



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

MAR 09 2011

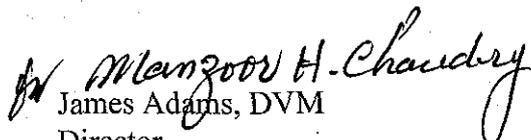
Dr. Jose Heriberto Amador Salinas  
General Director  
Servicio Nacional de Sanidad Agropecuaria (SENASA)  
Secretaría de Agricultura y Ganadería (SAG)  
Ave. La FAO, Boulevard Miraflores  
Contiguo a INJUPEM  
Edificio SENASA, 3er Piso  
Tegucigalpa, M.D.C.  
Honduras

Dear Dr. Amador:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Honduras' meat inspection system March 2 to March 23, 2010. Comments received from the government of Honduras have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at [james.adams5@fsis.usda.gov](mailto:james.adams5@fsis.usda.gov).

Sincerely,

  
James Adams, DVM

Director  
International Audit Staff  
Office of International Affairs

Enclosure

CC:

Robert Hoff, Counselor, US Embassy, Guatemala City  
Ana Gomez, Agricultural Specialist, US Embassy, Tegucigalpa  
Luis Sauzo, Minister, Embassy of Honduras, Washington, DC  
OSTA/FAS  
Hugh J. Maginnis, FAS Area Director  
Cecilia Choi, State Department  
Alfred Almanza, Administrator, FSIS  
Ronald Jones, Assistant Administrator, OIA  
Steve McDermott, Sr. Director, OIA  
James Adams, Director, IAS, OIA  
Andreas Keller, Director, IES, OIA  
Rick Harries, Director, EPS, OIA  
Jerry Elliott, Director, IID, OIA  
Lisa Wallenda Picard, OA  
David Smith, IES, OIA  
Dan Engeljohn, Assistant Administrator, OPPD  
Mary Stanley, Director, IPD, OPPD  
John K. Greifer, APHIS  
Yolande Mitchell, IES  
Country File

MAR 09 2011

FINAL REPORT OF AN AUDIT CONDUCTED IN

HONDURAS

MARCH 2 THROUGH 23, 2010

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
THE PRODUCTION OF MEAT PRODUCTS INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA

---

Food Safety and Inspection Service  
United States Department of Agriculture

## *Executive Summary*

This report describes the outcome of an on-site audit of Honduras meat inspection system conducted by the Food Safety and Inspection Service (FSIS) from March 2 through 23, 2010.

This was a routine ongoing equivalence verification audit with special emphasis on Central Competent Authority (CCA) controls that address the contamination of raw meat products by *E. coli* O157:H7 in response to United States Port-of-Entry (POE) violations since the last audit conducted in April 2008. The audit objective was to ensure that Honduras continued to maintain a food safety system for meat products that was equivalent to the U.S., with the outcome to produce products that are safe, unadulterated, and properly labeled. Between January 1 and December 31, 2009, Honduras exported 3,548,961 pounds of raw beef products to the United States.

Honduras is eligible to export raw and processed beef to the United States. All exported beef products were raw not ground (03C). At the time of the audit, one establishment was eligible to export to the U.S. This establishment received two POE violation notices for *E. coli* O157:H7, March 2 and 27, 2010. On March 29, 2010, FSIS delisted the establishment making them ineligible to export to the U.S. for multiple POE violations of *E. coli* O157:H7. The establishment was relisted on August 31, 2010, once FSIS received and reviewed corrective actions implemented by the CCA.

Although the CCA maintains the legal authority and the responsibility to enforce all applicable laws and regulations governing Honduras and third country requirements, the auditor found that these requirements were not adequately enforced.

The audit findings were significant and raised concerns regarding the CCA's ability to provide sufficient oversight within its system. Principal areas of weakness for Government Oversight of inspection/enforcement included:

- Inspection personnel were conducting final rail inspection of the carcasses and Hazard Analysis and Critical Control Point (HACCP) verification procedures for "zero tolerance" (control of fecal material, ingesta, and milk) after the final carcass wash. Honduras was not implementing their standards, which would include final rail inspection activities to be conducted prior to the carcass wash. Verification activities for the control of fecal material, ingesta, and milk need to be conducted after the final inspection but before final wash,
- Failure to adequately implement required post-mortem inspection procedures,
- Inability of inspection personnel to correctly implement HACCP verification procedures,
- Failure to identify these non-compliances when periodic supervisory reviews of establishment and inspection personnel were conducted.

The deficiencies identified above were address by the CCA through immediate corrective actions that were implemented and their committed response to the FSIS auditor on further corrective actions.

## TABLE OF CONTENTS

1. INTRODUCTION
2. BACKGROUND
3. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY
4. LEGAL BASIS FOR THE AUDIT
5. GOVERNMENT OVERSIGHT
6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS
7. SANITATION
8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM
9. CHEMICAL RESIDUE CONTROL PROGRAMS
10. CCA MICROBIOLOGICAL TESTING PROGRAMS
11. EXIT MEETING
12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS
13. ATTACHMENTS TO THE AUDIT REPORT

## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority
CIS	Sanitary Inspection Control
CVO	Chief Veterinary Officer
DAC	Corrective Actions Demand
<i>E. coli</i>	Generic <i>Escherichia coli</i>
FIMEC	Format of Inspection of Slaughter Houses and Processing of Meat
FSD	Food Safety Division
FSIS	Food Safety and Inspection Service
GMP	Good Manufacturing Practices
LANAR	<i>Laboratorio Nacional de Analisis de Residuos</i> , National Laboratory of Residue Analysis
OAI	Official Auxiliary Inspector
OVI	Official Veterinary Inspector
OVS	Official Veterinary Supervisor
POE	Ports of Entry
PR/HACCP	Pathogen Reduction/ Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SAG	<i>Secretaria de Agricultura y Ganaderia</i> , or Department of Agriculture and Livestock
SENASA	<i>Servicio Nacional de Sanidad Agropecuaria</i> or Nacional Service of Plant and Animal Health
SPS	Sanitation Performance Standards
SRM	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures

## 1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an audit of Honduras meat food safety system from March 2 through 23, 2010.

The audit began with an entrance meeting held on March 2, 2010, in Tegucigalpa with the participation of representatives from the Central Competent Authority (CCA) the, Department of Agriculture and Livestock (*Secretaria de Agricultura y Ganaderia*), SAG - National Plant and Animal Health Service (SENASA) Food Safety Division (FSD) and one auditor from the FSIS.

## 2. BACKGROUND

Honduras is eligible to export raw and processed red meat products to the United States. Between January 1 and December 31, 2009, Honduras exported 3,548,961 pounds of raw beef products to the United States, of which 3,291,116 pounds were re-inspected at U.S. Ports of Entry (POE). A total of 126,240 pounds were rejected at POE, of which 84,000 pounds were rejected because of microbiological verification sample failures for *E. coli* O157:H7 in ground beef. Consequently, this led to the delistment of one of Honduras' two establishments on December 22, 2009. All exported beef products are raw not ground (03C).

The Honduran food safety system was previously audited by FSIS in April 2008. The findings of that audit resulted in no restrictions of the ability of any eligible establishments to export meat products to the United States. This routine audit identified non-compliances in the following risk areas:

- *Government Oversight*: Lack in enforcement of some aspects of FSIS regulatory requirements were reported in one of two establishments, indicating a lack of inspection system control.
- *Sanitation Controls*: Failure to implement and verify sanitation programs within the system.
- *Slaughter/Processing Controls*: Failure to verify basic Hazard Analysis and Critical Control Point Systems (HACCP) regulatory requirements, including improper hazard analysis and description of Critical Control Points (CCP).

*Microbiology Laboratory Audits*: FSISMLG 5.03 method was used for the detection of *E. coli* O157:H7 instead of FSISMLG 5.04 and Check samples, were not signed by the supervisory microbiologist.

FSIS final *audit reports for Honduras' Food Safety System* are available on the FSIS' website at: [http://www.fsis.usda.gov/Regulations & Policies/Foreign Audit Reports/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/Foreign%20Audit%20Reports/index.asp)

## 3. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit with special emphasis on CCA controls addressing the contamination of raw meat products by *E. coli* O157:H7. The audit objective was to ensure that Honduras' food safety system governing meat maintain equivalence

to that of the United States, with the outcome to produce safe, unadulterated, and properly labeled products.

In pursuit of this objective, FSIS applied a risk-based procedure to determine the audit scope, which involved an analysis of country performance within six equivalence components, in addition to product types and volumes, frequency of prior audit-related site visits, POE testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included data collected by FSIS over a three-year timeframe.

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA and local inspection office. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government oversight, (2) Statutory authority and food safety regulations, (3) Sanitation, (4) HACCP, (5) Chemical residues, and (6) Microbiological testing programs.

Administrative functions were reviewed at CCA headquarters and one local inspection office, during which the auditor evaluated the implementation of those management control systems in place, which ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

A single establishment was certified as eligible to export to the United States. During the establishment visit, particular attention was 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.

Additionally, one residue and one microbiology laboratory were audited to verify their ability to provide adequate technical support to the Honduras meat inspection system.

**Table 1: Audit Scope Summary**

Competent Authority Visits			Locations
Competent Authority	Central Authority	1	Tegucigalpa
	Local Office	1	Catacamas
	Microbiology Laboratory	1	Government Laboratory: Tegucigalpa
	Residue Laboratory	1	Government Laboratory: Tegucigalpa
	Bovine Slaughter/Processing Establishment	1	Catacamas

#### 4. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

The audit was undertaken under the specific provisions of the United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations.

The audit standards applied during the review of Honduras meat inspection system included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Honduras has no subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

## 5. GOVERNMENT OVERSIGHT

The first of the six equivalence components that the auditor reviewed was Government Oversight. FSIS import eligibility requirements require that the foreign inspection system be organized and administered by the national government of the foreign country and must provide standards equivalent to those of the Federal system of meat and poultry inspection in the United States.

The CCA maintains the legal authority and the responsibility to enforce all applicable laws and regulations governing Honduras' requirements. For Honduras, the authority to enforce SAG inspection laws is granted in the Phytosanitary Law No 157-94, modified by Decree 344-2005; and in the Meat and Meat Product Regulation No.078-00; and is exercised through the National Plant and Animal Health Service (SENASA) and Food Safety Division (FSD).

The SAG-SENASA, through the FSD and Animal Health Sub-Directorate have direct control over imported livestock and meat products including control over products refused at U.S. POE. When SENASA is notified of the refusal of entry for meat products, the local exporting establishment must request an import certificate from SENASA for the return of refused POE product. When the returned product arrives, SENASA quarantine personnel at the port will inspect the shipment; they will affix a new seal, and the shipment will be sent to the local establishment. FSD will notify the Official Veterinary Inspector (OVI) of the return of refused POE product. The shipment will be retained under the control of the OVI who is responsible for verifying the product's disposition. The disposition of product depends on the POE violation identified which led to the refused entry determination.

An important component of FSIS' eligibility requirements is the need for *the assignment of competent, qualified inspectors*. The SENASA-FSD officials are responsible for the hiring, training, assigning, and overseeing of inspection personnel. During the course of the audit, the following non-compliances were identified as they relate to this component:

- At the only eligible establishment, one Official Auxiliary Inspector (OAI) did not incise the right and left tracheobronchial lymph nodes during the post-mortem inspection, which are required by Honduras' procedures for post-mortem inspection. The proper inspection of all the thoracic lymph nodes for the detection of certain diseases is significant in its impact for the safety of public health.
- The last six months of official inspection records were reviewed. Both the OVI and the Official Veterinary Supervisor (OVS) had failed to observe and/or document this non-

compliance. Training records reviewed indicated that the inspector was initially trained in inspection procedures, which included post-mortem inspection procedures.

The OVI immediately reacted to the auditor's finding and the inspection procedure was corrected. The OVI demonstrated and instructed the OAI to follow the proper post-mortem inspection procedures.

The auditor conducted a review of inspection system documents at the headquarters office and in the inspection office in the one establishment audited. These document reviews focused primarily on food safety hazards which were found to be complete and demonstrated equivalence with U.S. requirements.

The FSD has oversight of the National Laboratories which are the Residues Analysis *Laboratorio Nacional de Analisis de Residuos* (LANAR) and the National Laboratory of Microbiology Analysis. The General Director of the SENASA is the direct supervisor of the FSD Coordinator.

The FSD Coordinator or personnel visit the National Laboratory on a monthly basis and performs annual formal audits of the National Laboratory to ensure that FSIS-approved methods are used to test U.S.-eligible products. Additionally, the FSD auditor performs an annual review of the National Residue Program.

Since 2002, FSD has had an established program for microbiological audits. The National Laboratory performs the audits every three months at the U.S.-eligible establishments. The audit includes the collection of meat products and environmental samples. The National Laboratory has performed annual evaluations of the establishment's internal laboratory since December 2008.

Since February 23, 2010, The National Laboratory has been accredited for ISO 17025 by the Costa Rica Accreditation Organization for the isolation and determination of *Salmonella spp.* in meat products. The National Laboratory performs an annual audit of the private laboratory at each U.S.-eligible establishment. In addition, The National Laboratory sends check samples to the private laboratory at the U.S.-eligible establishment on a monthly basis.

Hard-copy analysis reports produced by the National Laboratories and provided to FSD include a notation of the methodology employed. The most recent results were requested by FSIS and FSD presented the following:

- *E. coli* O157:H7, analyzed March 9, 2010, using FSIS Microbiology Laboratory Guidebook (MLG) 5.04 (January 28, 2008), and
- *Salmonella*, analyzed January 7, 2010, using MLG 4.04, (February 4, 2008).

The auditor noted that all methods being used were FSIS-approved and were currently listed in the Microbiology Laboratory Guidebook. All regulatory microbiological samples and residue samples are analyzed in the official, government-owned and -operated National Laboratory. This will be discussed further in Sections 9 and 10 of this report.

The FSD has adequate administrative and technical support oversight of Honduras meat inspection system to ensure compliance with U.S. requirements. However, there was a lack of compliance in this component for *the assignment of competent, qualified inspectors* previously noted in this section.

## 6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations.

The inspection system must be organized and administered by the national government of the foreign country. The system must provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection and periodic supervisory visits to official establishments.

An important component of FSIS' eligibility requirements is the need for *inspection system control*. Official veterinary inspection is provided in the U.S.-eligible establishment daily; the OVI performs daily inspection activities regarding Sanitation Standard Operating Procedures (SSOP), Good Manufacturing Practices (GMP), HACCP, and other programs (Specified Risk Materials (SRM), Humane Handling, Microbiology and Residue Analyses, *E. coli* O157:H7 Control Program and records the results on the Sanitary Inspection Control (CIS-01) form. When non-compliances are found, the OVI fills out a Corrective Action Demand (DAC) form. During the course of the audit, the following non-compliances were identified as they relate to this component:

- The OAI conducts final rail inspection of the carcasses and HACCP verification procedures for "zero tolerance" (the control of fecal material, ingesta, and milk) **after** the final carcass wash. Honduras was not implementing their standards, which include:
  - Final rail inspection activities are to be conducted prior to carcass wash
  - Verifying that carcasses are free of fecal material, ingesta, and milk, offline inspection program personnel are to select carcass units at the post-mortem rail inspection station for examination on-line, at or after the post-mortem rail inspection station. This inspection should occur **before** the final wash.
- The auditor reviewed the last six months of official inspection verification records of inspection and HACCP verification procedures for "zero tolerance" and found no record indicating that OAI's had identified and documented a DAC during their verification procedures. OVI informed the auditor that they only verbally inform the establishment of their observation and the establishment takes immediate corrective action. Inspection personnel were not following Honduras' procedures of documenting a DAC when non-compliance is observed for "zero tolerance". Additionally, the practice of not documenting the non-compliance does not allow Honduran inspection system officials to verify the establishment's corrective actions and preventive measures are implemented within their system and identify if trends are occurring.

Another important component of FSIS' eligibility requirements is the need for *periodic supervisory reviews*. FSIS expects that documented periodic supervisory reviews, addressing core components of a foreign country's export eligibility requirements, be performed in all establishments that are eligible for export to the United States. These reviews serve as a fundamental layer of oversight to ensure that the standards are being met on a routine basis.

During the establishment visit, the auditor verified that the OVS routinely conducted monthly supervisory reviews for official inspection activities and establishment procedures as described in SAG's DIA-GIPC-05 Inspectors Guide for Meat and Meat Product Establishments. These reviews are documented on a "Format of Inspection of Slaughter Houses and Processing of Meat" (FIMEC) form.

During the course of the audit, the following non-compliance was identified as it related to this component:

- Supervisory inspection personnel's review of inspection verification procedures failed to identify or document that inspection personnel were not documenting a DAC when non-compliance was observed for "zero tolerance" (the control of fecal material, ingesta, and milk).

The review of relevant manuals and procedures at SAG-SENASA administrative offices indicated that the CCA continues to maintain equivalent legislative controls for Statutory Authority and Food Safety Regulations. However, there was a lack of compliance in this component for *inspection system control* and *periodic supervisory reviews*.

## **7. SANITATION**

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures.

The review of relevant manuals and procedures at SAG-SENASA administrative offices indicated that the CCA continues to maintain equivalent legislative controls for sanitation. The actual conditions of the establishment visits were consistent with the corresponding documentation.

The establishment visits by the auditor indicated that both in-plant inspection personnel and OVS conducting supervisory reviews were routinely conducting verification procedures as described in the SAG's DIA-GIPC-05 Inspectors Guide for Meat and Meat Product Establishments. There were no non-compliances to report for this equivalence component.

## **8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require each official establishment to develop, implement and maintain a HACCP plan.

The establishment visit by the auditor and review and observations of their HACCP system controls, resulted in the identification of non-compliance for this equivalence component concerning fundamental aspects of the HACCP system, such as:

- The establishment's HACCP plan for Slaughter and Deboning had two CCPs that addressed "zero tolerance" (the control of fecal material, ingesta, and milk): CCP1 at the tying and removal of the rectum, and CCP 2 for carcass evisceration.

The CCPs specifically addressed the monitoring and verification of the procedures for CCP1 tying and removal of the rectum, and CCP 2 for the removal of the viscera from the carcass. Both CCPs were located at the individual stations where these procedures were conducted. Neither CCP addressed the monitoring and verification of "zero tolerance" for the entire carcass. The establishments only intervention included a pre-chill carcass wash.

The establishment was unable to provide supporting decision-making documentation for the selection and location of these CCPs to address "zero tolerance" associated with the contamination of the carcass through improper sanitary dressing procedures.

This non-compliance associated with the selection and location of CCPs for the monitoring and verification activities for "zero tolerance" may have been contributing factors that led to the POE violations detected by FSIS for this establishment on March 2 and 27, 2010, and the delisting of this establishment by the U.S.

## **9. CHEMICAL RESIDUE CONTROL PROGRAMS**

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residues. 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 inspection authorities or by FSIS as potential contaminants.

As part of the verification methodology, the auditor's preparatory review of POE findings before going to Honduras did not identify areas of concern within this risk area. An on-site audit of the residue laboratory was included in the scope of this audit.

In addition, the auditor's interviews with SAG-SENASA personnel and the review of relevant records including sampling protocols and testing reports at headquarters and establishment level indicated that Honduras' residue control plan was being followed appropriately.

## **10. CCA MICROBIOLOGICAL TESTING PROGRAMS**

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs used by the CCA. 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.

An on-site audit of the microbiological laboratory was included in the scope of this audit. The microbiology laboratory is presently using the FSIS MLG 5.04 method for detection of *E. coli* O157:H7. Two verification samples (N 60) are being taken from each lot by official inspectors for *E. coli* O157:H7 at the establishment, and are analyzed by LANAR. If either of the two sample results is positive, that lot will not be exported to U.S. and will be destroyed under the supervision of government inspection officials.

Honduras has regulatory requirements including sampling strategy for their regulatory testing program for *Salmonella* species in beef. There were no positive results for *Salmonella* samples reported in 2009 for the establishment visited during this audit. However, there were two positive sample results in 2009 reported for the establishment that was delisted on December 22, 2009. In the event of positive *Salmonella* results, the CCA does not analyze the sample to determine the serotype.

In addition, the auditor's interviews with SAG-SENASA personnel and the review of relevant records including sampling protocols and testing reports at headquarters and establishment level indicated that Honduras microbiological control plan was being followed appropriately.

## **11. EXIT MEETING**

An exit conference was held in Tegucigalpa on March 23, 2010, with the SENASA-FSD. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

## **12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS**

An analysis of prior systemic non-compliances within the context of the current audit findings indicated that the non-compliances encountered during the 2008 audit were all corrected and verified by the SENASA, except for one issue involving the failure to verify basic HACCP regulatory requirements in the design and support for the HACCP plan.

The current audit revealed systemic concerns in Honduras meat inspection system both in system design and system execution where the CCA had questionable control over inspection procedures, HACCP verification procedures, and other enforcement requirements.

- Inspection personnel failed to properly conduct the post-mortem inspection procedure for the incision of the right and left tracheobronchial lymph nodes as described in Honduras food safety system. Even though the corrections to inspection procedures were implemented immediately, the CCA needs to demonstrate that inspection personnel are fully competent, qualified and aware of required post-mortem inspection procedures outlined in SENASA's food safety system to meet FSIS equivalency requirements for post-mortem inspection procedures including the verification of those actions.
- Inspection personnel are not implementing inspection procedures as described in Honduras' food safety inspection system. Final rail inspection of the carcasses and HACCP verification procedures for "zero tolerance" - control of fecal material, ingesta, and milk are conducted by inspection personnel **after** the final carcass wash. Honduras

has adapted FSIS standards, which would include final rail inspection activities to be conducted **prior** to the carcass wash, and verification activities for the control of fecal material, ingesta, and milk need to be conducted **after** the final inspection and should occur **before** the final wash.

- Inspection personnel were not documenting non-compliance reports (Demand of Corrective Actions) when inspection personnel identified “zero tolerance” failures. Inspection personnel were only verbally informing the establishment of their observation and the establishment took immediate corrective action. The CCA failed to demonstrate control of observed non-compliances in the documenting and the issuing of non-compliance reports as their system design indicate including the verification of all corrective actions that the establishment has taken in response to non-compliance identified by inspection personnel.
- In plant, supervisory inspection personnel’s review of inspection verification procedures failed to identify or document that inspection personnel were not documenting a DAC when non-compliance was observed for “zero tolerance”.
- The periodic supervisory reviews conducted by the CCA at the U.S.-eligible establishment failed to identify or document that inspection personnel were not documenting a DAC when non-compliance was observed for “zero tolerance” and required post-mortem inspection procedure were not conducted.
- Inspection personnel failed to identify that the establishment’s HACCP system lacked certain fundamental aspects. The establishment was unable to provide supporting decision-making documentation for the selection and location of their CCPs in their HACCP plan for Slaughter and Deboning. These CCPs specifically addressed the monitoring and verification of the procedures for CCP1 tying and removal of the rectum, and CCP 2 for the removal of the viscera from the carcass which were located at the individual stations where these procedures were conducted. Both CCPs failed to address the monitoring and verification of “zero tolerance” associated with the contamination of the carcass through improper sanitary dressing procedures. The establishments only intervention was a pre-chill carcass wash.

The deficiencies identified above were address by the CCA through immediate corrective actions that were implemented and their committed response to the FSIS auditor on further corrective actions.

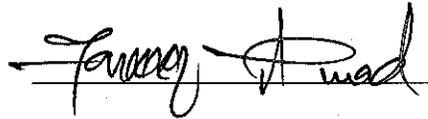
During and immediately following the audit, the only establishment eligible to export to the U.S. received two POE violations for *E. coli* O157:H7 detected by FSIS on March 2 and 27, 2010, subsequently the U.S. delisted the establishment on March 29, 2010.

On August 30, 2010, SAG-SENASA notified FSIS that they had completed their verification activities of ensuring appropriate corrective and preventive measures were implemented by the two establishments delisted by the U.S. on December 22, 2009 and March 29, 2010 for *E. coli*

O157:H7, POE violations. Additionally, they have implemented new policies and directives established by the SAG-SENASA in the program for the control of *E. coli* O157:H7.

Honduran SAG-SENASA stated these activities provide assurance that the process is under control and it complies with U.S. requirements. Additionally, Honduras provided notification that the two establishments that were delisted on December 22, 2009 and March 29, 2010, were certified by CCA-SENASA for export of meat and meat products to the U.S. and fully compliant with the requirements of Honduras' equivalence. Additionally, they requested to relist these establishments to be eligible for the export of meat products into the U.S. FSIS relisted the establishments on August 31, 2010.

Farooq Ahmad, DVM  
Senior Program Auditor

A handwritten signature in black ink, appearing to read "Farooq Ahmad", written over a horizontal line.

### 13. ATTACHMENTS

Foreign Country Response to the Draft Final Audit Report attached.

Attachment:

MAR 09 2011

## **Honduras comments to the USDA-FSIS findings during the 2010 on-site audit to the meat inspection system:**

Following-up on the 2010 US-FSIS audit on the Honduras' meat system, we are providing the comments on the actions that have been implemented and have been verified by CCA-SENASA.

*USDA-FSIS Findings:*

### **GOVERNMENT OVERSIGHT**

*At the one eligible establishment, one Official Auxiliary (OAI) did not incise the right and left tracheobronchial lymph nodes during the post-mortem inspection, which are required by Honduras' procedures for post-mortem inspection. The proper inspection of all the thoracic lymph nodes for the detection of certain diseases is significant in its impact for the safety of public health.*

*The last six months of official inspection records were reviewed. Both the OVI and the Official Veterinary Supervisor (OVS) has failed to observe and/or document this non-compliance. Training records reviewed indicated that the inspector was initially trained in inspection procedures which included post-mortem inspection procedures.*

### **Corrective Action implemented by CCA-SENASA and Official Inspection Program Personnel:**

According to the Guide for the Inspection of Meat and Meat Products (DIA-GIPC-05), CCA-SENASA must ensure that Official Inspection Program Personnel at US-eligible establishments receive on-going training on the inspection activities and carry out performance-based evaluations on an annual basis:

- FSD Coordinator performs evaluation on the Official Veterinary Supervisor (OVS),
- OVS performs evaluation on the Official Veterinary Inspectors (OVI),
- OVI performs evaluations on the Official Auxiliary Inspectors (OIA).

Regular training and evaluations include the mandatory ante-mortem and post-mortem inspection activities described in the Regulation for the Inspection of meat and meat products No. 078-00 as well as the Guide for the inspection of meat and meat products DIA-GIPC-05.

Considering the FSIS findings during the 2010 audit, the Official Veterinary Inspector (OVI) performed specific training activities which included theory and practice classes for the Official Auxiliary Inspectors (OAIs) regarding the location, visual inspection, and incision of the lymph nodes associated with the lungs, including the mediastinal (posterior, middle, and anterior) and bronchial (right and left tracheobronchial lymph nodes); as well as the hepatic, mesenteric and regional lymph nodes of the head and other viscera.

### **See attachment #1: Training activities postmortem inspection OIAs**

The effectiveness of these training activities was verified by the OVI through a specific evaluation test to each of the OAIs.

### **See attachment # 2: Specific evaluation postmortem inspection OIAs**

#### **CCA verification activities over the corrective actions:**

During periodic supervisory visits, the OVS performs direct observation activities on the OIA post-mortem inspection procedures, in order to assure that they are being performed as required in the Regulation for the Inspection of Meat and Meat Products No. 078-00, Chapter IX, Article 289 #15:

- *The post-mortem inspection of cattle is composed of macroscopic visual observation, palpation, cuts of organs and lymph nodes, viscera and parietal muscles. In addition, the lungs must be evaluated through observation, palpation, and incision of the parenchyma, as well as the inner cuts of the mediastinal and bronchial lymph nodes.*

OVS has evaluated compliance of these post-mortem inspection activities and has recorded the results on the FIMEC-01 form (Section III Slaughter 017: Inspection of the head (incision of lymph nodes, retropharyngeal, parotideal and submandibular; 018: Inspection of the bronchial lymph nodes, hepatic and mediastinal)

#### **See attachment # 3: Supervisory visit FIMEC-01 form**

*US-FSIS Finding:*

#### **STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

*The OAI conducts final rail inspection of the carcasses and HACCP verification procedures for "zero tolerance" (the control of fecal material, ingesta and milk) after the final carcass wash. Honduras was not implementing their standards, which include:*

1. *Final rail inspection activities are to be conducted prior to carcass wash*
2. *Verifying that carcasses are free of fecal material, ingesta and milk, offline inspection program personnel are to select carcass units at the post-mortem rail inspection station for examination on-line, at or after the post-mortem rail inspection station. The inspection should occur **before** the final wash.*

#### **Corrective actions implemented by CCA-SENASA and Official Inspection Program Personnel:**

CCA enforcement actions over the findings reported by the USDA-FSIS 2010 audit regarding zero tolerance included:

- Official notification requesting the reassessment of the HACCP plans: the results of this assessment included the modification on the location of the CCP for zero tolerance (performed prior to any washing of the carcasses), the monitoring activities on 100% of the carcasses and the intensified verification activities over the carcasses.
- Official notifications to the OVIs with the written verification procedures for the control of fecal material, ingesta and milk in slaughter operations. This procedure is accordingly with the FSIS Directive 6420.2 and includes instructions for the on-line and off-line inspection activities, which shall be performed in the final inspection station **prior to any washing of the carcass.**

**See attachment # 4: Notification to the OVI (zero tolerance)**

**CCA-verification activities over corrective actions:**

According to the Program for the control of *Escherichia coli* O157:H7 implemented in the establishments, the Official Veterinary Supervisor (OVS) performs periodic (semi-monthly) visits to each establishment and the results of the audit are recorded in the FIMEC-01 form. OVS performs direct observation activities over the CCP for zero tolerance including the monitoring and verification activities, the frequencies that have been established in each establishment and the records associated with these activities.

**See attachment #5: Program for the Control of E. coli O157H7**

OVS also verifies that the Official Inspection Program implements the procedure for the control of fecal material, ingesta and milk as required. OVS performs direct observation over the verification activities of the Official Inspection Program Personnel as well as the records associated with the verification activities.

Finally, the supervisory activities over zero tolerance are recorded in the FIMEC-01 form, Part III Slaughter Area No.019 Inspection of zero tolerance (records and location).

In case of non-compliance regarding the requirements for zero tolerance, OVS follows the procedures established in the Guide for the inspection of meat and meat products (DIA-GIPC-05), and emits a Demand of Corrective Action (DAC) to the establishment. Corrective actions in response to non-compliances must be presented immediately.

**See attachment # 3: Supervisory visit FIMEC-01 form**

*US-FSIS Finding:*

*The auditor reviewed the last six months of official inspection verification records of inspection and HACCP verification procedures for "zero tolerance" and found no record indicating that OAI's had identified and documented a DAC during their verification procedures. OVI informed the auditor that they only verbally inform the establishment of their observation and the establishment takes immediate corrective action.*

**Corrective actions implemented by CCA-SENASA and Official Inspection Program Personnel:**

CCA-SENASA has implemented a procedure for controlling fecal material, ingesta and milk, accordingly with the FSIS Directive 6420.2:

- Official Inspection Program is required to record on-line and off-line verification activities in the FICT-01 and FVCT-01 forms. These forms are to be filled out by the Official Auxiliary Inspectors (OAI's) during their on-line inspection activities and by the Official Veterinary Inspector during the off-line verification activities.
- Whenever the Official Inspection Program identify non-compliance during the verification activities on zero tolerance for fecal material, ingesta and milk, OVI must emit a Demand of Corrective Action to the establishment.

- If the official inspection program personnel find repeated fecal material non-compliances and determine that these findings evidence a systemic problem, the OVI should review all relevant records including generic E. coli results, HACCP requirement, SSOP compliance, and Salmonella test results.

**See attachment #6: Procedure for controlling zero tolerance**

- **CCA-verification activities over corrective actions:**

During periodic supervisory visits, OVS verifies that the Official Inspection Program implements the procedure for the control of fecal material, ingesta and milk as required and that on-line and off-line verification activities are being documented in the FICT-01 and FVCT-01 forms.

**See attachment #7: FICT-01 and FVCT-01 forms zero tolerance OIP**

**3. US-FSIS Finding**

*Inspection personnel were not following Honduras' procedures of documenting a DAC when non-compliance is observed for "zero tolerance". Additionally, the practice of not documenting the non-compliance does not allow Honduran inspection system officials to verify the establishment's corrective actions and preventive measures are implemented within their system and identify if trends are occurring.*

*Supervisory inspection personnel review of inspection verification procedures failed to identify or document that inspection personnel were not documenting a DAC, when non-compliance was observed for "zero tolerance" (the control of fecal material, ingesta and milk)*

**Corrective actions implemented by CCA-SENASA and Official Inspection Program Personnel:**

According to the Guide for the inspection of meat and meat products (DIA-GIPC-05), during the inspection activities, the OVI must record non-compliance on SPS, SSOPs, HACCP and other regulatory requirements in the Demand for Corrective Action (DAC) form. OVI must verify that the establishment implements appropriate corrective actions and preventive measures in response to a DAC.

OVI's are currently documenting non-compliances (including the findings over zero tolerance) on the DAC form.

**See attachment #8: DACs of the OVI & OVS**

**CCA-SENASA verification activities over corrective actions:**

CCA ensures that OVI implements adequate enforcement actions as required by the regulation: during periodic supervisory visits, OVS is verifying that OVI's document non-compliances of the establishments on the DAC form.

OVS also verifies that establishments implement adequate corrective actions and preventive measures in response to non-compliances documented by the OVI in the DAC forms.

In order to identify trends on non-compliances, OVI is required to fill on a monthly basis a summary for demand of corrective actions (SDAC) on the (DIA-SDAC-03-07) form, which identifies consecutive number of the DAC, description and type of non-compliance, the corrective action plan of the establishment, and the date of completion or closure of the DAC. CCA-SENASA maintains copies of the status of the corrective action plans of the establishment in response to non-compliances identified during inspection and supervisory activities.

**See attachment #9: SDAC-03-07 form 2010**

**4. US-FSIS Finding**

*The establishment visit by the auditor and review and observations of their HACCP system controls, resulted in the identification of non-compliance for this equivalence component concerning fundamental aspects of the HACCP system, such as:*

*The establishment's HACCP plan for slaughter and deboning had two CCPs that addressed "zero tolerance" (the control of fecal material, ingesta, and milk): CCP 1 at the tying and removal of the rectum, and CCP 2 for carcass evisceration.*

*The CCPs specifically addressed the monitoring and verification of the procedures for CCP 1 tying and removal of the rectum, and CCP 2 for the removal of viscera from the carcass. Both CCPs were located at the individual stations where these procedures were conducted. Neither CCP addressed the monitoring and verification of "zero tolerance" for the entire carcass. The establishments only intervention included a pre-chill carcass wash.*

*The establishment was unable to provide supporting decision-making documentation for the selection and location of these CCPs to address "zero tolerance" associated with the contamination of the carcass through improper sanitary dressing procedures.*

**Corrective actions implemented by the establishment:**

As requested by CCA, on March 2010, establishment #4 performed the reassessment of the HACCP plan. This assessment included the modification of the CCP (zero tolerance) for controlling fecal material, ingesta and milk during slaughter operations accordingly with the FSIS Directive 6420.2. The inspection activities of the establishments have been intensified and are being performed on 100% of the carcasses prior to any washing of the carcasses.

**CCA-SENASA verification activities over corrective actions:**

During the April 2010 audit to the HACCP plan of the establishment, OVS verified that zero tolerance has been considered as a critical control point (CCP for zero tolerance) and that the visual inspection activities are being performed on 100% of the carcasses prior to any washing. The establishment provided support decision making based on the FSIS Directive 6420.2 for controlling fecal material, ingesta and milk.

**See attachment #10: OVS notification of verification activities over HACCP modifications**