



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



February 16, 2006

TO: Mike Johanns
Secretary of Agriculture

THROUGH: Phyllis K. Fong /s/
Inspector General

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

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)