



United States
Department of
Agriculture

Food Safety
and Inspection
Service

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FROM: Lloyd C. Day
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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

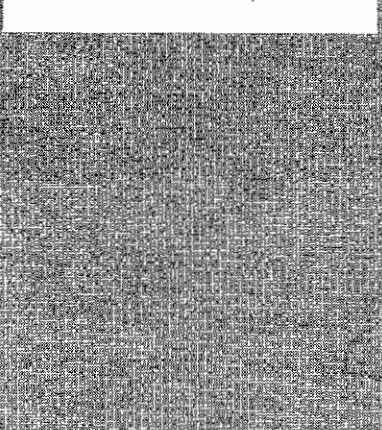

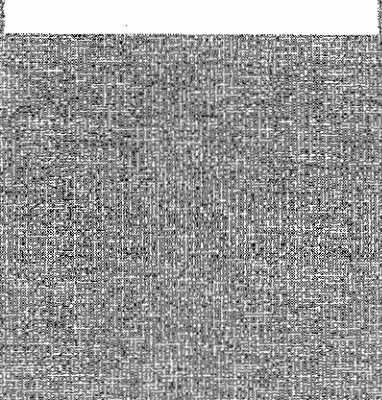
FSIS should increase supervisory oversight of the export certification process by revising the IPPS review guidance to incorporate procedures that specifically evaluate the ability of inspection personnel to perform export certifications.

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.