

General Background Information

- In response to the Japan export investigation report, the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) issued the following documents:
- On March 1, 2006, FSIS issued FSIS Directive 9000.1 Revision 1 *Export Certification* to inspection program personnel. The document clarifies FSIS policy regarding the export certification process. Directive 9000.1 Rev. 1 provides a clear set of standards for FSIS District Offices and inspection program personnel. FSIS Directive 9000.1 Revision 1 *Export Certification* is available on the FSIS Web site at: <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/9000.1Rev1.pdf>
- On March 1, 2006, FSIS issued FSIS Directive 9040.1 Revision 3 *Re-Inspection Of Product Intended For Export* to inspection program personnel, which includes the procedures for reinspecting product that has been presented for export. These responsibilities and procedures apply whether the product is located at the establishment or off-site at a non-official establishment. This directive provides for the examination of boxes or containers in situations where inspection program personnel have a reason to question whether the product as labeled meets the importing country's requirements. FSIS Directive 9040.1 Revision 3 *Re-Inspection Of Product Intended For Export* is available on the FSIS Web site at: <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/9040.1Rev3.pdf>
- On March 1, 2006, FSIS issued FSIS Notice 09-06 *Certifying Beef Products Under Export Verification (EV) Programs* to inspection program personnel. This notice provides FSIS personnel with new instructions related to the FSIS certification process for meat products exported under EV programs. This notice announces that when FSIS personnel certify products for export produced under Export Verification (EV) programs, they are to verify, among other requirements, that the applicant provides a signed document from the Agricultural Marketing Service (AMS) confirming that each EV requirement has been met by the establishment or establishments that produced the product being presented for export. FSIS Notice 09-06 *Certifying Beef Products Under Export Verification (EV) Programs* is available on the FSIS Web site at: http://www.fsis.usda.gov/Regulations_&_Policies/Notice_09-06/index.asp

1. Overall

The incident that occurred this time is an extremely regrettable one as it violated the rule Japan and the United States agreed upon. In order to resume import procedures it is necessary to ensure that incidents like this will not be repeated. In that regard, the following issues must be addressed/clarified.

- 1) Despite the premise that compliance with Japan EV Program should have been*

ensured by appropriate functioning of each of the measures including establishment approval, FSIS inspection/verification, monitoring by establishments themselves, and FSIS export certification, why did this incident occur?

Both the FSIS investigation and the Office of the Inspector General's (OIG) audit thoroughly reviewed the incident at all stages. This incident occurred as a result of the establishment not following its approved Quality System Assessment Manual and the deviations not being detected by the FSIS inspector. The investigation revealed that 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 Agricultural Marketing Service (AMS) Export Verification (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. The investigation concluded that FSIS inspectors should be notified of all export certification changes relevant to the plants where they work. FSIS inspectors are now required to participate in the establishment certification application process.

Shouldn't problems at each stage be identified, sorted out, and verified in a recapitulating manner?

The problems have been identified and appropriate actions have been taken. The establishments involved were immediately removed from the approved list, and extensive training has been conducted with all involved FSIS personnel. AMS and FSIS also have strengthened coordination between their personnel. Eligibility of both the establishment and the products for export must be confirmed prior to FSIS certifying export documents.

On March 1, 2006, FSIS issued FSIS Directive 9000.1 Revision 1 *Export Certification* to inspection program personnel to clarify FSIS policy regarding the export certification process. This directive provides a clear set of standards for FSIS District Offices and inspection program personnel.

Also on March 1, 2006 FSIS issued FSIS Notice 09-06 *Certifying Beef Products Under Export Verification (EV) Programs* to inspection personnel. This notice provides FSIS personnel with new instructions related to the FSIS certification process for meat products exported under EV programs. This notice directs FSIS personnel certifying products for export under Export Verification (EV) programs, to verify, among other requirements, that the applicant provides a signed document from the Agricultural Marketing Service (AMS) confirming that each EV requirement has been met by the establishment or establishments that produced the product being presented for export.

All FSIS inspection program personnel assigned to an establishment with an approved Export Verification program must complete Export Verification training.

FSIS inspection program personnel are now required to pass an Export Verification Examination and to complete and submit an Export Verification Survey. Successful completion of the training will be recorded for each employee in the FSIS' training database.

2) *Was exporting of veal with vertebral column and ineligible offal a unique incident?*

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

In December 2005, FSIS headquarters held a conference call with District Managers to review 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, this is a unique situation because Atlantic Veal and Lamb, Inc. was not yet certified to export to Japan so the FSIS Deputy District Manager responsible for the plant did not participate in the conference call. Subsequently, the FSIS Deputy District Manager was not made aware when Atlantic Veal and Lamb, Inc. was approved to export product to Japan. Therefore, he did not provide the Japan EV program requirements to the district's field inspectors.

Through ongoing audits, reviews and customer feedback from numerous other nations requiring an EV program, we are confident that FSIS personnel in other approved plants are knowledgeable of the requirements, and only approved products are exported.

Were audits/accreditation and inspections at other establishments properly conducted in that there is no possibility for similar incidents occurring? Shouldn't verification be made in that regard together with the basis for such argument?

Through reviews of all audit check lists and reports, it was determined that all audits/accreditations were properly conducted, including the ones at Atlantic Veal and Lamb Inc. and Golden Veal Corp.

While preparing the veal shipment to Japan, the offending establishments did not adhere to their Quality System Assessment Manual. As a result, they have been removed from the list of approved establishments as required by the EV program.

USDA is very confident that this detection of ineligible product in a single veal shipment does not indicate weakness in the overall U.S. beef processing, inspection or export systems. Moreover, based upon the findings of the investigation, USDA has incorporated additional protections into the U.S. system to avoid repetition of this incident.

On February 13, 2006, AMS and FSIS implemented a proactive notification system to communicate establishment EV approval from AMS to FSIS. AMS now will notify FSIS when an establishment is audited and approved or delisted under an EV program. This notification process is described below:

- 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), which will then notify the FSIS District Office where the establishment is located. 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 training has been completed.
- 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.
- When an establishment is delisted, AMS immediately will notify the FSIS TSC which will notify the FSIS District Office where the establishment is located.
- The approved establishment will maintain a copy of all EV program audit reports in its records, and management will discuss the audit reports in the next weekly meeting with FSIS establishment inspection program personnel. This will be added as a requirement for EV program approved establishments. FSIS will acknowledge receipt of all audit results and reports provided by AMS.
- FSIS will conduct unannounced visits of EV approved establishments to verify that FSIS inspectors are correctly following procedures for certifying exports. These unannounced visits will begin in April 2006.
- AMS also will conduct unannounced reviews of all plants participating in EV programs. Reviews will be conducted in the plants. AMS will observe the establishment's product preparation processes and adherence to specific requirements.
- AMS will also conduct scheduled reviews of all EV approved establishments. These reviews will target each establishment's implementation of the specified product requirements (e.g., vertebral column removal) listed in the EV program. These reviews will be completed prior to the shipment of products to Japan.

These reviews supplement the ongoing bi-annual audits of approved establishment's Quality System Assessment Program. The audits are a systematic, documented process for obtaining evidence and determining that establishments are adhering to their approved Quality System Manual. These audits evaluate the establishment's

processes in place to ensure compliance with the specified product requirements.

FSIS has provided additional training for its inspectors assigned to establishments participating in the EV program and will continue to provide training.

FSIS inspection personnel are provided computer-based follow-up and supplemental training. Inspectors who rotate into any establishment that produces product that is subject to EV requirements will also undergo training. All new employees hired after March 2006 of course will receive training.

FSIS' Export Verification training reviews policies pertaining to Export Certification, Re-Inspection of Product intended for Export, and Certifying Beef Products under the EV Programs and all pertinent Export Directives.

An Export Verification Manual can be easily printed at any time by inspection personnel directly from USDA/FSIS training web site.

The training includes a mandatory examination that tests inspectors' knowledge of FSIS Export Directives and verification responsibilities associated with the Export Certification process.

All FSIS directives and notices relating to export certification are available in printed form in each plant, on the FSIS web site <http://www.fsis.usda>, on the FSIS employee intranet and on the FSIS e-mail system.

Also, FSIS inspection program personnel have access to the FSIS Export Library, which includes export requirements for meat and poultry products, export requirements for egg products, export-related notices and directives, and a listing of eligible U.S. establishments.

2. Regarding AMS

The Report points out that there were problems at Atlantic Veal and Golden Veal with their QSA programs and the employees' understanding of the requirements. The fact that these establishments were approved under such circumstances raises questions as to whether or not AMS accreditation itself of these two establishments and other Japan EV establishments was properly done. In that regard, the following issues must be addressed/clarified.

- 1) Upon each stage of accreditation process from desk audit to on-site audit, for each of the criteria necessary to be confirmed in the QSA program, what exactly was confirmed and what made the auditor determine that the program was adequate and feasible?*

The EV program requires each establishment to use internationally recognized process control standards to ensure compliance. The establishment's process is documented in a

Quality System Assessment (QSA) manual that outlines Standard Operating Procedures.

AMS has developed several additional measures that will be incorporated into the EV Program to strengthen and improve the accreditation process to ensure that all product requirements are met. AMS has conducted and provided additional training to all EV Program participants and will continue to provide periodic refresher training to them. AMS has developed additional EV Program operating procedures that will help ensure that only conforming product is produced under the program. AMS is working with FSIS to develop an enhanced coordinated audit program that will focus on:

- The implementation of the QSA Program by EV Program participants.
- The production practices of the EV Program participants.
- Ensuring that USDA officials are providing the necessary program oversight to ensure that product that is shipped under the EV Program conforms to the program requirements.

For the past two months, USDA has taken great strides to raise awareness of the EV Program requirements to all those participating in the program. The latest incident that resulted in the closure of the market has underscored the need to ensure that the utmost care and due diligence is exercised and that all program requirements are strictly followed.

The Evaluation results of Golden Veal and Atlantic Veal should be shown.

AMS provided the audit reports to OIG and FSIS during the investigation. And, AMS included the audit reports in the package of Atlantic report materials provided to Japan on February 17, 2006.

2) What level of understanding and experience did the AMS official(s) who audited Golden Veal and Atlantic Veal, for desk audit and on-site audit, have regarding accreditation of QSA programs?

The Program Manager has been with the USDA over nine years and in the current position for more than 2 ½ years. The Program Manager is a fully trained Quality System Auditor who passed the ISO 9001:2000 and ISO 14001:2000 Lead auditors training class. The Program Manager has reviewed hundreds of QSA/EV programs and is very knowledgeable of all requirements of the EV Program for Japan and other countries. The Program Manager has also conducted onsite QSA audits, and accompanied auditors on other program audits. In the initial review of the documentation, each requirement was discussed in detail with a representative of these companies.

The AMS auditor that reviewed Golden Veal's activities pertaining to the Japan EV Program has over 25 years of experience with the USDA including more than 10

years as a Quality System Auditor. The auditor has attained the level of Certified Quality Auditor and has conducted numerous audits for the QSA/EV program.

The AMS auditor that conducted the audit at Atlantic Veal and Lamb has more than 20 years of experience working as a Veterinary Food Inspection Non-Commissioned Officer for the U.S. Army. The auditor also spent 13 years as a Supervisory Consumer Safety Officer for the National Marine Fisheries. He audited processing operations in domestic and foreign facilities to assess risks associated with the product, processes and compliance with U.S. requirements. The auditor has served for two years as a Quality System auditor for the USDA AMS and has conducted numerous QSA/EV audits. The auditor has attained the title of ISO 9001:2000 Lead Auditor.

Did they have sufficient understanding as to the requirements each of the establishments must meet in each QSA program when slaughter and fabrication are done separately at each plant?

Yes. The desk audit was performed by the USDA Program Manager in consultation with the Branch Chief and Branch Quality Manager. The AMS officials who conducted the desk and on-site audits had complete understanding of the requirements that both establishments were obligated to meet under the EV program. The auditor's checklist for each establishment demonstrates that they were knowledgeable in the auditing process for establishments that both slaughter and fabricate beef and veal carcasses.

3) Atlantic Veal and Golden Veal officially submitted applications on December 15 and desk audit took place on January 4, on-site audit and accreditation on January 6. This appears to be an extremely short accreditation time frame. This raises questions as to whether or not adequate evaluation based on set procedures was made upon desk audit and on-site audit. Especially, was appropriate evaluation made with regard to employee education at Golden Veal and Atlantic Veal?

Atlantic and Golden Veal began developing their QSA manuals in November of 2005 and subsequently submitted the QSA manuals to the USDA Audit Review and Compliance (ARE) program manager on December 15, 2005. Before the desk audit, there were numerous communications between the establishment representatives and the ARC program manager in order to enhance the QSA manuals. During the development of the QSA manuals, the establishments began implementing the process control systems described in the QSA manuals. Following the desk audit conducted on January 4th, the auditor deemed the QSA manuals sufficient and informed the ARC program manager. Subsequently, the onsite auditors were notified of pending audits and made preparations to conduct the audits.

The onsite audits were conducted on January 6th. Audit documentation confirms the thoroughness of the evaluation. The responsible company personnel at both establishments were knowledgeable of the requirements. Their knowledge was

evaluated through detailed questioning and observations. Following the submission of favorable audit reports, the establishment became eligible on the day the audits were completed (January 6, 2006), as the establishments had to be working under the procedures in the QSA manuals in order to be audited against the manuals. The failure by company personnel to apply the demonstrated knowledge in this instance led to their removal from the list of approved establishments.

4) Considering the above, weren't there any problems with AMS audit/accreditation that approved the QSA programs of these establishments that eventually did not function?

No. The establishments' QSA manuals correctly addressed the requirements and the in-plant audit confirmed that responsible company personnel were trained and knowledgeable. Because the establishments failed to comply with their documented processes, they were removed from the list of approved establishments.

3. Re: Establishments

As to the work process at Golden Veal and Atlantic Veal that allowed ineligible veal with vertebral column and offal to pass for exports, the Report points out that there were problems at both plants with work procedures including identification upon shipping. It is necessary to verify the cause further. In addition, in order to confirm that these problems do not occur at other EV establishments, the following issues must be addressed/clarified.

1) Who was responsible for ensuring compliance with EV program at Golden Veal and Atlantic Veal?

For Golden Veal, employees in the following positions were responsible for carrying out the documented procedures of the QSA manual: General Manager, Quality Assurance Manager, Slaughter Manager, Fabrication Manager, and Shipping/Receiving Manager. For Atlantic Veal, the General Manager, Quality Assurance Manager, Fabrication Manager, and Shipping/Receiving Manager were the personnel responsible.

Why didn't (s)he fulfill that responsibility?

It is clear that they failed to comply with their responsibilities as outlined in their QSA Manual. However, we have been unable to obtain additional information on why this occurred. We would expect to learn more information following completion of the pending OIG investigation.

2) What specific education program was implemented regarding the difference in requirements in veal for BEV export markets, specifically Japan (i.e. SRM removal and age limit) as opposed to U.S. domestic market?

The additional requirements applicable to the EV Program for Japan were clearly identified in the establishments' QSA Quality Manual. The manual outlines the topics covered by the establishment to train the employees for the EV Program for Japan, including all materials that are included in the specified product requirements for Japan. Responsible personnel in both plants were confirmed to be knowledgeable of the requirements. For example, in addition to the non-complying "Veal Hotel Rack, 7 Ribs" (with vertebral column attached), Atlantic Veal and Lamb, Inc. also shipped the complying product "Veal Hotel Rack, Chop-Ready, 7 Ribs" (with vertebral column removed). This example clearly demonstrates the establishment personnel knew how to properly remove the vertebral column from the Veal Hotel Rack.

3) *It appears that the personnel at the establishments considered that veal was eligible under Japan EV program even if vertebral column was not removed and offal from calves was not segregated. If that was the case, why did they think so?*

As demonstrated by their QSA Quality Manual and their responses during the in-plant audit, company personnel and management were fully aware of the requirement to remove the vertebral column and segregate offal.

4. *Re: FSIS*

The Report points out that one of the problems was that the FSIS inspector determined the veal with vertebral column and offal as "Japan EV compliant" at the final checking stage. This raises the question of FSIS inspection regime itself as being inadequate. In this regard, the following issues must be addressed/clarified.

1) *How is the education/training of FSIS inspectors set up with regard to Japan EV program?*

The investigation revealed that 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 to export to Japan under the AMS EV program.

In response to this incident and the findings of the investigation, the USDA took the following steps:

- AMS will not approve an establishment for an EV program until FSIS notifies AMS that all inspection program personnel assigned to that establishment have successfully completed the Export Verification Training, which now includes passing an examination.
- FSIS has provided additional training for its inspection workforce assigned to establishments participating in the EV program and will continue to provide periodic training.

FSIS inspection personnel are provided computer-based follow-up training. Employees rotating into an assignment that includes any EV certified establishment are required to undergo training. And, all new employees, hired after March 2006, will complete the EV training program.

An Export Verification Manual can be easily printed at any time by inspection personnel directly from USDA/FSIS training web site.

The training includes a mandatory examination that tests inspectors' knowledge of FSIS Export Directives and verification responsibilities associated with the Export Certification process.

All FSIS directives and notices relating to export certification are available in printed form in each plant, on the FSIS web site <http://www.fsis.usda>, on the FSIS employee intranet and on the FSIS e-mail system.

Also, FSIS inspection program personnel have access to the FSIS Export Library, which includes export requirements for meat and poultry products, export requirements for egg products, export-related notices and directives, and a listing of eligible U.S. establishments.

Is it any different from that for other countries' EV programs like Canada?

The Export Verification Training addresses verification procedures for all EV programs. The training emphasizes the need to verify that each product is eligible for export to the specific importing country. For example, the training contains digital images showing examples of product ineligible for export to Japan.

FSIS is providing the same robust training for all inspection program personnel assigned to establishments participating in any EV program. This complements the FSIS Export Library which includes export requirements for meat and poultry products, export requirements for egg products, export related notices and directives, and a list of eligible U.S. establishments.

Additionally, an FSIS internal web site will contain a list of the specific products approved for export to each country participating in EV programs. FSIS inspection program personnel trained in the EV program will have access to this information.

All FSIS inspection program personnel currently assigned to an establishment with an approved EV program must successfully complete the on-line training course by March 21, 2006.

What kind of education/training program did the inspectors involved in this incident participate in?

Prior to the incident, inspection personnel were trained through an export certification

directive (FSIS Directive 9000.1) which explains current FSIS policy regarding the export certification process. This directive communicates 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.

Paper copies of FSIS Directive 9000.1 are available in each FSIS office within an establishment and FSIS employees have access to this directive electronically on the FSIS web site <http://www.fsis.usda.gov> and the FSIS employee intranet.

Prior to January 20, no additional actions were taken to ensure that FSIS field staff understood their responsibilities for signing and certifying export certificates for Japan.

In December 2005, FSIS headquarters held a conference call with District Managers to review the requirements for export to Japan. In addition, a series of e-mail messages were sent to all District Managers again emphasizing the need to ensure compliance. However, the investigation revealed that the FSIS Deputy District Manager responsible for Atlantic Veal and Lamb, Inc. did not participate in the conference call because, at that time, none of the plants in the district were approved to export to Japan. Subsequently, the FSIS Deputy District Manager was not made aware when Atlantic was approved to export product to Japan. Therefore, he saw no need to communicate the Japan EV program requirements to the district's field inspectors if no plants were approved to ship to Japan.

Since January 20, FSIS has taken positive actions to ensure that personnel are well informed and knowledgeable of all requirements.

- On January 23, 2006, FSIS conducted interactive web-based training with inspection personnel assigned to all EV approved establishments to reaffirm requirements relative to the EV program.
- FSIS has provided additional training for its inspection personnel assigned to establishments participating in the EV programs and will continue to provide periodic training.
- In addition, all EV program requirements are available on the FSIS Export Library.

2) *Education/training is supposed to be done via information posted on the website. How is it set up to thoroughly inform FSIS inspectors?*

On March 1, 2006, all materials used in the Export Verification Training, including PowerPoint presentations, digital images of ineligible products, scenarios, an overview of AMS EV programs, and all related directives and notices, were compiled into a computer-based training program for FSIS inspection personnel. All FSIS inspection personnel assigned to EV certified establishments are this training. All FSIS inspection program personnel currently assigned to an establishment with an approved EV program must successfully complete the on-line training course by

March 21, 2006. New employees and employees who rotate into an assignment that includes any EV certified establishment are also provided computer-based training.

Specifically, how was confirmation made as to whether the inspectors read the information on the website and whether they have learned the requirements?

FSIS inspection program personnel, at the time of the incident, had available extensive directives and training materials and were responsible for understanding their duties and obligations in signing and certifying export certificates. Paper copies of FSIS Directive 9000.1 are available in each FSIS office within an establishment and FSIS employees have access to this directive electronically on the FSIS web site <http://www.fsis.usda.gov> and the FSIS employee intranet. In addition, all EV program requirements are available on the FSIS Export Library.

Since January 20, FSIS has implemented additional measures necessary to strengthen its controls and processes for ensuring compliance with the EV program for Japan.

- On January 23, 2006, FSIS conducted interactive web-based training with inspection program personnel assigned to all EV approved establishments to review and reaffirm requirements relative to the EV program. All FSIS inspection program personnel assigned to EV approved establishments were required to certify their participation.
- FSIS has provided additional training for its inspection program personnel assigned to establishments participating in the EV programs and will continue to provide periodic training.
- On March 1, 2006, all materials used in the Export Verification Training, including Power Points, digital images of ineligible products, scenarios, and questions and answers, along with an overview of AMS EV programs and all related references, such as revised directives and notices, were compiled into a comprehensive computer-based training program. All FSIS inspection program personnel assigned to an establishment with an approved EV program are required to successfully complete the on-line Export Verification Training by March 21, 2006. Employees also must complete periodic follow-up training. Employees who rotate into an assignment that includes any establishment that produces product that is subject to EV requirements also must complete training. And, new employees hired after March 2006 also must be trained.
- To successfully complete the Export Verification Training, inspection program personnel must pass the Export Verification Examination and submit the Export Verification Survey. Successful completion of the training will be recorded for each employee in the Agency's training database.

3) *What inspection, verification and certification did the inspector stationed at*

Golden Veal implement in relation to Japan EV program? What was his understanding of the eligibility/ineligibility of offal exports and vertebral column removal?

The FSIS inspector assigned to Golden Veal, Corp. was responsible for ensuring that the veal and offal products were safe, wholesome and accurately labeled for shipment to Atlantic Veal and Lamb, Inc. as evidenced by the mark or inspection. This inspector ensured that all food safety requirements were met to ship the product to Atlantic Veal and Lamb, Inc. This inspector was not responsible for certifying the shipment as eligible for Japan.

The personnel of Golden Veal had the responsibility under their QSA program quality manual to ship products for fabrication with a “shipping declaration”. This shipping declaration that accompanied the product to Atlantic Veal stated that the “product meets EV Program requirements for Japan”.

4) How was notification system set up for communicating establishment accreditation from AMS to FSIS?

The AMS website identifies the establishments approved for the Japan EV program, along with company name, type of operation and the date of approval. Access to this website and other pertinent information were provided to FSIS inspection personnel through the FSIS Export Library. The Export Library Web site is: www.fsis.usda.gov/Regulations_&_Policies/Export_Information/index.asp

On February 13, 2006, AMS and FSIS implemented a proactive notification system to communicate EV approval from AMS to FSIS.

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

- 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), which will then notify the FSIS District Office where the establishment is located. FSIS will train the establishment inspection personnel on the requirements of the pending export certification. FSIS will ensure that training of the inspection personnel is completed within five (5) business days of the AMS notification.
- 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.
- When an establishment is delisted, AMS immediately will notify the FSIS

TSC which will notify the FSIS District Office where the establishment is located.

- 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 inspection personnel. This will be added as a requirement for EV program approved establishments. FSIS will acknowledge receipt of all audit results and reports provided by AMS.

As for each of the other 38 establishments how did the FSIS inspectors learn that the establishment where they are stationed had received accreditation?

The information was provided through the FSIS Export Library. This notification was made more proactive on February 13, 2006. AMS now more directly notifies FSIS when an establishment receives approval.

Was there any possibility that a similar problem (to what happened at Golden Veal and Atlantic Veal) might have happened at the other establishments?

No. Through ongoing audits, reviews and customer feedback from numerous other nations participating in EV programs, we are confident that other establishments only exported approved products and FSIS personnel in the other approved plants were knowledgeable of the requirements. The other establishments were accustomed to exporting product to countries that participate in an EV Program.

5) In principle, even if the program failed to function due to lack of understanding on the part of the establishment, wasn't the FSIS inspector supposed to conduct confirmatory inspection to prevent EV-ineligible products from getting exported?

The FSIS inspection program personnel conducted re-inspection. However, the investigation revealed this incident was the result of inadequate familiarity on the part of the exporter and the USDA inspector with the specific products that were and were not eligible for shipment to Japan.

Under U.S. law, no meat product can move in either interstate or foreign commerce unless it has been inspected by FSIS and found to not be adulterated. At the time of export, the sanitary condition of the product is verified by an FSIS official prior to signing the export certificate. The products involved in this incident were verified as safe, wholesome, and not adulterated as evidenced by the USDA mark of inspection. FSIS Directive 9000.1 "Export Certification" provides inspection personnel the authority to perform reinspection at any time determined necessary. On a random basis, boxes are opened and reinspected to ensure that product has been properly handled and labeled. Although the products were safe, wholesome, and not adulterated, they did not meet the country specifications for Japan.

On March 1, 2006, FSIS issued FSIS Directive 9000.1 Revision 1 *Export Certification* which provides a clear set of standards for FSIS District Offices and inspection program personnel.

5. Re: Corrective Actions to Prevent Recurrence

The Report lays out various corrective actions to prevent recurrence of non-compliance. In light of the cause of the incident that occurred, it is necessary for appropriate corrective measures to be implemented so that the rules bilaterally agreed upon will be followed. In this regard, the following issues must be addressed/clarified.

1) AMS is to re-inspect all of the EV-accredited establishments within two weeks following GOJ's acceptance of the corrective measures by the United States. What is the specific content of this re-inspection, and what is the expected effect?

These re-inspections will focus on the establishment's adherence to the specific product requirements in the EV Program. For example, requirements such as the removal of the spinal cord and the removal of the vertebral column will be observed and evaluated. This will confirm adherence to the specified product requirements and require corrective action when appropriate.

2) Please provide information as to the specific method for the unannounced on-site audit AMS is to implement from April?

Following the resumption of production for Japan, AMS will randomly select establishments for unannounced reviews. The frequency will depend on past observations and export production levels.

3) Please provide information as to the specific method for signing off on the export certificate where an AMS official is to provide secondary signature as a measure for FSIS and AMS to collaborate/coordinate. AMS will review all Export Certificates before they are presented to the FSIS inspector signature.

When FSIS inspection program personnel certify products for export produced under Export Verification (EV) programs, they are to verify, among other requirements, that the applicant provides a signed document from AMS confirming that each EV requirement has been met by the establishment or establishments that produced the product being presented for export.

After determining that the establishment is eligible to export to the destination country, and that the specific products are eligible to be exported to that country, the inspection program employee will then re-inspect the product as set out in FSIS Directives 9000.1, Revision 1, and 9040.1, Revision 3.

Beginning on April 1, 2006, as part of its EV-approved program, the establishment, before it can forward the export certificate to an FSIS certifying official for signature, must receive a letter from AMS confirming that the EV program requirements have been met and the products are eligible for export.

When AMS signs the letter, they will forward a copy to the establishment. The FSIS Technical Service Center (TSC) will receive an electronic copy. The TSC will acknowledge receipt of the letter.

When signing an export certificate, an FSIS certifying official should receive the following from an establishment: 1) the original FSIS Form 9060-5, Meat and Poultry Export Certificate of Wholesomeness; 2) any other certificates required by the importing country; and 3) a copy of the letter from AMS that confirms that AMS conducted a review and that AMS has determined the items listed are approved for export to the country listed on the certificate and from the facilities listed.

When an FSIS certifying official receives documentation, he or she is to verify that the documents are complete and accurate and that the AMS letter confirms that EV program requirements were met.

If all documents are acceptable, FSIS certifying official will sign all certifications and maintain a copy of the AMS letter in the government file along with the certifications.

4) Please provide information as to the specific method for planned education/training targeting FSIS inspectors on export certification, the specifics of the improvement in the system to evaluate the proficiency of inspectors, and the specific method for unannounced evaluation of inspectors' inspection. Particularly, what are the strengthened points compared to the education/training programs thus far implemented?

On March 1, 2006, all materials used in the Export Verification Training, including PowerPoint presentations, digital images of ineligible products, scenarios, an overview of AMS EV programs, and all related directives and notices, were compiled into a computer-based training program for FSIS inspection personnel. All FSIS inspection personnel assigned to EV certified establishments are this training. All FSIS Inspection Program Personnel currently assigned to an establishment with an approved EV program must successfully complete the on-line training course by March 21, 2006. New employees and employees who rotate into an assignment that includes any EV certified establishment are also provided computer-based training.

FSIS has strengthened its Export Verification Training by now requiring inspection program personnel to pass a mandatory examination. To successfully complete the course, personnel must pass the Export Verification Examination and submit the Export Verification Survey. Successful completion of the training will be recorded for each employee in the Agency's training database.

All FSIS directives and notices relating to export certification are available as paper copies in each FSIS office within an establishment, on the FSIS web site <http://www.fsis.usda>, on the FSIS employee intranet and on the FSIS e-mail system.

Also, FSIS inspection program personnel have access to the FSIS Export Library, which includes export requirements for meat and poultry products, export requirements for egg products, export related notices and directives, and a list of eligible U.S. establishments.

To continue ensuring a high level of integrity, security and accuracy with the export certification process, FSIS will conduct audits of inspection program personnel and exporting establishments to determine that: 1) the requirements of the AMS Export Verification (EV) Program are understood and carried out and 2) establishments and the products being certified for export adhere to the applicable EV Program requirements and standards.

Audit teams will identify all FSIS export certification regulations, policies and guidelines. They will also identify EV Program requirements and AMS methods for approving establishments for the EV Program. AMS audit reports and any complaints by approved EV Program establishments or countries will be reviewed.

Audit teams will use audit worksheets that include all export certification procedures and requirements in a step-by-step question format to determine whether FSIS inspection program personnel understand and consistently verify compliance with the regulations. In addition to the worksheets, auditors will examine specific records. The worksheets will allow for additional explanation and supporting documentation to be obtained to determine final findings and recommendations.

6. Other Issues

- 1) *It is reported that the OIG's investigation section is investigating the situation that allowed this incident to occur and that the results of this investigation will be reported in a separate document. What are the purpose and the content of this investigation, and what is its relation to the Report this time? When will it be published?*

OIG Response:

OIG's Office of Investigations is conducting an investigation into allegations that arose pertaining to acts or omissions by private, non-governmental entities involved in the incident. The investigation does not involve U.S. government personnel at this time. OIG's investigation will include conducting interviews and compiling and assessing relevant information, as necessary. The investigation is a separate initiative and it should not impact the USDA report and the independent audit that OIG previously conducted. An estimated date for completion of this investigation is not currently available. When

completed, OIG's investigative findings will be provided to the appropriate government officials for consideration as to any actions warranted.

This is not to be confused with the audit that was done by the OIG's Audit Office and has been released in its entirety to the GOJ. The OIG audit concluded that AMS and FSIS could strengthen their controls over the BEV program by improving processes used to communicate BEV requirements, clearly define roles and responsibilities, and implement additional oversight. The OIG recommended six actions to be taken by the USDA to correct the circumstances that allowed this to happen.

USDA Additional Response:

Three points of clarification will help in understanding the OIG response (above):

- The investigation is focusing on private, non-governmental personnel rather than U.S. Government personnel. U.S. Governmental personnel are conducting the investigation.
- A definitive timeline cannot be predicted for an investigation that the U.S. Government wants to be very thorough and complete. Each question asked may produce an answer that creates more questions and naturally extends the length of time needed for the investigation. It is important that all contributing factors are discovered and evaluated and are part of the conclusion that will be reached and shared with the appropriate authorities.
- This investigation is not to be confused with the audit that was done by the OIG's Audit Office and has already been released in its entirety to the Japanese Government. The OIG audit looked at U.S. Government personnel and agency actions and came to the conclusion that there were circumstances surrounding the shipment that were the result of human error but were not the result of criminal intent on the part of US government personnel, and recommended six actions to be taken by the USDA to correct the circumstances that allowed this incident to happen.

2) *There is mention in the Report to the effect that Japan notified the United States shortly before trade resumption that veal was required to be added as part of the EV program. It is suggested that revision of this mention be considered as it is not factual. EV program targets cattle at or younger than 20 months from its conception, which has always included veal.*

Correct. The EV program was inclusive of all cattle 20 months of age and younger – which would include veal. The U.S. discussed the development of an alternative program for veal, but discussions with the Government of Japan were still underway when trade was suspended on January 20, 2006.