後、農務省は調査結果に対処するための適切な追加措置を決定した。例えば、輸出証明プログラム参加国向けの輸出品目を食品安全検査局担当官に周知徹底させるため、農業マーケティング局は、食品安全検査局の研修を受けた担当官がアクセスできる内部用ウェブサイトに、各国別に認可された個別の品目リストを掲載する。さらに、施設が査察を受けたり、プログラムに追加、あるいは除外される場合、その都度、農業マーケティング局が食品安全検査局に通知する。(本報告書第4章参照)

2006年1月27日、米国農務長官は、日本向け牛肉輸出証明プログラムについての農務省の調整、管理プロセスが適切かどうかを評価するため、議会を通じてアメリカ国民への説明責任を持つ農務省の独立調査機関である監査室に、査察を行うよう依頼した。2006年2月10日、農務省監査室が査察報告書を提出し、査察は終了し、本報告書にも調査結果が記載されている(本報告書第3章参照)。本報告書に示されている調査結果、農務省の対応措置(本報告書第4章参照)は、食品安全検査局の「日本向け輸出調査報告書、ゴールデン、ヴィール社、アトランティック、ヴィール、アンド、ラム社」、監査室の「日本向け牛肉輸出証明プログラムに対する農務省の管理に関する評価」の結果である。調査結果、事実関係、措置は各調査とも同様のものである。

米国は、日本の輸入牛肉安全基準を満たすことを非常に重視している。われわれは日本の条件を十分理解している。それらの条件は非常に明確なものであり、われわれのシステムは、それらの条件に対応すべく構築されている。徹底的な調査の結果、今回の子牛肉の1出荷例にかかわる不適格な製品の発見が、米国の牛肉加工、検査、あるいは輸出制度の全体にかかわる不備を示唆しているのではないことを確信している。今回の事例の調査、対応を経て、われわれは同様の事例再発防止のため、さらなる防止策を米国の制度に導入した。

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-onsite 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

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product. The companies who can supply beef and beef offal that are eligible for export to Japan will be listed on FSIS web-site”.

“According o USMFF Japan office,

1, Above also applies to VEAL.

2, Only products produced after QSA Program is approved will be imported, which means you cannot export the current stocks to Japan”.

On December 13, 2005, Mr. Yoshimitsu Ichii, Nihon SiberHegner, again e-mailed Mr. Peerless pertaining to EV approval.

December 13, 2005 4:31pm Email

To: Philip Peerless

From: Yoshimitsu Ichii

“Dear Philip san

I hope your company will be on the list in the below web today!

<http://www.ams.usda.gov/lsg/arc/evjapanlisting.htm>.

Please keep in touch.

Yoshimitsu”

DKSH – Market Intelligence

Yoshimitsu Ichii

Senior Sales Executive IFP Dept.

Nihon SiberHegner. K.K

<http://www.dksh.com>

These e-mails are the first indication that the company Nihon SiberHegner wanted to place an order with Atlantic.

On December 27, 2005, Nobuo Shiraiwa, Nihon Siber Hegner K.K. of Japan, e-mailed Mr. Peerless with an order, listing various veal cuts, as follows:

- 1 box Hotel Rack (7 ribs) – 45 pounds total
- 4 boxes Hotel Rack Chop - Ready (7 Ribs) – 44 pounds total
- 1 box Boneless Ribeye – 16 pounds total
- 1 box Trimmed Loin Boneless (1x1) – 16 pounds total

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- 2 boxes Trimmed Loin (4x4) – 34 pounds total
- 1 box Strip Loin – 13 pounds total
- 1 box Top Round – 18 pounds total
- 6 boxes Breast Boneless Finger Meat – 264 pounds total
- 2 boxes Plates – 50 pounds total
- 1 box Full Tenders – 16 pounds total
- 1 box Loin Tenders – 10 pounds total
- 25 boxes Sweetbreads – 250 pounds total
- 1 box Tongues – 10 pounds total and
- 1 box bones – 60 pounds total

In this email, Mr. Shiraiwa stated, “I’d like you to dispatch our ordering products on the 16th of January.”

Approval Process

Mr. Peerless, President Atlantic, emailed USDA FSIS officials on December 13, 2005 outlining concerns with the process of obtaining approval for export to Japan and the importance of being able to ship products to Japan for his business.

December 13, 2005 4:49pm Email
To: Rick.Harris@usda.gov; dana.stahl@usda.gov.
Cc: Mark Dopp
Subject: Veal export to Japan
From: Philip Peerless

“Mr. Harries,

Atlantic Veal & Lamb is a veal company based in Brooklyn, New York. We have shipped our veal product’s to Japan for the past 15 years. The Japanese market had become a very important part of our business. Previous to the border closing we employed over 300 people. Due to the lack of margin as a result of the Japanese border closing, we had to decrease our work for by 75 people. Relative to the beef industry our numbers are small, but to me and the amount of small mom and pop veal farmers that are affected (including the loss of veal production to Canada), the closing and the subsequent re-opening of the border is very important to us.

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Back in April, I personally went to Japan in anticipation of the border re-opening. All of our customers were waiting eagerly for us to start shipping our veal to them. I had my quality control person, Elvra Cunha, call six months ago the FSIS and ARC to make sure that we would be on track when the border was re-opened. After some back and forth communication we received an e-mail from David Hildreth dated July 12, 2005 stating that per FSIS, dedicated veal plants Do Not need a BEV Japan program. I forwarded this information to my agent in Japan”.

“Last week I spoke to my agent in Japan and was told that in anticipation of the border being re-opened this week, they would have an order for me to ship this week. I asked my quality control person Elvira Cunha to follow up on the export documents with USDA. After waiting for two days and no one from FSIS communicating at all with us, I called around myself. I finally received a call back this morning from Dana Stahl, QSVP Program Manager for ARC, who informed me that veal plants do need an EV Japan QSA and that I would have to submit our request to be approved for the program to be eligible to ship to Japan. She said they might get to my application sometime in January and then an audit would then be scheduled.

The veal industry never should have been included in the ban to Japan. When Canada had there first case of BSE, the U.S. was quick to close their borders to Canadian ‘bovine’ products. Canada, on behalf of their veal industry complained to the U.S. that veal, because of their age and milk diet never should have been included in the ban to begin with. The U.S. agreed and exempted Canadian veal from the ban and carcass’ were allowed to be shipped to the U.S., even with the SRM’s in them. The U.S. should have made the same case to the Japanese all along about American veal, but unlike the Canadian government, which cares about their veal industry, the U.S. decided it’s better to use the veal industry as canon fodder for the beef industry.

It was interesting to note today when I went on the ARC website to see all the companies that are listed as approved to ship to Japan as of yesterday (I believe yesterday was the day the ban was lifted), I realized that sometimes it would be better to have some local congressmen directly representing us.

At the very least, because of the mis-information from the government, all I asked for is ARC fast track my application and sent an auditor in here next week, we’ve had the program before, we know what to do, I asked for the audit for the BEV

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program six months ago and was told I did not need it. I was told that they can't do help me.

I will tell my agent in Japan to wait because my government made a mistake in what they told me, and the people that have lost their jobs in the veal industry can wait also. The import thing is Cargill and Smithfield can ship this week, that's what's most important to our government and economy.

Thank You,
Philip Peerless
President

Cc: Senator Clinton
Senator Schumer

Ms. Dana Stahl, Quality Systems Verification Program Manager, USDA AMS Audit, Review and Compliance, confirmed through a conversation she had in mid-December with Mr. Peerless, that Mr. Peerless was upset because he wanted to export veal initially to Japan as soon as possible and it would take time for him to apply for EV approval.

Exhibit 5

On December 15, 2005, Elvira Cunha, Quality Assurance Manager, formally requested the services of AMS in an effort to obtain EV certification for slaughter only, of veal carcasses for Golden Veal Corporation and fabrication and distribution of veal products by Atlantic Veal and Lamb Incorporated. This process included the submission of Quality System Assessment (QSA) Quality Manuals for both establishments to meet USDA EV Program for Specified Products for Beef-Japan. Both establishments had previously provided an Application for Service (LS-313) on September 22, 2003. At that time, Atlantic planned on exporting veal products to Canada. AMS begun reviewing previous Atlantic and Golden's QSA Manuals but discontinued the reviews upon notification FSIS had determined dedicated veal establishments were not required to have an EV Program. No additional action was taken by AMS concerning Atlantic and Golden's Service or Manual reviews until Japan notified AMS on December 8, 2005, that all beef establishments, including veal plants, would be required to have an EV Program for export to Japan. It was at this time that Atlantic and Golden requested approval for export certification to Japan. **Exhibit 1, 2 and 3**

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Ms. Cunha requested Dana Stahl, AMS, review the documentation accompanying the letter requesting service from AMS which outlined Golden's and Atlantic's procedures in meeting the requirements of the EV Program. Ms. Cunha also requested on-site audits by AMS to gain certification in the EV Program. **Exhibit 3**

Quality Systems Verification Programs (QSVP) are designed to provide independent verification that special processes or marketing claims are clearly defined and verifiable by an independent third party. The process begins by the company submitting an Application for Service. The company then submits documentation in the form of a QSVP Quality Manual. An AMS Auditor performs a desk audit, a review of the company QSVP Quality Manual to ensure that all program requirements are met. An on-site audit is then conducted by an AMS Auditor at the establishment to verify the establishment conformance with the requirements of the quality standard and compliance with regulatory requirements. The AMS Quality Systems Verification Program Manager makes the final decision on approval based upon the results of the audits. This procedure was followed for the USDA EV Program for Specified Products for Beef-Japan requests submitted by Atlantic and Golden.

During the week of December 19, 2005, AMS Quality Systems Verification Program Manager Dana Stahl stated she spoke on the telephone to Philip Peerless, President of Atlantic and Golden, and Elvira Cunha, Quality Manager for both Atlantic and Golden, about the USDA EV Program for Specified Products for Beef-Japan process. Stahl stated that she clearly discussed with them the requirement that vertebral column must be removed from animals of all ages to comply with the EV program for Japan. AMS Program Manager Stahl stated that if Golden and Atlantic were going to export offal, they would need a control mechanism to identify which offal went with each carcass. Golden and Atlantic did not have a mechanism in place and since no mechanism was in place at either plant, they were not eligible for export to Japan. **Exhibit 2 and 5**

On January 4, 2006, AMS Auditor Darrell Wilson conducted desk audits which entail review of the Golden and Atlantic Quality (QSA) Program manuals to ensure they meet USDA AMS EV program requirements for Japan. Auditor Wilson stated that both firms submitted sufficient documentation to warrant initial on-site audits under the QSA Program requirements and the requirements of the EV Program. **Exhibits 2, 6 and 7**

On January 6, 2006, AMS conducted conformance and compliance on-site audits at both Golden and Atlantic facilities. **Exhibit 8**

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During Golden's audit, they slaughtered 14 head of calves. When AMS Auditor Wilson arrived on the floor, the calves were already hanging as carcasses. These 14 calves were not eligible to be marked as EV certified because the calves were slaughtered for the AMS auditor as a demonstration of Golden's QSA program prior to it being approved. AMS Auditor Wilson observed the removal of the spinal cord, as required by Japan. During this audit, Auditor Wilson also discussed the need for the removal of the vertebral column with Mr. James Fisher, Golden Plant Manager, and Ms. Cunha, Quality Manager. Mr. Fisher said the vertebral column would not be removed at Golden, but would later be removed, as required by Japan, during fabrication at Atlantic.

Also at this time, AMS Auditor Wilson asked Mr. Fisher about offal shipments. Mr. Fisher told AMS Auditor Wilson that Golden did not have plans to ship offal to Japan because Golden did not have a quality management system procedure in place to separate out offal derived from carcasses certified as 20 MOA or younger from offal derived from uncertified carcasses. Under the AMS QSA Program, establishments are required to have documented procedures to identify product (raw materials and/or finished product) by suitable means throughout production and to maintain records of all products identified and records of all changes of identities. **Exhibits 7 and 9**

During Atlantic's audit, AMS Auditor David Hildreth stated that there was no demonstration of fabrication of any veal carcasses or cuts. However, Hildreth stated there had been discussions with Atlantic officials that the vertebral column and other parts needed to be removed during fabrication. Eddie Cruz, Plant Manager for Atlantic, was in attendance during these discussions. In addition, Mr. Hildreth stated that during his audit in the fabrication room, Mr. Cruz displayed yellow containers which Mr. Cruz stated would be used to carry away vertebral column material during the fabrication of any product marked "EV for Japan." The need for the removal of the vertebral column is also documented in AMS Auditor Hildreth's handwritten notes on the Audit Report stating, "vertebral column to be removed during fabrication." AMS Audit Branch Chief James Riva stated the ARS audit procedures do not require an actual observation of SRM removal. Chief Riva stated it is the professional judgment of the Auditor to determine if it is necessary to actually observe the removal of SRMs (e.g. vertebral column). Chief Riva stated the auditor can determine that a QSA Program is in compliance with EV Program requirements through interviews, evaluation of employee training, and review of records and written procedures, without an actual observation of SRM removal. **Exhibits 11 and 36**

AMS ARC Branch Chief James Riva stated that on January 6, 2006, Atlantic and Golden were both approved, respectively, as the only exporter and approved supplier, to export

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veal cuts to Japan. Mr. Riva also stated that Atlantic would have needed certification from Golden in order for the veal offal shipped to Atlantic, intended for export to Japan, to have met EV program requirements. Chief Riva stated Atlantic did not have approval to export veal offal to Japan unless the product was from an approved supplier. Chief Riva advised that the reason Atlantic was not approved to ship offal to Japan was because there was no source of veal offal eligible for export to Japan. Chief Riva further stated Golden did not have a system in place to ensure identification and traceability of offal products and this was the reason Golden could not produce veal offal products that were in compliance with EV Program requirements. Chief Riva advised that Atlantic's approved QSA includes adequate identification and traceability procedures to allow Atlantic to export veal offal to Japan, but only if Atlantic receives veal offal that meets EV Program requirements for export to Japan. **Exhibits 27 and 36**

After the AMS audit, both Atlantic and Golden were verbally notified by Dana Stahl, AMS Program Manager, of the two plants' eligibility and listing on the AMS approved website as of January 6, 2006.

Characteristics of Specific Shipment to Fulfill Order from Japan

On January 10, 2006, Golden slaughtered 202 veal calves. Of these 202 calves, 21 were split, the spinal cords removed, and the carcasses segregated in the cooler for EV approved age certification the following day by AMS Meat Grading and Certification (MGC) Lane Biddle.

On January 11, 2006, at Golden, AMS MGC Biddle determined the age verification (physiological maturity) of the 21 segregated carcasses, from the previous day's slaughter, to satisfy the EV Program specified product requirement of determining the age verification, AMS MGC Biddle assigned a rating to each carcass. A rating of A40 or less qualifies the veal carcass to be exported to Japan. In this instance, AMS MGC Biddle evaluated each veal carcass as A00, identifying all calves as six months of age or younger. **Exhibits 12 and 13**

AMS MGC Biddle then observed Golden personnel as they stamped the 21 carcasses with a "J," as specified in Golden's Quality Manual. The use of a "J" marking, by Golden, means that the carcass has been certified by the grader and is designated for Japan. Under Golden's program, this "J" stamp, which is marked on each EV certified carcass hindquarter, must remain with the product through processing, packaging, storing, and shipping. After this mark was placed, AMS MGC Biddle then overlapped the "J" stamp with an "Accepted as Specified" stamp. The combination of stamps signified

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that the carcass was age certified as less than 20 months, which permits the carcass to be EV eligible for export to Japan.

No offal products from the 21 certified by physiological maturity calves were segregated or identified at the time of slaughter, and no procedures to do so are included in Golden's approved QSA Program. Under the AMS QSA Program, if Golden had intended to export offal from the certified carcasses, they would have been required to have documented procedures to identify product (raw materials and/or finished product) by suitable means throughout production and to maintain records of all products identified and records of all changes of identities.

Ms. Elvira Cunha, Quality Assurance Manager for both plants, stated on February 2, 2006, the veal sweetbreads and tongues were from the slaughter of EV Program approved veal calves and non EV Approved veal calves on January 10, 2006, at Golden. Ms. Cunha also stated the veal sweetbreads and tongues were co-mingled together and then shipped to Atlantic under Bill of Lading (BOL) G-5140 with a Shipping Declaration that stated, "Product Meets EV Program Requirements for Japan". Ms. Cunha stated it was a "mistake" to co-mingle the EV Program approved veal sweetbreads and tongues with non EV Program approved veal sweetbreads and tongues. **Exhibit 33**

Golden's Plant Manager James Fisher stated on February 2, 2006, the veal sweetbreads and tongues from the EV Program approved 21 carcasses slaughtered on January 10, 2006, were co-mingled with the veal sweetbreads and tongues from the 202 veal calves that were also slaughtered at Golden on January 10, 2006. (clarification note: Total slaughter for the day was 202 veal calves, thus 21 were EV certified and 181 were not EV certified). Mr. Fisher stated veal sweetbreads and tongues were considered "veal offal" and were not specifically listed on the BOL but were in the two barrels of offal listed on BOL G-5140. Ms. Lisa Meese, Administrative Assistant/Auditor for Golden, stated on February 2, 2006, the Shipping Declaration that accompanied BOL G-5140 contained co-mingled EV Program veal sweetbreads and tongues with non-EV Approved veal sweetbreads and tongues but "did not know why." She stated the Shipping Declaration and BOL G-5140 accompanied the shipment because that was how she was trained by Ms. Elvira Cunha. **Exhibits 31 and 35**

Mr. Eliseo (Eddie) Cruz, Atlantic's General/Plant Manager, stated on February 2, 2006, the veal tongues were not specifically listed on BOL G-5140 dated January 11, 2006, but were on the truck from Golden. Mr. Cruz stated it was his understanding that all of the products listed on BOL G-5140 were EV Program approved because the Shipping Declaration "stated so". Mr. Phillip Peerless, President of Golden and Atlantic, stated on

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February 2, 2006, the veal sweetbreads and tongues from January 10, 2006, were co-mingled with offal from non EV certified carcasses from the rest of the 202 veal calves slaughtered at Golden on the same day. Mr. Peerless stated looking back on the program now and the Shipping Declarations and BOLs he sees there were mistakes and he would indeed make changes and would have the offal boxes/barrels marked with a "J" if they were derived from "J" certified carcasses. Golden only receives live calves and slaughters these animals and all the veal products are derived from those calves.

Exhibits 32 and 34

On January 11, 2006, Golden shipped the 21 EV approved veal carcasses and 14 various other veal products to Atlantic utilizing two BOLs, numbers 5140 and 5141.

BOL #5140 included:

- 11 boxes Sweetbread – 477 pounds total
- 21 veal carcasses – 5,762 pounds total
- 23 boxes Hind Pieces – 3,135 pounds total
- 2 boxes Fries – 44.4 pounds total
- 2 boxes Cheekmeat – 21.1 pounds total
- 2 barrels Offal – 600 pounds total
- 2 boxes Liver – 2,400 pounds total
- 88 boxes Val Pak Liver – 1,538.6 pounds total

BOL #5141 included:

- 130 boxes 031 Rack/Loins – 3,263.5 pounds total
- 1 barrel Bones – 300 pounds total
- 7 combos Legs – 13,401.8 pounds total
- 25 boxes 246 Chux – 1,293.85 pounds total
- 1 combo 212 Chux – 1,827.8 pounds total
- 1 barrel Clop Tops – 400 pounds total
- 3 barrels Foreshanks – 1,275 pounds total

Shipping Declarations accompanying BOLs 5140 and 5141 indicated that all products from both BOLs had met the EV Program requirements to export to Japan. However, records indicate that the shipments included veal cuts and offal that were not certified under the EV Program requirements for Japan. Ms. Lisa Meese, Administrative Assistant/Auditor at Golden, stated she was not comfortable with the position of an auditor (clarification note: position auditor as defined in the establishment QSA Manual) in regards to the EV Program and part of her job duties were to sign the Shipping Declarations for the EV Program. Ms. Meese stated she was not sure what the program

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EV or BEV means and could not define the term traceability. Ms. Meese stated she understood that all products shipped from Golden to Atlantic must be accompanied by a Shipping Declaration. Ms. Meese stated she verified the product met the EV Requirements through the "metaphysical" report from USDA MGC Biddle. **Exhibits 14 and 35**

Mr. Fisher, Golden's Plant Manager, was interviewed as to why a Shipping Declaration for Japan accompanied all products on BOLs 5140 and 5141, including several products that AMS had not certified eligible for shipment to Japan. Mr. Fisher stated that the AMS Grading Service required the Shipping Declaration for each shipment that included EV certified product and that he knew this could lead to major problems.

AMS personnel Lane Biddle, Darrell Wilson, and James Riva stated they never told Mr. Fisher that a Shipping Declaration was required to be used to identify shipments containing EV certified veal carcasses regardless of whether or not all products met the EV Program requirements for Japan. **Exhibits 7, 13, 15, and 27**

On the morning of January 12, 2006, a fire engulfed the Golden plant causing severe damage. All remaining veal carcasses and offal products were destroyed. However, no damage was done to the office area of the plant, and therefore, all records (plant and FSIS) remained safe. **Exhibit 16**

Atlantic's receiving record #3959, dated January 12, 2006, documented receipt of 21 calves and various veal cuts and veal offal shipped from Golden on January 11, 2006. Their EV Program Receiving Log dated January 12, 2006, listed only the receipt of the 21 EV approved veal carcasses. Mr. Wesley Martinez, Shipping and Receiving Manager at Atlantic, stated on February 2, 2006, that Atlantic received 21 carcasses on January 12, 2006, from Golden marked with a "J" and this was the only item entered on the EV Program Receiving Log since nothing else was marked with a "J". **Exhibits 17, 18, and 37**

Atlantic's daily EV production logs for January 12th and 13th listed various veal products that were assembled and fabricated which included uncertified veal sweetbreads and veal tongues. Both EV production logs identified each product with a code that began with a "7" to denote EV products for Japan. This documentation identifies the uncertified veal sweetbreads and veal tongues as meeting EV program requirements for Japan. **Exhibits 19 and 20**

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In addition, the EV production log dated January 13th listed 1 box of "Veal 7 Rib Rack Blade in" (Hotel Rack) and 2 boxes of "Veal Loin Trim 4x4" (Trimmed Loin), as requested in the December 27, 2005 order from Nihon Siber Hegner K.K. of Japan. Under the EV Program requirements for Japan, and identified in Atlantic's QSA manual, these products were not eligible for export to Japan because the cuts contained portions of the vertebral column.

Atlantic was aware of this requirement because their QSA Program states that "Conforming product must meet the specified product requirements of the QSA Program requirements for Japan referenced in [AMS Audit, Review, and Compliance Branch Form] ARC 1030J, Section 5.1.1." Section 5.1.1 includes a requirement that products must be produced in a manner that ensures the hygienic removal of the vertebral column. **Exhibit 3**

On January 13, 2006, Atlantic requested, as required under Title 9 of the Code of Federal Regulations, Section 322.2, from FSIS, an Application for Export Certificate MPF-455142. The completed application had all the same products listed as Nobuo Shiraiwa had ordered to Phillip Peerless on December 27, 2005. The difference in Mr. Shiraiwa's order and the actual Application and Export Certificate's (Number MPF-455142) products listed were the 25 boxes of sweetbreads, totaling 250 pounds. MPF-455142 stated 25 boxes at a total weight of 203.7 pounds. Consumer Safety Inspector (CSI) or provided the Application for Export Certificate MPF-455141 to Ms. Cunha, Quality Manager. The Application was signed by Mr. Robert Buxbaum, Export Coordinator at Atlantic and CSI Or. The Export Certificate MPF-455142 was signed by Public Health Veterinarian (PHV) Wills. This certificate reflected a total of 928.4 pounds/48 boxes of products. Ms. Cunha later asked that the certificate be voided because there were some boxes being removed. MPF-455142 was voided by FSIS personnel. **Exhibit 21**
This is the 1st order.

- 1 box Hotel Rack (7 Ribs) – 60.15 pounds total
- 4 boxes Hotel Rack Chop - Ready (7 Ribs) – 105.1 pounds total
- 1 box Boneless Ribeye – 16.9 pounds total
- 1 box Trimmed Loin Boneless (1x1) – 17 pounds total
- 2 boxes Trimmed Loin (4x4) – 38.8 pounds total
- 1 box Strip Loin – 14.8 pounds total
- 1 box Top Round – 19.5 pounds total
- 6 boxes Breast Boneless Finger Meat – 299.3 pounds total
- 2 boxes Plates – 54.85 pounds total
- 1 box Full Tenders – 15.4 pounds total

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- 1 box Loin Tenders – 12.5 pounds total
- **25 boxes Sweetbreads – 203.7 pounds total**
- 1 box Tongues – 10.4 pounds total and
- 1 box Veal Bones – 60 pounds total

Subsequently on January 13, 2006, a second Application, Export Certificate MPF-455143, was requested by Atlantic. The Application was signed by Mr. Robert Buxbaum, Export Coordinator at Atlantic and CSI Or. The Certificate package was completed by Atlantic. MPF-455143 was signed by Dr. Chaudhry M. Saleem. Ms. Cunha later explained there was a problem with this certificate concerning weights, and indicated a request for a third certificate would be forthcoming. The difference between MPF-455142 and MPF-455143 was the 25 box count of sweetbreads was changed to 19 boxes of sweetbreads but no change to the weight on the sweetbreads. This certificate reflected a total of 928.4 pounds/42 boxes of products. MPF-455143 was voided by FSIS personnel upon the request of Atlantic. **Exhibit 22**
This is the revised 2nd order.

- 1 box Hotel Rack (7 Ribs) – 60.15 pounds total
- 4 boxes Hotel Rack Chop - Ready (7 Ribs) – 105.1 pounds total
- 1 box Boneless Ribeye – 16.9 pounds total
- 1 box Trimmed Loin Boneless (1x1) – 17 pounds total
- 2 boxes Trimmed Loin (4x4) – 38.8 pounds total
- 1 box Strip Loin – 14.8 pounds total
- 1 box Top Round – 19.5 pounds total
- 6 boxes Breast Boneless Finger Meat – 299.3 pounds total
- 2 boxes Plates – 54.85 pounds total
- 1 box Full Tenders – 15.4 pounds total
- 1 box Loin Tenders – 12.5 pounds total
- **19 boxes Sweetbreads – 203.7 pounds total**
- 1 box Tongues – 10.4 pounds total and
- 1 box Veal Bones – 60 pounds total

On January 18, 2006, Atlantic requested a third complete export certificate (MPF-455144). CSI Or stated at approximately 09:30 a.m. on January 18, 2006, while he was at Water Lillies Food Inc., Ms. Cunha called him on his personal cell phone and informed him of a problem with the weight on MPF-455133 and that he needed to get to Atlantic

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as soon as possible as the product had to be at the airport by 3:00 p.m. CSI Or stated he informed Ms. Cunha that he would be there as soon as possible but the firm still needed to get the signature from the Supervisory Veterinary Medical Officer (PHV). Ms. Cunha informed CSI Or she would take care of that part and obtain the signature. Upon CSI Or's return to Atlantic, he provided Atlantic with a blank FSIS Form 9060-6, "Application for Export Certification," and the establishment's secretary completed blocks 3 through 17 on the application. CSI Or stated that he performed a visual check of the boxes, counted the boxes, determined the poundage was correct, and then completed blocks 18 through 20 on the application. The application accompanied FSIS Form 9060-5, "Meat and Poultry Export Certificate of Wholesomeness" and FSIS Form 9290-1, "Certificate for Export to Japan." FSIS Forms 9060-5 and 9290-1 were completed by the plant's secretary. CSI Or stated at approximately 12:30 p.m. to 1:00 p.m. Atlantic returned with the export package (Meat and Poultry Export Certificate of Wholesomeness, the Certificate for Export to Japan, and the Letterhead Certificate for Export for Beef and Beef Offal to Japan) bearing the signature of PHV Keith Wills.

Exhibit 24

On January 18, 2006, FSIS Public Health Veterinarian (PHV) Keith Wills received the export certificate package from Atlantic to review and sign at his duty station (Est. 20138, Bo-Bo Poultry Market, Brooklyn, New York). In two separate sworn statements, PHV Wills stated he never saw the product at the establishment. PHV Wills stated he looked for CSI Or's signature to verify that inspection was performed. PHV Wills also stated that he was not aware of any concerns regarding an AMS approved EV establishment, and that he never had any conversation with Atlantic regarding exporting products to Japan. PHV Wills stated he was not aware that Atlantic had an approved Export Verification (EV) Program, nor did he know what EV was prior to this incident, because there was no communication between AMS and FSIS at the field level.

Exhibit 25

Once CSI Or received the completed export certificate package with PHV Wills' signature, CSI Or performed a random visual check on some of the product. Upon completion of the random visual inspection, CSI Or personally stamped each box with the export stamp. CSI Or stated he never received or observed any documentation stating that the product was under 20 MOA and was unaware of any concerns regarding an AMS approved EV establishment. **Exhibit 23**

The changes from the previous certificate, MPF-455143, to Export Certificate MPF-455144 was the removal of 1 box (60 pounds) of bones. This change was made at the

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request of Mr. Shiraiwa, Nihon Siber Hegner K.K. of Japan, who e-mailed Mr. Peerless on 1/18/06 stating, "After having discussion here, I found it much better not to load bones one case, which might make a mess of everything. Please unload one case of bone for our smooth custom clearance here so that my forwarder [Mitsui O.S.K. Lines, Ltd.] can urgently coordinate the air freight shipment." **Exhibit 28**

This certificate reflected a total of 865 pounds/41 boxes of products. Both the Application for Export Certificate and the Meat and Poultry Export Certificate for Wholesomeness number MPF-455144 listed the following products for export to Japan:

- 1 box Hotel Rack (7 Ribs) – 60 pounds total
- 4 boxes Hotel Rack Chop - Ready (7 Ribs) –104.7 pounds total
- 1 box Boneless Ribeye – 17 pounds total
- 1 box Trimmed Loin Boneless (1x1) – 17 pounds total
- 2 boxes Trimmed Loin (4x4) – 38.6 pounds total
- 1 box Strip Loin – 14.9 pounds total
- 1 box Top Round –19.2 pounds total
- 6 boxes Breast Boneless Finger Meat – 298.6 pounds total
- 2 boxes Plates – 54.6 pounds total
- 1 box Full Tenders – 15.3 pounds total
- 1 box Loin Tenders – 12.4 pounds total
- 19 boxes Sweetbreads – 202.3 pounds total and
- 1 box Tongues – 10.4 pounds total.

The Application for Export Certificate bore the statement "Product meets EV Program requirements for Japan" and was signed by Ms. Elvira Cunha, Quality Control Manager. The Letterhead Certificate for Export of Beef and Beef Offal to Japan bore the statement, "The exported beef to Japan fulfilled all the required conditions described in the EV Program" and was signed by PHV Keith Wills.

The following products did not meet the EV Program requirements for Japan.

- The "Hotel Rack (7 ribs)" and the "Trimmed Loin (4x4)" were not eligible because the vertebral column was not removed from these products cuts.
- The "Sweetbreads" and the "Tongues" were not eligible because these offal products did not meet the EV program requirements for export to Japan. Note: even if Golden had procedures in place to segregate and

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identify veal sweetbreads for EV certification, the maximum amount that could have been harvested from the 21 EV approved calves would have been about 21 pounds (approximately 1-pound per veal carcass).
Exhibit 26

AMS ARC Branch Chief James Riva stated that if Atlantic only received 21 veal carcasses from Golden, all meeting EV program requirements, the 21 carcasses could not have reasonably obtained the volume of offal listed on BOLs 5140 and 5141 and the Export Certificate, MPF-455144. **Exhibits 26 and 27**

Mr. Hector Lopez, Fabrication Manager for Atlantic, stated on February 2, 2006, stated he remembers only using 5 – 8 of the veal carcasses marked with a “J” in order to fill the whole muscle orders for Japan under Export Certificate MPF-455144 dated January 18, 2006. Mr. Lopez stated the rest of the “J” marked 21 veal carcasses received from Golden on January 12, 2006, were cut up and sold to other customers. **Exhibit 38**

On January 18, 2006 Atlantic shipped the veal products, as listed on Export Certificate MPF-455144, to Japan. **Exhibit 29**

Destination Arrival of Specific Shipment to Fulfill Order from Japan

On January 19, 2006, the veal products arrived in Japan. Upon arrival in Japan, an inspection revealed that three of the 41 boxes contained vertebral columns, 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.

The shipment also included veal sweetbreads and veal tongues which did not meet EV Program requirements for Japan. **Exhibit 30**

Investigative Facts

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- Golden's EV Program did not address the harvesting, processing, shipping, or exporting of any veal offal products. As such, none of these offal products were eligible for EV certification.
- Golden did not segregate or identify veal offal products for certification by the EV Program at the time of slaughter.
- Golden shipped 21 veal carcasses that met EV Program requirements for Japan and 14 other veal products that did not meet these requirements on 2 separate BOLs with accompanying Shipping Declarations which indicated all products had met EV Program requirements for Japan.
- AMS personnel Lane Biddle, Darrell Wilson, and James Riva stated they never told Mr. Fisher that a Shipping Declaration was required to be used to identify all shipments of veal carcasses whether the products met or did not meet the EV Program requirements for Japan.
- Atlantic Daily Production Logs (EV) listed various veal products including veal sweetbread and veal tongues, which were unapproved and did not meet EV Certification requirements.
- According to Atlantic's QSA program, all EV products are identified with a "7." On Atlantic's Daily Production Logs (EV), the plant listed unapproved veal product codes starting with a "7."
- Atlantic Export Certificate package MPF-455144 included the statement "Product meets EV Program Requirements for Japan" when in fact the hotel rack (7 ribs), loin, veal sweetbread, and veal tongues do not meet EV Program Requirements for Japan.
- Atlantic exported 202.3 pounds of sweetbread. With the approximate yield per veal carcass being one pound, and only 21 veal carcasses having been EV approved, the largest total poundage which could have resulted would be approximately 21 pounds of sweetbread. Approximately 181.3 pounds of unapproved sweetbread could not be attributed to the 21 EV approved carcasses.
- Golden's records document that products supplied under the EV Program did not meet requirements to export to Japan.
- Atlantic's records document that the exported veal cuts and offal to Japan did not meet EV Program requirements in order to export to Japan.

Next Steps

On January 24, 2006, the USDA Office of Inspector General (OIG) issued a Case Opening Memorandum (COM), HY-24381.

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The FSIS, OPEER, will provide its investigative report to OIG, and will support OIG, as requested, in the further investigation of this matter and in any legal action under the jurisdiction of the appropriate United States Attorney.



U.S. Department of Agriculture



Office of Inspector General
Food and Marketing Division

Audit Report

Assessment of USDA's Controls for The Beef Export Verification Program for Japan

Report No. 50601-11-HQ
February 2006



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



TO: Mike Johanns
Secretary of Agriculture

THROUGH: Phyllis K. Fong
Inspector General

Phyllis K. Fong

FEB 16 2006

FROM: Robert W. Young
Assistant Inspector General
for Audit

Robert W. Young

FEB 16 2006

SUBJECT: Assessment of USDA's Controls for the Beef Export Verification Program for Japan (Audit Report No. 50601-11-HQ)

Summary

At your request, we performed an audit¹ to identify the controls put in place to ensure beef products met the requirements of the beef export verification (BEV) program for Japan, examine whether the controls broke down, and determine whether additional actions can be taken to ensure future compliance by responsible agency employees. We concluded that the Agricultural Marketing Service (AMS) and the Food Safety and Inspection Service (FSIS) could strengthen their controls over the BEV program by improving processes used to communicate BEV program requirements, clearly defining roles and responsibilities, and implementing additional oversight of FSIS inspection personnel.

Background

Japan banned beef and beef products from the United States in December 2003 after the first case of Bovine Spongiform Encephalopathy, widely known as BSE or "mad cow disease," was found in the State of Washington. In October 2004, representatives from the Governments of the United States and Japan met in Tokyo to discuss the resumption of beef trade between the two countries. As a result of the discussions, the two Governments shared the view that the two countries would resume two-way trade in beef and beef products, subject to their respective domestic approval processes based upon science. On December 11, 2005, the Secretary of Agriculture (Secretary) announced that the Japanese market was open to U.S. beef products. Under the agreement with Japan, the United States was able to export beef from cattle 20 months

¹ See Scope and Methodology for additional details.

of age and younger. Prior to the December 2003 ban, the United States exported \$1.4 billion worth of beef and beef products to Japan.

The export of U.S. meat products to foreign countries is facilitated by the activities of three separate but interdependent entities: the U.S. meat industry, FSIS, and 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 other requirements imposed by importing countries. For example, Japan required the removal of vertebral columns from the carcasses of cattle.
- FSIS is responsible for the inspection of meat products and the certification of products for export to other countries. For the domestic market, FSIS' regulatory activity is complete when FSIS applies the USDA mark of inspection. When product is then prepared for export to foreign countries, additional verifications are necessary after inspection is complete in order for FSIS officials to execute the certifications that products meet export requirements.
- AMS provides a bridge between the U.S. meat industry and FSIS to facilitate export certifications. AMS' export verification program is designed to encompass importing country requirements that are not components of FSIS inspection activities. In December 2005 and January 2006, AMS approved a total of 40 U.S. plants as eligible to provide product for export to Japan under the export verification program.

On January 20, 2006, Japanese officials announced that their nation halted the import of beef products from the United States. This action was taken because veal product from a U.S. plant contained the vertebral column in violation of the agreement between the United States and Japan.²

On the same date, in response to Japan's decision, the Secretary announced 12 actions USDA would undertake to facilitate resuming trade. These actions include delisting and investigating the plant that exported the ineligible product, requiring a second signature on export certificates, providing training to inspection personnel on export certification, and holding meetings with inspection officials and industry representatives to reaffirm program requirements. These actions are intended to address weaknesses in the controls for the BEV program for Japan.

On January 27, 2006, the Secretary requested that the Inspector General perform an audit to evaluate the adequacy of USDA's coordination and control processes for the beef export verification program for Japan.

² Atlantic Veal and Lamb, Inc. (Atlantic) was the U.S. plant that exported ineligible veal product to Japan. The ineligible product was made from veal carcasses that Atlantic received from Golden Veal Corporation (Golden).

Objective

Our objective was to evaluate the adequacy of USDA's coordination and control processes for the BEV program for Japan. Specifically, we examined the (1) adequacy of AMS and FSIS procedures and controls to ensure that the specified product requirements were met for beef products exported to Japan; (2) processes used by the agencies to communicate the procedures and controls to affected agency employees and to train these employees; and (3) adequacy of agency controls to validate that agency employees understood and implemented the procedures.

Scope and Methodology

We performed our audit at AMS and FSIS Headquarters in Washington, D.C. We also relied on the results of interviews conducted by FSIS' Office of Program Evaluation, Enforcement, and Review (OPEER) and the Office of Inspector General's (OIG) Investigations Division.³ We performed our audit fieldwork from January 30 to February 7, 2006. To accomplish our objectives we interviewed appropriate officials, examined pertinent documentation, and reviewed applicable policies and procedures.

We interviewed AMS and FSIS officials to gain an understanding of the procedures and controls used to ensure that the specified product requirements were met for beef products exported to Japan; the processes used to communicate expectations to affected agency employees; and the controls the agencies used to validate that procedures were adequately implemented.

- At AMS, we interviewed the Deputy Administrator for Livestock and Seed Programs; the Chief of the Livestock and Meat Standardization Branch; and the Chief of the Audit, Review, and Compliance Branch.
- At FSIS, we interviewed the Assistant Administrator for Field Operations; the Deputy Assistant Administrator for International Affairs; the District Manager in Chicago, Illinois; and Deputy District Managers for the Albany, New York and Des Moines, Iowa District Offices.
- We also gained an understanding of the agreement with Japan by interviewing the Acting Under Secretary for Marketing and Regulatory Programs, who was a member of the team that negotiated the agreement.

To gain an understanding of the actions by individuals that caused Japan to decide to halt imports of beef products from the United States, we relied on the results of interviews conducted by FSIS' OPEER and OIG's Investigations Division. They interviewed plant management for Atlantic and Golden. They also interviewed FSIS inspection personnel at these plants and AMS

³ At the time we began this review, FSIS' OPEER and OIG's Investigations Division were interviewing agency and plant personnel and obtaining pertinent export documents to investigate the circumstances that allowed this event to occur. The results of that review will be reported in a separate document. This audit relies, in part, on the information obtained during the course of the joint investigation.

personnel that reviewed and approved the plants as eligible to provide product for export to Japan.

We analyzed AMS' policies and procedures regarding its BEV program for Japan. In addition, we examined FSIS' policies and procedures for certifying product for export and evaluating the performance of inspection personnel. Finally, we analyzed the Quality System Assessment, Export Verification (QSA/EV) Program Manual for Japan (QSA/EV Manual) for Atlantic and Golden.

We conducted the audit in accordance with Government Auditing Standards established by the Comptroller General of the United States. We did not visit any plants to analyze and observe how AMS, FSIS, and plant personnel audited, verified, and implemented the requirements of the beef export verification program. This type of analysis was not possible because our fieldwork occurred during the period when there was no trade of United States beef products with Japan. As a result, the scope of our work was limited because we could not perform tests to fully assess how (1) FSIS district and inspection officials verified requirements related to the beef export verification program, (2) AMS officials audited requirements to determine plants were eligible to export product to Japan, and (3) plants, other than Atlantic and Golden, adhered to the specified product requirements for exporting beef products to Japan.

Audit Results

Both AMS and FSIS have begun to formulate the procedures and controls they will implement to address the 12 actions announced by the Secretary and to provide assurance that BEV requirements are met in the future. In addition to these actions, we concluded that management controls over the BEV program can be further strengthened. We found that the enforcement of compliance with BEV requirements broke down because the processes and documents used to communicate the specific plants and Japanese requirements for export to the field inspectors were insufficient and non-specific. In this case, neither the FSIS Consumer Safety Inspector (CSI) nor the Supervisory Public Health Veterinarian (VMO) were familiar with the Japan BEV program or understood their roles and responsibilities for signing and certifying export documents. Our observations follow.

- AMS publishes a list of the plants it approves for the Japan BEV program on its web site; FSIS' web-based Export Library is linked to the AMS web site. FSIS requires its inspectors to check its Export Library to review the requirements for the importing country and determine if a plant submitting an application for export has been approved for the BEV program. Plants approved for the Japan BEV program are required to have processes in place that assure compliance with the specified product requirements. In part, AMS requires⁴ the exclusion of specified risk materials (SRM) and certain other materials. The FSIS Export Library identifies eligible and ineligible products in a broad sense (i.e., beef and beef offal, etc.) and by listing the materials required to be excluded. Although Japan does not identify specific products that are eligible, any product that

⁴ ARC 1030J Procedures, USDA Export Verification Program Specified Product Requirements for Beef – Japan, dated December 12, 2005.

includes any of the listed materials is not eligible. To facilitate confirmation of compliance with the agreement with Japan, we recommend that AMS include on its web site the specific beef products that would be consistent with the agreement. We also recommend that AMS and FSIS jointly develop an operational process (compensating control) that requires confirmation of both the eligibility of the plant and the products for export, prior to FSIS certifying export documents.

- AMS requires plants on the approved list to prepare a QSA/EV Manual.⁵ The QSA/EV Manuals for Atlantic and Golden included the specified product requirements for Japan but did not contain all the specific process controls required (although the latter had been communicated to all participating plants). Instead, the QSA/EV Manuals refer only to plant HACCP, SSOP, and SOP operational procedures,⁶ which are applicable to their domestic operations. The QSA/EV Manuals also refer to the plants' Application for Service, Form LS-313.⁷ During the interviews conducted by FSIS' OPEER and OIG's Investigations Division with AMS and plant personnel, differences were identified in plant personnel's understanding as to what the specific BEV requirements were, what products were eligible to export, and what specifically was discussed with AMS staff prior to being approved to export. To strengthen compliance and enforcement, we recommend that AMS work with plant personnel to revise the QSA/EV Manuals and include the specific products and process requirements necessary for the Japan BEV Program. AMS officials have advised that they plan to review all QSA/EV Manuals for all companies on the approved BEV list.
- FSIS needs to clarify the roles and responsibilities of personnel involved in the export certification process. The CSI stated he signed the application for export certifying that the box count and product descriptions matched the details on the application; the CSI thought the VMO was responsible for certifying that the requirements of the receiving country were met. The VMO, however, stated that his duties require that he make sure that the export paperwork is complete and accurate after the CSI completes an inspection on product destined for export. The VMO stated that since being assigned to the District in June 2005, he was directed by the Deputy District Manager to perform a document review only. The VMO was concerned that this conflicted with the Supervisory Public Health Veterinarian training he received in 2005 which included "hands on" (product review) export inspection verification. He did not review Japan BEV requirements since

⁵ AMS requires plants to establish and maintain a quality manual that includes such things as: (a) an organizational chart or similar document listing all personnel assigned to managerial positions within the program; (b) a description of the scope of the plant's quality management system, (c) the specified product requirements, and (d) documented procedures established for the quality management system.

⁶ Hazard Analysis and Critical Control Point (HACCP) is a systematic approach to food safety that addresses physical, chemical, and biological hazards as a means of prevention through the identification of Critical Control Points. These Critical Control Points are key actions that can be taken to reduce or eliminate the risk that food safety hazards will occur. Sanitation Standard Operating Procedures (SSOP) and Standard Operating Procedures (SOP) describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product.

⁷ Form LS-313 is used by parties interested in receiving services from AMS' Meat Grading and Certification Branch for such services as beef, calf, veal, or lamb grading or meat certification.

he no longer performs "hands on" export verification activities. The Deputy District Manager confirmed that the VMO is to review the export certificate and any other associated documents. He stated that the VMO is certifying that the paperwork is correct; therefore, performing "hands on" export verification is not normally needed. He explained that if there is a problem or question regarding the lot, then the VMO can examine the product.

- FSIS relied on its export certification directive (FSIS 9000.1, dated September 9, 1999) to communicate the roles and responsibilities of its staff in inspecting and certifying export requirements. FSIS also put the specific export requirements for Japan on its web-based Export Library. In December 2005, FSIS headquarters held a conference call with District Managers to discuss the requirements for exports to Japan. In addition, a series of e-mail messages were sent to the District Managers again emphasizing the need to ensure compliance. However, no additional actions were taken to ensure that FSIS field staff understood their responsibilities for signing and certifying export certificates for Japan. The FSIS Deputy District Manager responsible for Atlantic did not participate in the conference call because, at that time, none of the plants in the district were approved to export to Japan and was not made aware when Atlantic was approved to export product to Japan.⁸ Therefore, he stated that there was no need to further communicate the Japan BEV program requirements to the district's field inspectors. Neither the FSIS Frontline Supervisor nor the CSI were aware of the Japan BEV program requirements.
- AMS offered to provide FSIS copies of the QSA/EV Manuals of all companies on the approved BEV list. FSIS took the position that the manuals were proprietary business information and therefore did not want its inspectors to retain copies in their possession. FSIS instead asked AMS to require that plants make these manuals available to the inspectors upon request. (This position is consistent with how FSIS handles plant HACCP, SSOP, and SOP documents, which are also proprietary business documents.) In this case, since the inspector was not aware of the BEV program requirements, nor had he been trained on what documents and/or information was available, he did not know to ask the plant for their QSA/EV manual. To increase inspectors' awareness of the requirements for the BEV program and export certification, FSIS is developing training for CSIs. We are recommending that FSIS incorporate a proficiency test in its training for those assigned to perform export certification. This would be similar to the actions taken by AMS to test meat graders on their ability to determine the age of cattle through physiological maturity evaluations of carcasses. During testing, meat graders must demonstrate a performance level of 98 percent accuracy.
- FSIS had not established specific management controls or provided specific supervisory oversight to inspectors to ensure that they understood Japan BEV requirements and were properly certifying product for export. FSIS plans to use its In-Plant Performance System (IPPS) reviews to validate that FSIS inspection personnel perform export certifications in

⁸ Atlantic was approved to export product to Japan on January 6, 2006.

accordance with agency policy. However, the Performance Based Inspection System (PBIS) considers export tasks to be unscheduled inspection tasks and low risk for food safety. Therefore, IPPS does not include unique procedures for evaluating inspector performance on export tasks. FSIS needs to revise the IPPS review guidance to incorporate procedures that specifically evaluate the ability of inspection personnel to perform export certifications.

USDA has taken positive actions to identify additional measures necessary to strengthen its controls and processes for ensuring compliance with the BEV program for Japan. These actions, along with the actions taken in response to the following recommendations, should further strengthen the program.

Recommendations

1. AMS should include on its web site the specific beef products each plant has been approved to export.
2. AMS and FSIS should jointly develop an operational process (compensating control) that requires confirmation of the eligibility of both the plant and the products for export, prior to FSIS certifying export documents.
3. AMS should work with plant personnel to revise the QSA/EV Manuals to include the specific products and any additional process control requirements determined to be necessary for the BEV program for Japan.
4. FSIS should clarify the roles and responsibilities of FSIS personnel involved at every stage of the export certification process.
5. FSIS should expedite the development of training on export certification for CSIs. FSIS should also incorporate a proficiency test in its training for those assigned to perform export certification.
6. FSIS should increase supervisory oversight of the export certification process by revising the IPPS review guidance to incorporate procedures that specifically evaluate the ability of inspection personnel to perform export certifications.

We met with officials from FSIS and AMS on February 7, 2006, to obtain their verbal comments on the findings and recommendations. AMS and FSIS officials expressed agreement with the report's findings and recommendations.

We appreciate the assistance and cooperation we received from AMS and FSIS staff during this audit.

Informational copies of this report have been distributed to:

Administrator, AMS

ATTN: Agency Liaison Officer (6)

Administrator, FSIS

ATTN: Agency Liaison Officer (20)

Government Accountability Office (1)

Office of Management and Budget (1)

Office of the Chief Financial Officer

Director, Planning and Accountability Division (1)

IV. USDA Findings and Action Plan

On January 20, 2006, U.S. Secretary of Agriculture Mike Johanns initially announced 12 action steps in response to an ineligible shipment of veal that was exported to Japan. USDA's Food Safety and Inspection Service's Office of Program Evaluation, Enforcement, and Review investigated the two establishments in question, and those results are captured in the FSIS *Japan Export Investigation Report, Golden Veal Corp., and Atlantic Veal and Lamb, Inc.* USDA's Office of the Inspector General conducted an audit on the *Assessment of USDA's Controls for the Beef Export Verification Program for Japan*. Many findings and actions taken to address the findings may be repeated in each of these documents.

1. INITIAL ACTIONS ANNOUNCED JANUARY 20, 2006, BY U.S. SECRETARY OF AGRICULTURE MIKE JOHANNNS

On January 20, 2006, the U.S. Department of Agriculture (USDA) responded rapidly when notified that an ineligible shipment of veal had been exported to Japan. The Food Safety and Inspection Service (FSIS) Office of Program Evaluation, Enforcement, and Review investigation of the establishments and all FSIS inspection program personnel involved in the veal shipment began on Friday morning, January 20, 2006. As part of this investigation, FSIS has reviewed and assessed the regulatory history of the establishments involved in the veal shipment. The FSIS investigation was done in cooperation with the USDA Office of the Inspector General (OIG). FSIS has also investigated the performance and conduct of the employees who conducted the verification inspection of the product in question and approved it for shipment into the Japanese marketplace.

Also on Friday, January 20, 2006, USDA identified 12 action steps that would be pursued or, in some cases, had already been taken by the time of the public announcement that would prevent the repeat occurrence of this type of incident.

The first action announced on January 20, 2006, was to submit a report to the Government of Japan on our investigation and our actions that have been or will be taken. This is that report.

The second action announced on January 20, 2006, was the delisting of establishments in question that had produced veal products for export or had exported veal products into Japan that were ineligible.

Atlantic Veal and Lamb, Incorporated (Brooklyn, New York), and its supplier, Golden Veal Corporation (Creston, Ohio), have both been delisted from the Agricultural Marketing Service (AMS) Export Verification (EV) program. Atlantic Veal and Lamb, Inc., and Golden Veal, Corp., were the only two establishments certified to export veal to Japan. Golden Veal, Corp., is no longer an operational establishment due to fire damage incurred on January 12, 2006. Atlantic Veal and Lamb, Inc., was delisted on January 20, 2006, at 8:34 a.m. Eastern Time.

The third action announced on January 20, 2006, was the requirement of a second signature on EV export certificates.

To add another step in the process to confirm that the requirements have been met, it was determined that both FSIS and AMS should have shared responsibility to confirm shipments for the EV program. Because of this finding, AMS will be providing the second signature. (Detailed steps are in the "FSIS Findings and Actions.")

The fourth action announced on January 20, 2006, was that unannounced USDA inspections will be a part of the EV program.

FSIS will conduct unannounced visits of EV approved establishments to verify that FSIS inspection program personnel are correctly following established procedures for certifying exports. These unannounced visits to verify the procedures will begin in April 2006.

AMS will conduct unannounced reviews of all EV programs. Reviews will be conducted on the premises of the establishment and be an observation of the establishment's product preparation processes used to adhere to the specified product requirement.

The fifth action announced on January 20, 2006, was that FSIS would hold a conference call with all FSIS District Managers to review established export requirements for countries with EV programs.

That same day, January 20, 2006, FSIS held a conference call with all FSIS District Managers to review established procedures and export requirements for countries with EV programs. FSIS District Managers were told that they and all FSIS inspection program personnel with export responsibilities would be held accountable for knowing and understanding export requirements. Further, the call reaffirmed the critical need for all inspection program personnel to assure that exporting establishments adhere to all export requirements. It was made clear that employees will be held accountable for fulfilling their obligations in this area.

The sixth action announced on January 20, 2006, was that a conference call with FSIS inspection program personnel would be held on January 23, 2006, to reaffirm requirements for all countries relative to the EV program.

On January 23, 2006, FSIS conducted interactive web-based training with responsible inspection program personnel assigned to all EV approved establishments to reaffirm requirements relative to the EV program.

This web-based training was an intensive review of export requirements to ensure that the integrity, security, and accuracy of requirements are maintained. Specifically, the program reviewed in detail FSIS Directives 9000.1, *Export Certification*, and 9040.1, *Reinspection of Product Intended for Export*. Correlation material on exports, country requirements, EV programs, and export procedures were delivered to all meeting

participants. The training also addressed the responsibility of certifying officials to verify that information on the export certificates is accurate, to ensure that appropriate attachments from the exporting establishment are included with export certificates, and that they have checked the FSIS Export Library for any additional requirements of the receiving country.

All materials used in the training, including PowerPoints, digital images of eligible products, scenarios, and questions and answers, along with an overview of AMS EV programs and all related references, such as revised Directives and Notices, are being formatted into computer-based training for FSIS inspection program personnel. Employees will be provided computer-based training for follow-up training and for employees who rotate into an assignment that includes any establishment that produces product that is subject to EV requirements. The training will also be used for supplemental training, and for training new employees who are hired after January 2006. Successful completion of the training will be documented for each employee in the Agency's training database.

The seventh action announced on January 20, 2006, was that inspectors in the EV establishments review procedures to ensure compliance.

In addition to the unannounced reviews described in the fourth action, AMS will conduct reviews for all EV approved establishments for each country that requires an EV program. These reviews will target each plant's implementation of the specified product requirements (e.g., vertebral column removal) listed in the EV program. These reviews will be completed within two weeks of the Government of Japan reviewing and accepting this report and its actions, and prior to the shipment of products to Japan.

These reviews supplement the ongoing bi-annual audits of an approved establishment's Quality System Assessment/Export Verification Program. The audits are a systematic, documented process for obtaining evidence and evaluating that information to objectively determine if the establishment is adhering to their approved Quality System Manual. These audits evaluate the establishment's processes in place to assure compliance with the specified product requirements.

The eighth action announced on January 20, 2006, was that no additional establishments would be approved under the EV program for Japan until the investigation is complete and related actions are in place.

No additional establishments will be audited or approved for EV programs to Japan until further notice. This went into effect on January 20, 2006.

The ninth action announced on January 20, 2006, was the intent to dispatch a team to Japan if requested to work with the Government of Japan.

If requested, USDA is willing to send a technical team to Japan to work together.

The tenth action announced on January 20, 2006, was that FSIS would conduct an investigation of the establishments in question.

The summary, exhibits, findings, and action steps from that investigation are included elsewhere in this report.

The eleventh action announced on January 20, 2006, was that further training of FSIS inspection program personnel on EV requirements and a required signed validation that they have completed the training would be instituted.

FSIS has provided additional training for its inspection workforce in the EV programs and will continue to provide training on these actions. On Monday, January 23, 2006, FSIS conducted an interactive web-based training for responsible inspection program personnel at all EV approved establishments. This meeting was an intensive review of export requirements to ensure that the integrity, security, and accuracy of requirements are maintained. Specifically, the program reviewed in detail FSIS Directives 9000.1, *Export Certification*, and 9040.1, *Reinspection of Product Intended for Export* (Directive 9000.1, *Export Certification*, will be revised to clarify current FSIS policy regarding the export certification process.) Correlation material on exports, country requirements, EV programs, and export procedures were delivered to all meeting participants. The training also reiterated the responsibility of certifying officials to verify that information on the export certificates is accurate, to ensure that appropriate attachments from the exporting establishment are included with export certificates, and that they have checked the FSIS Export Library for any additional requirements of the receiving country.

All materials used in the training, including PowerPoints, digital images of eligible products, scenarios, and questions and answers, along with an overview of AMS EV programs and all related references, such as revised Directives and Notices, are being formatted into computer-based training for FSIS inspection program personnel. Employees will be provided computer-based training for follow-up training and for employees who rotate into an assignment that includes any establishment that produces product that is subject to EV requirements. The training will also be used for supplemental training, and for training new employees who are hired after January 2006. Successful completion of the training will be documented for each employee in the Agency's training database.

FSIS is preparing an updated Notice, *Certifying Beef Products Under Export Verification Programs*, to clarify the roles and responsibilities regarding responsibilities for certifying beef products under EV programs and additional training for inspection program personnel will be provided regarding this Notice. FSIS will require documentation that

inspection program personnel have completed the training, and are proficient in the certification process through performance assessment. FSIS will implement this training by March 15, 2006.

The twelfth action announced on January 20, 2006, was a meeting with representatives of establishments participating in the EV programs to ensure they meet the requirements.

On January 24, 2006, USDA officials held a meeting at USDA headquarters in Washington, D.C., with representatives from establishments that participate in EV programs. Senior management, including Chief Executive Officers and quality assurance directors for establishments exporting beef to Japan, were notified by the U.S. Secretary of Agriculture that they were expected to be in attendance, and all of those establishments were represented. In addition, USDA also encouraged the participation of senior management from all establishments with approved EV programs that export to countries other than Japan, and many attended. 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.

In the January 24, 2006, meeting, FSIS and AMS jointly addressed critical issues for industry compliance with export requirements. Specifically, export verification procedures were reviewed and followed by an in-depth discussion of country requirements and the export certification process. The presentations were electronically transmitted to all EV-approved establishments, and have been posted on both FSIS and AMS public web sites. A copy of the invitation to participate, the agenda, and presentations are enclosed in this report as Appendix H.

**12 Actions Announced by USDA on January 20, 2006
USDA Beef Export Verification Program For Japan**

Action No.	Action	Color Code Green = Complete Yellow = In Development	Status/Comments
1	Submit a report to the Government of Japan on our investigation and our action(s) that have been or will be taken.		This action is completed upon delivery of this report.
2	Delist all establishments in question that have exported beef products into Japan that were ineligible.		The only two establishments certified to export veal to Japan were delisted on January 20, 2006.
3	Require a second signature on EV export certificates.		Starting on or before March 1. It was determined that both FSIS and AMS should have shared responsibility to confirm shipments for the EV program. To confirm requirements are being met, AMS will provide this second signature in the export certification process.
4	Make unannounced USDA inspections part of the EV program.		Starting on or before April 2006, FSIS will conduct unannounced visits of EV approved establishments to verify that FSIS inspection program personnel are correctly following established procedures for certifying exports. AMS will conduct unannounced reviews of all EV programs. Reviews will be conducted on the premises of the establishment and ensure that the establishment adheres to EV processes.
5	Hold a conference call with all District Managers.		Completed January 20, 2006 FSIS held a conference call with all FSIS District Managers to review established procedures and export requirements for countries with EV programs. It was emphasized that inspection program personnel must know and understand export requirements.
6	Hold a conference call to reaffirm		Completed January 23, 2006, FSIS conducted an

**12 Actions Announced by USDA on January 20, 2006
USDA Beef Export Verification Program For Japan**

Action No.	Action	Color Code Green = Complete Yellow = In Development	Status/Comments
	requirements for all countries relative to the EV program.		interactive web-based training with responsible inspection program personnel assigned to EV approved establishments.
7	Inspectors in the EV establishments review procedures to ensure compliance.		AMS will conduct reviews of all EV programs. These reviews will be completed within two weeks of the Government of Japan reviewing and accepting the report and its actions, and prior to shipment of product to Japan. These reviews supplement the on-going bi-annual audits.
8	No additional establishments would be approved under the EV program for Japan until the investigation is complete and related actions are in place.		Effective January 20, 2006 no additional establishments will be audited or approved for EV programs to Japan until further notice.
9	Dispatch a team to Japan, if requested, to work with Government of Japan.		USDA is willing to send a technical team to Japan to work together.
10	Conduct an investigation of the establishments in question.		Completed February 2, 2006, FSIS identified five findings and 18 additional actions to address opportunities for improvement.
11	Mandate further training of FSIS inspection program personnel on EV requirements and require a signed validation that the training has been completed.		On-going. FSIS has provided additional training for its inspection workforce in the EV programs and will continue to provide training on these actions. On January 23, 2006, FSIS conducted an interactive web-based training for responsible inspection program personnel at all EV approved establishments. This meeting was an intensive review of export requirements to ensure that the

**12 Actions Announced by USDA on January 20, 2006
USDA Beef Export Verification Program For Japan**

Action No.	Action	Color Code Green = Complete Yellow = In Development	Status/Comments
			integrity, security, and accuracy of requirements are maintained.
12	Meet with establishments participating in the EV programs to ensure they meet the requirements.		Completed January 24, 2006 USDA held a meeting with representatives from establishments that participate in EV programs to articulate 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.

IV. USDA Findings and Action Plan

2. FSIS INVESTIGATION FINDINGS AND ACTIONS

As a result of a thorough and complete investigation of this incident, 5 findings and 15 action steps were identified. They are detailed in this section of this report.

FINDING #1:

FSIS inspection program personnel at both establishments were unaware that Atlantic Veal and Lamb, Inc., or its supplier, Golden Veal Corp., had been recently approved under the AMS EV program to export to Japan. FSIS inspection program personnel first became aware that Atlantic Veal and Lamb, Inc., was an approved EV program establishment when the application for export certificate was presented for signature.

ACTIONS IN RESPONSE TO FINDING #1:

AMS will notify FSIS when an establishment is audited and approved or delisted under an EV program. This notification will happen as described below:

1. Upon submission of an establishment's Quality System Manual for approval by AMS for an EV program, AMS will notify the FSIS Technical Service Center (TSC). FSIS will provide training for the assigned establishment inspection program personnel on the requirements of the pending export certification. FSIS will ensure that training of the assigned establishment personnel is completed within five (5) business days of the AMS notification. FSIS will notify AMS when appropriate inspection program personnel have completed the training. AMS will not approve an establishment for export until it receives notification from FSIS that the training has been completed.
2. When an establishment is approved for an EV program, AMS will add the establishment to the list of approved establishments to send product to a particular country. AMS will notify FSIS of the listing by electronically transmitting a copy of the audit results to the FSIS TSC, which will notify the FSIS District Office. AMS will follow-up by electronically transmitting a full copy of the audit report to the FSIS TSC.
3. When an establishment is delisted, AMS immediately will notify the FSIS TSC which will notify the FSIS District Office. AMS will follow-up by electronically transmitting a copy of the notice of delisting, and if applicable, the audit report to the FSIS TSC.
4. The approved establishment will maintain a copy of all EV program audit reports in its records, and management will discuss the audit reports in their next weekly meeting with FSIS assigned establishment inspection program personnel. This will be added as a requirement for EV program approved establishments.
5. FSIS will acknowledge receipt of all audit results and reports provided by AMS.

* USDA implemented the above changes on Monday, February 13, 2006.

FINDING #2:

Golden Veal, Corp., was not eligible to supply offal to Atlantic Veal and Lamb, Inc. for shipment to Japan. In this specific incident, Golden Veal, Corp. shipped offal to Atlantic Veal and Lamb, Inc., and certified it as eligible to export to Japan. Atlantic Veal and Lamb, Inc., shipped offal to Japan, certifying it as eligible for export although it came from an establishment that was not certified to supply offal for shipment for Japan.

ACTIONS IN RESPONSE TO FINDING #2:

In the situation where a supplier and fabricator are separate establishments, AMS will require the fabricator to maintain a list of establishments that are approved EV suppliers for the fabricator.

In addition, AMS will require the fabricator to maintain a current list of products that each EV supplier is approved to provide under their approved EV program. As part of the approved EV program, participating establishments will be required to provide FSIS with access to these establishment records.

* AMS will implement on or before March 1, 2006.

FINDING #3:

It was found during the investigation that there was an unclear line of authority as to whether FSIS or AMS is ultimately responsible for confirming that the requirements of the EV program have been met.

ACTIONS IN RESPONSE TO FINDING #3:

To add another step in the process to confirm that the requirements have been met, it was determined that both FSIS and AMS should have shared responsibility to confirm shipments for the EV program. Because of this finding, AMS will be providing the second signature in the export certification process. The revised process is as follows:

For each EV associated export certificate from any EV approved facility:

- FSIS will certify and sign that all food safety requirements are met.
- AMS will require establishments approved under the EV Program to include in their QSA Quality System Manual a list of products intended for export. The list must contain all beef items, including offal products, that are intended for export. In addition, the list must include the specific product code numbers and an Institutional Meat Product Specification item number or a detailed item description.
- AMS will confirm that the supplier and fabricator establishments are approved under their EV program for the importing country to process and export each of the products listed on the Application For Export Certificate.

- After AMS confirms that the establishment is an approved establishment and the specific products listed on the Application For Export Certificate are approved for export for Japan. The statement of verification is as follows:
 “The exported beef to Japan fulfills all of the required conditions described in the EV Program. In case the slaughtered cattle have been legally imported from Canada, criteria 5.2.1.1 or 5.2.1.2 of the EV Program is applied in order to verify 20 months of age or younger. In case the slaughter cattle have been legally imported from third free countries, other than Mexico, and raised in the USA, only the criteria 5.2.1.1 of the EV Program is applied in order to verify that the cattle were 20 months of age or younger.”
 - For other EV approved countries, AMS will make any similar statements regarding the establishment and products meeting all EV requirements.
 - AMS will require that establishments provide copies of the signed AMS statements to FSIS inspection program personnel who will be signing the certificate for export. AMS will electronically deliver a copy of all electronically signed AMS statements to FSIS TSC.
 - FSIS will issue a Notice to its inspection program personnel describing this revised process and FSIS’ roles and responsibilities. FSIS will provide training to its inspection program personnel on this Notice.
- * Actions for Finding #3 will be initiated on or before March 1, 2006.

FINDING #4:

The FSIS inspection program personnel at Atlantic Veal and Lamb, Inc. were well trained on all certifications related to food safety issues. However, they were not sufficiently aware of the EV program.

ACTIONS IN RESPONSE TO FINDING #4:

1. On January 20, 2006, FSIS held a conference call with all FSIS District Managers to review established procedures and export requirements for countries with EV programs. It was emphasized that all inspection program personnel with export responsibilities must know and understand export requirements. Further, the call reaffirmed the critical need for all inspection program personnel with export responsibilities to assure that exporting establishments adhere to all export requirements. District Managers were told that they and all inspection program personnel with export responsibilities would be held accountable for knowing and understanding export requirements.
2. FSIS has provided additional training for its inspection workforce in the EV programs and will continue to provide training on these actions. On Monday, January 23, 2006, FSIS conducted an interactive web-based training for

responsible inspection program personnel at all EV approved establishments. This meeting was an intensive review of export requirements to ensure that the integrity, security, and accuracy of requirements are maintained. Specifically, the program reviewed in detail FSIS Directives 9000.1, *Export Certification*, and 9040.1, *Reinspection of Product Intended for Export* (Directive 9000.1 *Export Certification*, will be revised to clarify current FSIS policy regarding the export certification process.) Correlation material on exports, country requirements, EV programs, and export procedures were delivered to all meeting participants. The training also reiterated the responsibility of certifying officials to verify that information on the export certificates is accurate, to ensure that appropriate attachments from the exporting establishment are included with export certificates, and that they have checked the FSIS Export Library for any additional requirements of the receiving country.

3. All materials used in the training, including PowerPoints, digital images of eligible products, scenarios, and questions and answers, along with an overview of AMS EV programs and all related references, such as revised Directives and Notices, are being formatted into computer-based training for FSIS inspection program personnel. Employees will be provided computer-based training for follow-up training and for employees who rotate into an assignment that includes any establishment that produces product that is subject to EV requirements. The training will also be used for supplemental training, and for training new employees who are hired after January 2006. Successful completion of the training will be documented for each employee in the Agency's training database.
4. FSIS is preparing an updated Notice, *Certifying Beef Products Under Export Verification Programs*, to clarify the roles and responsibilities regarding responsibilities for certifying beef products under EV programs and additional training for inspection program personnel will be provided regarding this Notice. FSIS will require documentation that inspection program personnel have completed the training, and are proficient in the certification process through performance assessment. FSIS will implement this training on or before March 15, 2006.
5. As an additional communication measure, USDA created an e-mail subscription option for inspection program personnel in establishments with EV programs, as well as establishment personnel in EV establishments, who are now receiving e-mail alerts when any changes are made to EV programs. USDA conducted on-site sign-up for the e-mail subscription for all participants during the January 24, 2006, meeting with industry officials, and to date, the information is circulated to more than 600 recipients.
6. The action identified to address Finding #1 will also address Finding #4. Upon submission of an establishment's Quality System Manual for approval by AMS for an EV program, AMS will notify the FSIS TSC. FSIS will provide training for the assigned establishment inspection program personnel on the requirements

of the pending export certification. FSIS will ensure training of the assigned establishment personnel is completed within five (5) business days of the AMS notification. FSIS will notify AMS when appropriate inspection program personnel have completed the training. AMS will not approve an establishment for export until it receives notification from FSIS that the training has been completed. This provides an additional assurance that FSIS has adequate notice to train its inspection program personnel.

* USDA implemented the above changes on Monday, February 13, 2006.

FINDING #5:

The information concerning eligible and ineligible products for export to Japan on the FSIS web site was not specific enough in this isolated incident to determine eligibility of the products involved.

ACTION IN RESPONSE TO FINDING #5:

For each establishment with an approved EV program, AMS will maintain a list on an internal web site of the specific products approved for export to each country participating in EV programs. FSIS inspection program personnel trained in the EV program will be provided access to this information.

* This will be completed by March 1, 2006.

POLICY ACTION TO ENSURE IMPLEMENTATION

In order to effectively carry out these corrective actions, FSIS and AMS will implement a Memorandum of Understanding (MOU) between the two agencies to outline appropriate responsibilities and authorities.

* The MOU will be signed and in place by March 1, 2006.

15 Action Steps Identified by the FSIS Investigation USDA Beef Export Verification Program For Japan

Action Step	Action	Color Code Green = Fully Complete Yellow = In Development	Status/Comments
Finding #1			
1	Upon submission of an establishment's Quality System Manual for approval by AMS for an EV program, AMS will notify the FSIS TSC. FSIS will provide training for the assigned establishment inspection program personnel. FSIS will ensure training is completed within 5 business days. FSIS will notify AMS when training has been completed. AMS will not approve an establishment for export until it receives notification from FSIS that training has been completed.		Completed February 13, 2006.
2	When an establishment is approved for an EV program, AMS will add the establishment to the list of approved establishments to send product to a particular country. AMS will notify FSIS of the listing by electronically transmitting a copy of the audit results to the FSIS TSC, which will notify the FSIS District Office. AMS will follow-up by electronically transmitting a full copy of the audit report to the FSIS TSC.		Completed February 13, 2006.
3	When an establishment is delisted, AMS immediately will notify the FSIS TSC which will notify the FSIS District Office. AMS will follow-up by electronically transmitting a copy of the notice of delisting, and if applicable, the audit report to the FSIS TSC.		Completed February 13, 2006.

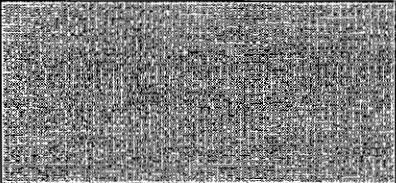
**15 Action Steps Identified by the FSIS Investigation
USDA Beef Export Verification Program For Japan**

4	The approved establishment will maintain a copy of all EV program audit reports in its records, and management will discuss the audit reports in their next weekly meeting with FSIS assigned establishment inspection program personnel. This will be added as a requirement for EV program approved establishments.		Completed February 13, 2006.
5	FSIS will acknowledge receipt of all audit results and reports provided by AMS.		Completed February 13, 2006.
Finding #2			
1	When supplier and fabricator are separate establishments, AMS will require the fabricator to maintain a list of establishments that are approved EV suppliers for the fabricator.		Completed on or before March 1, 2006.
Finding #3			
1	Both AMS and FSIS will share the responsibility to confirm shipments for the EV program. To add another step in the process to confirm that requirements have been met, AMS will provide a second signature in the export certification process.		Initiated on or before March 1, 2006, with ongoing development per discussion with importing countries.
Finding #4			
1	FSIS will hold a conference call with District Managers to review established procedures and export requirements for countries with EV programs.		Completed January 20, 2006.
2	FSIS will provide additional training for its inspection workforce in the EV programs.		Implemented on January 23, 2006, and training on revised directives and notices is ongoing.
3	All materials used in the training are being formatted into FSIS' e-training system for inspection program		Implemented on or before March 15, 2006, and ongoing after that.

15 Action Steps Identified by the FSIS Investigation USDA Beef Export Verification Program For Japan

	personnel. The system will allow follow-up training for new employees and for employees that rotate into an assignment that produces product subject to EV requirements. Successful completion will be documented for each employee.		
4	FSIS is preparing an updated FSIS Notice to clarify the roles and responsibilities regarding verification responsibilities for certifying beef products under EV programs. Additional training will be provided regarding the Notice.		Implemented on or before March 15, 2006, and ongoing after that.
5	USDA has created an e-mail subscription option for inspection program personnel and establishment personnel in EV establishments to alert them when any changes are made to EV programs.		Completed January 24, 2006. To date, there are more than 600 subscribers.
6	Upon submission of an establishment's Quality System Manual for approval by AMS for an EV program, AMS will notify the FSIS TSC. FSIS will provide training for the assigned establishment inspection program personnel. FSIS will ensure training is completed within 5 business days. FSIS will notify AMS when training has been completed. AMS will not approve an establishment for export until it receives notification from FSIS that training has been completed.		Completed February 13, 2006.
Finding #5			
1	For each establishment with an approved EV program, AMS will maintain a list on an internal web site of specific products approved for export to each country participating in EV programs. Trained FSIS inspection program personnel will have access to this information.		Completed on or before March 1, 2006.

**15 Action Steps Identified by the FSIS Investigation
USDA Beef Export Verification Program For Japan**

Policy Action to Ensure Implementation			
1	In order to effectively carry out these corrective actions, FSIS and AMS will implement a Memorandum of Understanding (MOU) between the two agencies to outline appropriate responsibilities and authorities.		Completed on or before March 1, 2006.



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

FEB 15 2006

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

FROM: Lloyd C. Day
Administrator *[Signature]*
Agricultural Marketing Service

Barbara J. Masters, D.V.M. *Barbara Masters*
Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Assessment of USDA's
Controls for the Beef Export Verification Program for Japan

We appreciate the opportunity to review and comment on this report. The Agricultural Marketing Service (AMS) and the Food Safety and Inspection Service (FSIS) have reviewed the draft report with great interest and have responded to each of the six audit recommendations.

Recommendation No. 1

AMS should include on its web site the specific beef products each plant has been approved to export.

Agency Response to Recommendation No. 1

For each establishment with an approved EV program, AMS will maintain a list on an internal website of the specific products approved for export to each country participating in EV programs. FSIS inspection program personnel trained in the EV program will be provided access to this information. This will be completed by March 1, 2006.

Recommendation No. 2

AMS and FSIS should jointly develop an operational process (compensating control) that requires confirmation of the eligibility of both the plant and the products for export, prior to FSIS certifying export documents.

Agency Response to Recommendation No. 2

AMS will notify FSIS when an establishment is audited and approved or delisted under an EV program. Effective February 13, 2006, this notification will happen as described below:

- i. Upon submission of an establishment's Quality System Manual for approval by AMS for an EV program, AMS will notify the FSIS Technical Service Center (TSC). FSIS will provide training for the assigned establishment inspection program personnel on the requirements of the pending export certification. FSIS will ensure that training of the assigned establishment personnel is completed within five (5) business days of the AMS notification. FSIS will notify AMS when appropriate inspection program

- personnel have completed the training. AMS will not approve an establishment for export until it receives notification from FSIS that the training has been completed.
- ii. When an establishment is approved for an EV program, AMS will add the establishment to the list of approved establishments to send product to a particular country. AMS will notify FSIS of the listing by electronically transmitting a copy of the audit results to the FSIS TSC, which will notify the FSIS District Office. AMS will follow-up by electronically transmitting a full copy of the audit report to the FSIS TSC.
 - iii. When an establishment is delisted, AMS immediately will notify the FSIS TSC which will notify the FSIS District Office. AMS will follow-up by electronically transmitting a copy of the notice of delisting, and if applicable, the audit report to the FSIS TSC.
 - iv. The approved establishment will maintain a copy of all EV program audit reports in its records, and management will discuss the audit reports in their next weekly meeting with FSIS assigned establishment inspection program personnel. This will be added as a requirement for EV program approved establishments.
 - v. FSIS will acknowledge receipt of all audit results and reports provided by AMS.

In the situation where a supplier and fabricator are separate establishments, AMS will require the fabricator to maintain a list of plants that are approved EV suppliers for fabrication. In addition, AMS will require the fabricator to maintain a current list of the products that each EV supplier is approved to provide under their approved EV program. As part of the approved EV program, participating establishments will be required to provide FSIS with access to these establishment records.

Recommendation No. 3

AMS should work with plant personnel to revise the QSA/EV Manuals to include the specific products and process requirements necessary for the BEV program for Japan.

Agency Response to Recommendation No. 3

AMS will review all EV plants, as announced by Secretary Johanns on January 20, 2006. In addition to the unannounced reviews described in the fourth action announced by Secretary Johanns, AMS will conduct reviews for all EV approved establishments for each country that requires an EV program. These reviews will target each plant's implementation of the specified product requirements (e.g., vertebral column removal) listed in the EV program. These reviews supplement the ongoing bi-annual audits of an approved establishment's Quality System Assessment/Export Verification Program. The audits are a systematic, documented process for obtaining evidence and evaluating that information to objectively determine if the establishment is adhering to their approved Quality System Manual. These audits evaluate the establishment's processes in place to assure compliance with the specified product requirements.

On January 24, 2006, USDA officials held a meeting at USDA headquarters in Washington, D.C., with representatives from establishments that participate in EV programs. Senior management, including Chief Executive Officers and quality assurance directors for establishments exporting beef to Japan, were notified by the U.S. Secretary of Agriculture that they were expected to be in attendance, and all of those establishments were represented. In addition, USDA also encouraged the participation of senior management from all establishments with approved EV programs that export to countries other than Japan, and many attended. 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.

During the January 24, 2006, meeting, FSIS and AMS jointly addressed critical issues for industry compliance with export requirements. Specifically, export verification procedures were reviewed and followed by an in-depth discussion of country requirements and the export certification process. The presentations were electronically transmitted to all EV-approved establishments, and have been posted on both FSIS and AMS public web sites.

Recommendation No. 4

FSIS should clarify the roles and responsibilities of FSIS personnel involved at every stage of the export verification process.

Agency Response to Recommendation No. 4

FSIS is revising FSIS Directive 9000.1 *Export Certification*, to clarify current Agency policy regarding the export certification process. This directive provides a clear set of standards for FSIS District Office and inspection program personnel to follow and further clarifies the roles and responsibilities of FSIS personnel involved at every stage of the export verification process. The FSIS Directive 9000.1 makes clear that a facsimile of FSIS form 9060-6 may be used to provide the information requested in that form and clarifies the purpose of the FSIS Export Library to inspection program personnel. The directive will clarify the steps to be followed in order to certify exports.

FSIS Directive 9000.1, Revision 1 will be issued by March 1, 2006.

FSIS is also issuing an FSIS Notice on Certifying Beef Products Under Export Verification Programs to clarify the roles and responsibilities regarding the certification of beef produced under EV programs.

This FSIS Notice will be issued by March 1, 2006.

Recommendation No. 5

FSIS should expedite the development of training on export certification for Consumer Safety Inspectors (CSIs). FSIS should also incorporate a proficiency test in its training for those assigned to perform export certification.

Agency Response to Recommendation No. 5

On January 20, 2006, FSIS held a conference call with all FSIS District Managers to review established procedures and export requirements for countries with EV programs. It was emphasized that all inspection program personnel with export responsibilities must know and understand export requirements. Further, the call reaffirmed the critical need for all inspection program personnel with export responsibilities to assure that exporting establishments adhere to all export requirements. District Managers were told that they and all inspection program personnel with export responsibilities would be held accountable for knowing and understanding export requirements.

FSIS has provided additional training for its inspection workforce in the EV programs and will continue to provide training on these actions. On Monday, January 23, 2006, FSIS conducted an interactive web-based training for responsible inspection program personnel at all EV approved establishments. This meeting was an intensive review of export requirements to ensure that the

integrity, security, and accuracy of requirements are maintained. Specifically, the program reviewed in detail FSIS Directives 9000.1, *Export Certification*, and 9040.1, *Reinspection of Product Intended for Export* (Directive 9000.1 *Export Certification*, will be revised to clarify current FSIS policy regarding the export certification process.) Correlation material on exports, country requirements, EV programs, and export procedures were delivered to all meeting participants. The training also reiterated the responsibility of certifying officials to verify that information on the export certificates is accurate, to ensure that appropriate attachments from the exporting establishment are included with export certificates, and that they have checked the FSIS Export Library for any additional requirements of the receiving country.

All materials used in the training, including PowerPoints, digital images of eligible products, scenarios, and questions and answers, along with an overview of AMS EV programs and all related references, such as revised Directives and Notices, are being formatted into computer-based training for FSIS inspection program personnel. Employees will be provided computer-based training for follow-up training and for employees who rotate into an assignment that includes any establishment that produces product that is subject to EV requirements. The training will also be used for supplemental training, and for training new employees who are hired after January 2006. Successful completion of the training will be documented for each employee in the Agency's training database.

FSIS is preparing an updated Notice, *Certifying Beef Products Under Export Verification Programs*, to clarify the roles and responsibilities regarding responsibilities for certifying beef products under EV programs and additional training for inspection program personnel will be provided regarding this Notice. FSIS will require documentation that inspection program personnel have completed the training, and are proficient in the certification process through performance assessment. FSIS will implement this training on or before March 15, 2006. Only FSIS inspection program personnel who have completed the training and are proficient in the certification process will sign the export certificates.

As an additional communication measure, USDA created an e-mail subscription option for inspection program personnel in establishments with EV programs, as well as establishment personnel in EV establishments, who are now receiving e-mail alerts when any changes are made to EV programs. USDA conducted on-site sign-up for the e-mail subscription for all participants during the January 24, 2006, meeting with industry officials, and to date, the information is circulated to more than 600 recipients.

The action identified to address Finding #1 will also address Finding #4. Upon submission of an establishment's Quality System Manual for approval by AMS for an EV program, AMS will notify the FSIS TSC. FSIS will provide training for the assigned establishment inspection program personnel on the requirements of the pending export certification. FSIS will ensure training of the assigned establishment personnel is completed within five (5) business days of the AMS notification. FSIS will notify AMS when appropriate inspection program personnel have completed the training. AMS will not approve an establishment for export until it receives notification from FSIS that the training has been completed. This provides an additional assurance that FSIS has adequate notice to train its inspection program personnel.

Recommendation No. 6

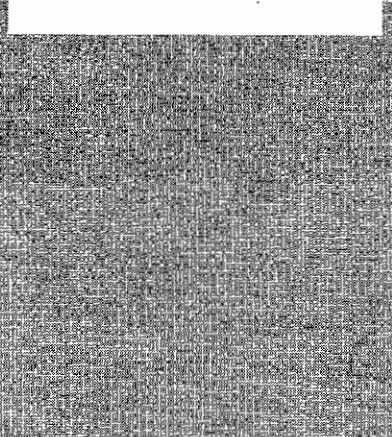
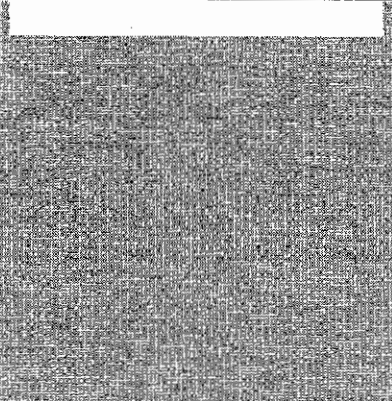
FSIS should increase supervisory oversight of the export certification process by revising the IPPS review guidance to incorporate procedures that specifically evaluate the ability of inspection personnel to perform export certifications.

Agency Response to Recommendation No. 6

FSIS Directive 4430.3, Rev. 1, In-Plant Performance System (IPPS), was issued on November 18, 2005, and describes the updated processes and procedures for supervisors within the Office Field Operations to follow when conducting IPPS assessments. Performance standards for export duties have been established in the IPPS process for all employees who are responsible for export duties. The "Export Duties" performance element includes eight sub-elements. Field Operations supervisors are to use the IPPS process to assess the work of nonsupervisory in-plant inspection program personnel in assuring that products approved for export are in compliance with laws, regulations, and foreign requirements. Results of IPPS reviews are recorded on FSIS Form 4430-8, In-Plant Performance System Assessment, which was also revised in November 2005. The IPPS Supervisory guidelines were also revised in November 2005 and separate guides were issued for several occupations.

FSIS Field Operations will partner with the FSIS Technical Service Center to update the IPPS Supervisory guidelines to provide more detailed guidance on export duties. FSIS will also develop a version of FSIS Form 4430-8 specific to employees who perform export duties exclusively. These will be in place by March 2006.

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Rec. No.	Recommendation	Color Code Green = Fully Complete Yellow = In Development	Status/Comments
1	AMS should include on its web site the specific beef products each plant has been approved to export.		Completed on or before March 1, 2006. For each establishment with an approved EV program, AMS will maintain a list on an internal website of the specific products approved for export to each country participating in EV programs. FSIS inspection program personnel trained in the EV program will be provided access to this information.
2	AMS and FSIS should jointly develop an operational process (compensating control) that requires confirmation of the eligibility of the plant and the products for export, prior to FSIS certifying export documents.		Effective February 13, 2006, AMS will notify FSIS when an establishment is audited and approved or delisted under an EV program.
3	AMS should work with plant personnel to revise the QSA/EV Manuals to include the specific products and process requirements necessary for the BEV program for Japan.		On January 24, 2006, USDA officials held a meeting at USDA headquarters in Washington, D.C., with representatives from establishments that participate in EV programs. To be completed within two weeks of the Government of Japan reviewing and accepting the report and its actions, and prior to the shipment of products to Japan, AMS will

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			conduct reviews for all EV approved establishments for each country that requires an EV program.
4	FSIS should clarify the roles and responsibilities of FSIS personnel involved at every stage of the export verification process.		On or before March 1, 2006, FSIS Directive 9000.1, Revision 1 will be issued. FSIS is revising FSIS Directive 9000.1 <i>Export Certification</i> , to clarify current Agency policy regarding the export certification process. The directive will clarify the steps to be followed in order to certify exports.
5	FSIS should expedite the development of training on export certification for Consumer Safety Inspectors (CSIs). FSIS should also incorporate a proficiency test in its training for those assigned to perform export certification.		On January 20, 2006, FSIS held a conference call with all FSIS District Managers to review established procedures and export requirements for countries with EV programs. FSIS has provided additional training for its inspection workforce in the EV programs and will continue to provide training on these actions. On Monday, January 23, 2006, FSIS conducted an interactive web-based training for responsible inspection program personnel at all EV approved establishments. All materials used in the training,

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			including PowerPoints, digital images of eligible products, scenarios, and questions and answers, along with an overview of AMS EV programs and all related references, such as revised Directives and Notices, are being formatted into FSIS' e-training system for inspection program personnel.
6	FSIS should increase supervisory oversight of the export certification process by revising the IPPS review guidance to incorporate procedures that specifically evaluate the ability of inspection personnel to perform export certifications.		On or before March 1, 2006, FSIS Field Operations will partner with the FSIS Technical Service Center to update the IPPS Supervisory guidelines to provide more detailed guidance on export duties. FSIS will also develop a version of FSIS Form 4430-8 specific to employees who perform export duties exclusively.

V. CONCLUSION

The U.S. Department of Agriculture (USDA) and its Office of Inspector General have thoroughly and carefully investigated this incident of ineligible product that was shipped to Japan.

The investigation revealed this incident was the result of a failure on the part of the exporter and USDA personnel to know which products were eligible for shipment to Japan. By agreement with the Government of Japan, no vertebral column was to be shipped. Vertebral column was shipped in 1 box labeled Hotel Rack and 2 boxes labeled Trimmed Loin. While Golden Veal, Corp. and Atlantic Veal and Lamb, Inc., were owned by the same individual, Golden Veal, Corp. was not eligible to supply offal for shipment to Japan and failed to recognize that distinction. 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 from these two establishments, we are confident in our assessment that the circumstances surrounding this ineligible shipment were unique.

As a result of these investigations, USDA has taken action to address the findings and is also incorporating further efficiencies and protections into our export system to prevent a similar incident from occurring.