Audit Entrance Conference

Spain

September 16, 2015

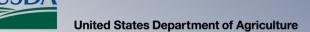United States Department of Agriculture

Food Safety and Inspection Service

Entrance Meeting Overview

- Audit Objective
- Audit Standards
- Audit History
- Audit Scope

- Audit Procedures
- Auditor Security
- Conflict of Interest
- FSIS Initiatives

Audit Objective

- This is a routine ongoing equivalence verification audit.

- The objective of the audit is to verify that Spain's food safety system governing meat inspection is functioning in the manner determined as equivalent to that of the United States, producing products which are safe, unadulterated, and properly labeled.

Audit Objective
Spain's Current Status

- Spain is eligible to export pork products to the United States.

 - APHIS has declared Spain as:

- Controlled Risk for Bovine Spongiform Encephalopathy (BSE).

- Free of Foot-and-Mouth Disease (FMD) and Rinderpest, with special restrictions.

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Audit Standards

■ Determinations concerning program effectiveness focused on performance within the following six equivalence components:

1. Government Oversight
2. Statutory Authority & Food-Safety Regulations
3. Sanitation
4. HACCP Systems
5. Chemical Residues
6. Microbiological Testing Programs

Audit History

The two most recent FSIS audits of Spain's meat inspection system were conducted in:

- April 17 – May 3, 2012
- January 7 – February 3, 2010

Audit History

Government Oversight: Core Requirements

- The inspection system must be organized and administered by the national government of the foreign country and must provide standards equivalent to the inspection system in the United States:

  - The Central Competent Authority (CCA) has the organizational structure and staffing to ensure uniform implementation of U.S. requirements.

  - The CCA has ultimate control and supervision over official activities of all employees and certified establishments.

  - The CCA ensures the assignment of competent qualified inspectors.

  - The CCA has the authority and the responsibility to enforce U.S. requirements.

  - The CCA has adequate administrative and technical support to operate the inspection system.

Audit History

Statutory Authority & Food-Safety Regulations: Core Requirements

- **The inspection system must provide for:**
  - Humane handling and slaughter of livestock
  - Ante-mortem inspection of animals or birds
  - Post-mortem inspection of carcasses and parts
  - Controls over condemned materials
  - Controls over establishment construction, facilities, and equipment
  - Daily inspection
  - Periodic supervisory visits to official establishments

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Audit History
Sanitation: Core Requirements

- The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures.

Audit History
HACCP Systems: Core Requirements

■ The inspection system must require that each official establishment develop, implement and maintain a HACCP plan.

Audit History
Chemical Residues: Core Requirements

- The inspection system must have a chemical residue control program, organized and administered by the national government, which includes random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

Audit History
CCA Microbiological Testing Programs: Core Requirements

■ The system must implement certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

Audit Scope

- FSIS used a risk-based procedure to determine the audit scope which included:

  - An analysis of country performance within six equivalence components

  - Production types and volumes

  - Frequency of prior audit-related site visits

  - Port-of-entry (POE) testing results

  - Specific oversight activities of government offices and testing capacities of laboratories

- The review process included data collected by FSIS over a three year timeframe, in addition to information obtained directly from the Central Competent Authority (CCA) through use of the self-reporting tool (SRT). (PHIS)

Audit Procedures
Establishment Visits

- FSIS relies upon the CCA to certify that each establishment meets FSIS standards.

- Particular attention will be paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

Audit Procedures
Establishment Visits

- The auditor will meet with the inspection officials after each establishment audit to review the findings and discuss:

  - The effectiveness of industry controls

  - The design of the inspection program's ability to identify and resolve non-compliances

  - The need for further corrective actions and corresponding timeframes proposed by the CCA

  - The need for any elevated enforcement action

Audit Procedures
Establishment Visits

- In some cases, the results will be discussed with FSIS officials, and CCA officials will be promptly advised of any resulting decisions.

- Notice of additional enforcement decisions may occur during the exit conference or after the auditor returns to the U.S.

Audit Procedures
Immediate Delistment

- If an establishment is delisted during an audit, the establishment may not be re-certified until the CCA has verified that all corrective actions have been taken.

- The CCA is to verify that corrective actions were taken, and provide FSIS with a description of the verification methodology utilized and its results.

Audit Procedures
Reporting

- Audit findings will be analyzed by FSIS upon the auditors return to the U.S.

- Results will be summarized on the foreign inspection system, within the six equivalence components.

Audit Procedures
Reporting

- FSIS will deliver a draft final audit report for your comments.

- Comments on the draft final audit report should be submitted within 60 days from the receipt.

- The final report will be posted on the FSIS web site:

  http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

Auditor Security

■ In order to ensure auditor security, FSIS requests that any significant safety concerns be identified prior to the auditors conducting their onsite visits.

Conflict of Interest

- Federal law prohibits FSIS personnel from accepting anything of value from any establishment or inspection personnel, with the exception of transportation to and from the individual audits, and such things as coffee and snacks.

- FSIS auditors must pay his or her fair share of any activities.

FSIS Initiatives

Food Defense Outreach (presentation will follow).

Security Guidelines for Food Processors are

available on the FSIS Website at:

http://www.fsis.usda.gov/wps/wcm/connect/457116c6-dccb-494a-a419-62d07d4123a4/PHVv2Homeland_Food_Security-Security_Guide.pdf?MOD=AJPERES

Security Guidelines for Transportation and

Distribution are available on the FSIS Website at:

http://www.fsis.usda.gov/wps/wcm/connect/4179ac1a-bfe1-4d5e-953e-4db64b179dc2/PHVv3-Homeland_Food_Security_Transportion_guide.pdf?MOD=AJPERES