



United States Department of Agriculture

Food Safety and  
Inspection Service

1400 Independence  
Avenue, SW.  
Washington, D.C.  
20250

JUN 01 2015

Dr. José Lizardo Reyes Puerto  
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. José Lizardo Reyes Puerto,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Honduras' meat inspection system from February 10 through February 19, 2015. Enclosed is a copy of the final audit report. The comments received from the government of Honduras are included as an attachment to the report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov)

Sincerely,

Dr. Shaukat H. Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement, and Audit

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN  
HONDURAS

FEBRUARY 10 TO FEBRUARY 19, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
MEAT PRODUCTS  
EXPORTED TO THE UNITED STATES OF AMERICA

June 1, 2015

Food Safety and Inspection Service  
United States Department of Agriculture

## *Executive Summary*

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from February 10 through February 19, 2015. The audit was to determine whether Honduras' food safety system governing the production of meat continues to be equivalent to that of the United States with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. Honduras currently exports raw beef products to the United States from one certified establishment.

The audit was designed to verify equivalence of the six system components of the meat inspection system of Honduras: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs. Prior to the on-site audit, FSIS reviewed the self-reporting tool (SRT) provided by the Central Competent Authority (CCA); and reports of point-of-entry (POE) re-inspection conducted by FSIS in calendar years (CY) 2013 and 2014.

The on-site audit reviewed management, supervision, and administrative functions at the CCA headquarters, the official reference laboratories, and one local inspection office located at the cattle slaughter establishment, to verify whether the national system of inspection, verification, and enforcement is being implemented as described by the CCA. The audit activities conducted revealed that past measures introduced by the Honduran meat inspection system within the production processes have remained in effect and continue to effectively prevent recurrence of POE violations. FSIS POE records show that in CY2013 and CY2014, raw beef products shipped to the United States from the certified establishment of Honduras were re-inspected, and no food safety violations were found. The on-site verification audit identified only minor observations with the Sanitation and HACCP components, which the CCA promptly and adequately corrected.

The ongoing analysis of available data and the results of the on-site audit verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for the six components of the meat inspection system. Furthermore, re-inspection of beef products from Honduras conducted by FSIS at POE shows those Honduran beef products continue to meet United States food safety standards. In conclusion, the Honduran meat inspection system is operating at an "average" level of performance.

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## **I. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Honduras' food safety system from February 10 to February 19, 2015.

The audit began with an entrance meeting held on February 10, in Tegucigalpa with the participation of representatives from the Central Competent Authority (CCA) – *Servicio Nacional de Sanidad Agropecuaria*-National Plant and Animal Health Service (SENASA) and an FSIS auditor.

## **II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat products maintains equivalence to that of the United States, with the ability to export products which are safe, wholesome, unadulterated, and correctly labeled and packaged.

FSIS conducted an analysis of the country's performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA, through a self-reporting process.

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA and representatives from the *Division de Inocuidad Alimentaria*-Food Safety Division (DIA). Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs. FSIS also verified the continued adequacy of the corrective measures that the CCA implemented to address findings reported during the FSIS ongoing equivalence audit conducted in 2013.

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

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 could adversely impact 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, the two official laboratories were audited to verify their ability to provide adequate technical support to the inspection system.

| Competent Authority Visits   |         | # | Locations   |
|--|---------|---|---|
| Competent Authority  | Central | 1 | SENASA, Tegucigalpa                                 |
| Laboratories   |         | 2 | Government Microbiological and Residue, Tegucigalpa |
| Establishment  |         | 1 | Establishment 4                                     |
| <ul style="list-style-type: none"> <li>• Meat Slaughter</li> </ul> |         |   |   |

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7),
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327), 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' inspection system for meat products included: (1) All applicable legislation originally determined by FSIS to be 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 equivalence determinations in place for the following:

- Generic *E. coli* Laboratories,
- Generic *E. coli* Sample Collector,
- Chemical Residue Program, and
- *E. coli* O157:H7 Program.

### III. BACKGROUND

Honduras is eligible to export meat products. In calendar year (CY) 2013, there were two Honduran establishments that exported to the United States 9,826,283 pounds and in CY 2014, 6,837,492 pounds of raw–not ground beef, a reduction due to Honduran beef being exported only from one establishment. FSIS re-inspection results of Honduran beef products at POE show that all imported products met United States food safety standards.

### IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the auditor reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such manner to provide ultimate control and supervision over all official inspection activities; insure the uniform enforcement of pertinent laws; provide sufficient

administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

Accordingly, FSIS evaluated this component by first conducting a review and analysis of documentation submitted by the CCA, as support for the responses provided in the self-reporting tool (SRT). Subsequently, FSIS conducted on-site record reviews, interviews, and observations at government offices, one establishment, and the official laboratories of the system.

The Servicio Nacional de Sanidad Agropecuaria-National Plant and Animal Health Service (SENASA) continues to serve as the CCA for the meat inspection system of Honduras. SENASA coordinates the functions of its sub-agencies which include the National Residue Laboratory (LANAR), which provides technical support to the chemical residues control and microbiological sampling programs of the inspection system; and the DIA, which develops and standardizes enforcement of regulatory food safety controls and provides verification and certification services at establishments certified to export raw beef products to the United States. DIA officials ensure that establishments certified to export to the United States, fulfill equivalent official requirements for construction of facilities, food safety controls, and sanitary requirements stipulated in the regulations of the DIA.

Documents reviewed by the FSIS demonstrate that the CCA has developed regulations, guidelines, and procedures that provide the legal, technical, and administrative frameworks needed by the DIA to provide regulatory verification in the slaughter establishment registered and certified to export raw beef products to the United States. FSIS assessed the organization of the DIA and verified that it is staffed with government officials who accomplish administrative and regulatory functions under the coordination of the CCA. Coordination of regulatory food safety activities is accomplished nationwide, and the laboratories and establishments of the system are overseen to ensure regulatory compliance with the equivalent laws and regulations of the system that are used to govern production of meat products for export to the United States.

The FSIS auditor reviewed documents maintained at the government offices and verified that the CCA's regulatory directives and regulatory procedures are designed to enforce Honduras' laws that apply to the safe production of meat products for human consumption destined for domestic and international markets. The CCA supplements core regulatory issuances with updates to export requirements and administrative notifications distributed to DIA officials in the field. FSIS interviewed inspection personnel and verified that they were knowledgeable of work instructions, operational procedures, and regulatory guidance provided to them by the CCA to conduct inspection of production activities and verify that food safety controls at the establishment certified to export raw beef products to the United States were adequate.

FSIS verified that the DIA maintains daily presence at the raw beef processing establishment certified to export raw beef products to the United States, and that inspectors stationed at that establishment exert the legal authority they possess to enforce the laws and regulations of the system. Additionally, official records reviewed by FSIS, document that inspection and verification activities take place during each production shift.

The records also demonstrate that the certified establishment is evaluated on a yearly basis to ensure that it meets United States requirements. The FSIS auditor verified that supervisory officials review the performance of inspection personnel and assess the food safety programs maintained by the establishment. The veterinarians in charge (VIC) ensure adequacy of ante- and post-mortem inspection and verify that the establishment complies with equivalent food safety and other consumer protection regulatory requirements of Honduras' meat inspection system.

The FSIS auditor observed at the different levels of the DIA that coordination of delivery of regulatory inspection and verification is accomplished in an effective manner. Furthermore, FSIS verified that enough inspectors conduct daily ante- and post-mortem inspection, as well as, verification tasks in the fabrication and other production areas of the certified establishment. The CCA provided documents that demonstrate that all personnel engaged in the enforcement of food safety– from the CCA to in-plant officials and laboratory personnel – are employees of the government of Honduras and are subject to administrative policies that apply to government officials.

The CCA also provided information that indicates that funds required for operations of the DIA originate from national budget appropriations supplemented by payments made by establishment for additional DIA services. The establishment certified to export beef products to the United States, pay for inspection services provided at its facilities; initial and yearly renewal of registration; periodic reviews; certification visits; evaluation of operating food safety manuals; sampling collection and analysis; and private laboratory oversight services, in accordance with a statutory fee-for-service schedule issued by the government of Honduras. Industry pays for services rendered to a third party organization, the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA), which manages those funds on behalf of the CCA. OIRSA collects all fees and releases funds upon CCA request.

The veterinarians who work as DIA officials are active members, in good standing of the College of Veterinarians of Honduras. Veterinary and non-veterinary personnel receive on-the-job training at a certified establishment when they are first hired. All new employees complete supplemental training on meat inspection regulations, inspection and verification activities, and country-specific export requirements. Successful completion of training is the fundamental requirement for personnel to be assigned to perform inspection and verification procedures.

FSIS reviewed records that indicate that in-plant inspection personnel have successfully completed training required to effectively perform their duties. Topics covered in the training provided to officials include: slaughter inspection; product sampling methodology; Hazard Analysis and Critical Control Points (HACCP) systems; Sanitation Standard Operating Procedures (SSOP) programs; food microbiology; meat technology; meat products inspection; regulatory handling of specified risk materials (SRMs); and United States' requirements. In addition, the records show that the proficiency of inspection personnel is regularly assessed by supervisors and corrective measures implemented to improve their performance.

FSIS assessed the adequacy of regulatory activities being conducted at one raw beef producing establishment. The FSIS auditor observed the conditions of one establishment of the system and

reviewed official records to verify the implementation of regulatory oversight. The observations revealed that inspection officials maintain effective regulatory controls at the certified establishment in a manner that is consistent with Honduras' requirements for exports to the United States.

The FSIS auditor also confirmed that the CCA provides oversight of its national laboratories. LANAR facilities house the microbiological and chemical residue analysis laboratories. At the national laboratory, the FSIS auditor interviewed laboratory personnel, observed operations, and examined laboratory audit reports presented by laboratory managers. The assessment revealed that the CCA coordinates the evaluations of the laboratories' performance, including proficiency testing schemes for analysts, and evaluations of the quality controls maintained by laboratory managers in accordance with the guidelines provided by International Organization for Standardization (ISO) 17025. FSIS also verified that laboratory managers possess relevant academic credentials and experience as analysts in their specialty areas. All laboratory analysts have received supplemental training on analytical methodology and analytical methods. Further discussion of the functions of the national laboratory, LANAR, as part of the technical support of the system is presented within the microbiological sampling and chemical residue control components sections of this report.

The ongoing analysis of available data and the results of the on-site audit verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component at an average level.

## **V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. An equivalent inspection system operates an appropriate regulatory framework that demonstrates equivalence with FSIS requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection (AMI), post-mortem inspection (PMI), establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to establishments certified to export beef to the United States. The evaluation of this component included an analysis of information provided by the CCA in the SRT and accompanying documents, as well as interviews and observations made during the on-site equivalence verification audit.

The FSIS review of government documents demonstrates that the Honduras CCA has the statutory authority to deliver inspection to the certified slaughter establishment. Furthermore, the CCA has developed a regulatory framework that is contained in documents that lay out requirements that apply to the design and construction of an establishment and the pieces of equipment used in meat production for human consumption. They also mandate that, in accordance with Honduras's legal<sup>1</sup> requirements, producers adopt sanitary measures that ensure that meat products are safe, wholesome, properly labeled and properly packaged. Additionally,

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<sup>1</sup> Chapter I, Article 2 of Honduras' Animal and Plant Health Law 157-94, as amended by Decree 344-2005

the CCA has instituted equivalent regulatory requirements that apply to slaughter and processing activities, control of inedible and condemned materials, delivery of daily inspection, and supervisory reviews twice per month of the certified establishment. The FSIS auditor verified that the CCA has adequately incorporated into its regulatory controls recent changes pertaining to the sampling protocols for chemical residues and the additional Shiga toxin producing *Escherichia coli* recently adopted by FSIS. There are no other regulatory changes associated with the export meat products in the United States since the last audit that would have required changes by the CCA.

On-site observations and reviews of government and establishment records conducted by FSIS demonstrate that from the point of receiving at the establishment, cattle are identified and inspected in accordance with established procedures to ensure that only animals that pass ante-mortem inspection continue to slaughter. The FSIS auditor verified the adequacy of ante-mortem facilities and observed operations in the ante-mortem inspection and receiving areas. The auditor determined that livestock inspection and handling were performed in accordance with instructions and requirements imposed by the CCA for equivalent humane handling and ante-mortem inspection of livestock.

The CCA prohibits slaughter of emaciated cattle for the production of raw beef for the export market and requires that cattle suppliers provide official documents that attest to the origin and legal ownership of their animals. In addition, the establishment requires an affidavit that discloses the type of compounds the ranchers used as parasiticide and the length of the withdrawal period that they followed. Records and other documents presented for FSIS review at the establishment demonstrated that these practices are consistently implemented by plant personnel and verified by in-plant officials.

The FSIS auditor reviewed daily inspection records maintained by in-plant officials and determined that the records demonstrate that production of meat products is only conducted when government officials are present at the certified establishment, in accordance with the regulations of the DIA. Further observations made by FSIS confirmed at the establishment level, that inspection stations used by government inspectors are well built and equipped, the establishment properly presents heads, viscera, and carcasses for inspection, and government inspectors conduct post-mortem inspection in accordance with Honduras regulatory protocols and United States requirements.

Under the direct supervision of the VIC, a team of inspectors, identify and segregate suspect cattle; and verify acceptability of carcasses and parts for human consumption. The VIC conducts disposition of suspects, prepares daily post-mortem disposition reports, and has the legal authority to condemn carcasses and adjust production rates in accordance with the characteristics of the livestock being inspected and the observed incidence of pathology. FSIS review of documents and observations made during the audit of the establishment activities, indicate that in-plant DIA officials deliver ante- and post-mortem inspection of cattle in a manner that is consistently equivalent to FSIS inspection.

Supervisory officials and the VIC conduct periodic reviews of the certified establishment to evaluate efficacy of food safety systems, adequacy of inspection and official verification

activities, and performance of in-plant inspection personnel, respectively. FSIS reviewed reports of establishment's monthly and quarterly reviews, periodic performance reviews of DIA personnel, and records of evaluations of sanitary conditions at the establishment. Additionally, FSIS observed supervisory officials as they evaluated the design and maintenance of the facilities, sanitary conditions of the premises, establishment's monitoring activities of food safety systems, as well as official verification activities and the technical competence of in-plant officials. FSIS' review of records and on-site observations indicate that supervisory government officials periodically verify the adequacy of the functions of inspection personnel and the level of compliance maintained by the establishment, document findings, verify adequacy of corrective actions, and provide guidance to the establishment and instructions to officials to ensure uniform and continued compliance with the regulatory requirements of the system.

The CCA of Honduras has the legal authority and a well-documented regulatory framework to implement requirements equivalent to those governing the United States system of meat inspection. The document analyses and on-site verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. Therefore, FSIS concludes that this component of system continues to perform at an average level.

## **VI. COMPONENT THREE: SANITATION**

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of SSOP.

The evaluation of this component included a review and analysis of the responses provided by the CCA in the sanitation component portions of the SRT and observations gathered during the on-site verification audit of one establishment and its corresponding government office. FSIS reviewed legislation, regulations, and official instructions issued to inspection personnel to verify that the CCA exercises its legal authority to require an establishment to develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

The review of the information provided by the CCA demonstrates that it has legal authority to require that the establishment develop and maintain a sanitation program to prevent the creation of insanitary conditions and direct product contamination of meat products. Furthermore, the CCA requires that in-plant officials verify that the establishment's sanitation program is adequately implemented on production days.

FSIS verified that the DIA's verification and inspection functions are adequate, by conducting observations of production activities; reviewing monitoring records for pre-operational and operational sanitation verification activities maintained by the establishment and in-plant inspection personnel; and by observing inspection personnel as they assessed the adequacy of the establishment's sanitation program. DIA records reviewed on-site showed that inspection personnel verify that the establishment consistently follows their sanitation program by

identifying sanitary deficiencies, requesting corrective actions, verifying their implementation, and documenting the events.

FSIS verified that inspection personnel use their authority to enforce equivalent regulations that relate to the sanitation requirements by following instructions issued by the CCA to uniformly perform their tasks. The FSIS auditor observed that the overall construction and maintenance of the facility meets equivalence requirements at one certified establishment.

The Honduran meat inspection system has the legal authority and a well-documented regulatory framework that implements sanitation requirements equivalent to those governing the United States' system of meat inspection. The document analyses and on-site verification activities indicate that this component of the system continues to meet the core equivalence requirements and performs at an average level.

## **VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEMS**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. This component of the system pertains to the mechanisms that allow the CCA to use its legal authority to impose requirements upon an eligible establishment to develop, implement, and maintain HACCP systems for the production of meat products for export to the United States. The evaluation of this component included a review and analysis of the responses provided by the CCA in the HACCP portion of the SRT and supplemental documents that included inspection manuals and samples of forms used by officials to document results of monitoring activities. Additionally, FSIS gathered additional information by conducting on-site observations at one establishment and one local government office, as well as, by conducting interviews of official personnel to assess the adequacy of the performance of this component of the system.

The FSIS auditor verified that the CCA has issued regulations that mandate that an establishment develop, implement, and maintain a HACCP program, as well as pre-requisite programs to receive certification to export its products to the United States. The CCA requires that an establishment submit a copy of their current HACCP program and written pre-requisite programs for DIA's evaluation with their written request for initial approval and on a yearly basis thereafter.

The FSIS auditor also verified that DIA issued instructions for in-plant officials on how to verify the adequacy of the establishment's implementation of their HACCP plans. Inspection personnel perform those tasks on production days, by reviewing records and performing measurements to directly monitor critical control points (CCP). On a monthly basis, the DIA supervisor assesses selected aspects of the design and implementation of the establishment's HACCP system, to ensure that it remains aligned with the seven principles of HACCP and in compliance with equivalent regulatory requirements of Honduras.

The FSIS auditor reviewed inspection and the establishment's records and conducted in-plant observations during production hours. The results of the verification showed that DIA officials exert the legal authority they possess to ensure that the establishment complies with the HACCP

rules issued by the CCA that require that a certified establishment maintain HACCP documents that include flow of product charts, written hazard analyses, and associated documents that support decisions to establish CCPs and critical limits. The establishment generates and maintains HACCP records that document the results of CCP monitoring activities and corrective actions implemented when deviations occur, as well as records that document the monitoring of the adequacy of prerequisite programs that support their HACCP system.

The FSIS auditor reviewed documents and records maintained by the establishment and government officials and confirmed that supervisory government officials document results of regular visits to the establishment to verify the adequacy of HACCP programs. In addition, the records document that during each production shift, in-plant DIA officials verify the adequacy of implementation of the establishment's HACCP plan, including verification activities, documentation of monitoring results, and corrective actions to address CCP deviations.

FSIS' review of documents showed that inspection officials verify that the establishment adequately monitors food safety controls in operation, documenting deviations from the critical limits, and implementing adequate corrective actions that include effective preventive measures. The FSIS auditor verified that the establishment and government officials maintain implementation of a HACCP system in accordance with equivalent regulatory requirements. Furthermore, HACCP plan verification activities are being implemented appropriately, along with effective prerequisite programs that indicate that, the CCA continues to demonstrate the ability to meet the core equivalence requirements, and that this component of the system performs at an average level.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS**

The fifth of six equivalence components that the FSIS auditor reviewed was Chemical Residue Testing Programs. The inspection system is to present a chemical residue control program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

FSIS assessed this component of Honduras' meat inspection system by reviewing the results of the Honduras National Residue Program 2013 (HNRP) and the plan for HNRP 2014, interviewing LANAR personnel on-site, and conducting observations at the official chemical residue laboratory and one certified slaughter establishment. This evaluation made evident that the CCA organizes and administers the program, which is designed to detect chemical residues known to occur in food animals by using FSIS's detection methodology and applying the capabilities of the official chemical residues laboratory of the LANAR.

The FSIS auditor verified that personnel from the CCA, in cooperation with LANAR and DIA officials, develop and implement the annual residue monitoring plan. The CCA prepares the sampling schedules and instructions for random collection of samples of specific matrices within a defined period. The DIA officials collect meat samples at the slaughter facility as prescribed by sampling protocols. The HNRP delegates to LANAR the responsibility to analyze tissues to

detect chemical residues and to issue a food safety alert that prohibits export of involved meat products to the United States when chemical residues are detected above tolerance levels. The HNRP establishes tolerance levels for the analytes of interest according to Honduran meat inspection regulations, Codex Alimentarius standards; the United States Food and Drug Administration (FDA); the United States Environmental Protection Agency (EPA); and the Directorate General for Health and Consumers of the European Commission (DG SANCO) requirements.

FSIS verified that the CCA provides requirements and procedures to be followed to implement the HNRP at the establishment level. These instructions are supplemented by the standardized sample collection and handling protocols issued by the LANAR. The regulations specify compounds that are prohibited for use in food animals, and designate the VIC, as the official in charge of collecting samples at the establishment. Records made available for FSIS review at the establishment and the laboratory demonstrate that supervisory visits to the establishment, include verification of adherence of in-plant officials to scheduled sampling protocols. Samples are adequately handled and shipped to the laboratory in accordance with protocols issued by LANAR. LANAR tracks the samples and provides feedback to the in-plant VIC concerning adequacy of sample shipping and results of analysis.

The audit reports maintained at the laboratory demonstrate that the technical and organizational aspects of the functions of the laboratory are periodically evaluated by the laboratory quality control manager, the CCA and by a third party accrediting institution. Findings reported during laboratory audits are promptly addressed with adequate corrective actions and documented as required by the ISO 17025 standard. The CCA coordinates periodic audits of the laboratory as part of an agreement maintained with the Costa Rican Accreditation Entity (ECA)<sup>2</sup>. A fundamental aspect of the evaluation of the laboratory includes proficiency evaluation schemes that are designed to assess the analytical proficiency of the analysts and to expand the scope of their accreditation as members of the laboratory.

The FSIS auditor verified that the HNRP contains instructions to all sectors of the system on how to proceed when a violative result is reported. Additionally, the instructions issued by DIA require test and hold of carcasses to prevent distribution of product that tests positive for the presence of chemical residues. In accordance with HNRP, the LANAR will immediately notify the CCA when residues over the established levels are detected. The CCA in turn will notify the establishment and the VIC of this violation. The VIC will request the establishment to perform corrective actions and preventive measures in response to this violation. For this purpose, the VIC would issue a Demand for Corrective Action (DAC) and request that the establishment reassess its HACCP program, implementing corrective actions and preventive measures in response to the violation. The VIC and CCA representatives would subsequently proceed to evaluate the adequacy of the proffered corrective actions, and the VIC would verify adequacy of their implementation.

Additional regulatory measures would include intensified sampling of meat products for analysis targeting the chemical compound identified in the violation. The CCA would double the amount

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<sup>2</sup> An agency of the government of Costa Rica that provides third party accreditation of regional official laboratories in accordance with ISO/IEC 17025,

of samples to be collected for analysis, and normal sampling frequency would resume only after obtaining 16 negative consecutive results.

During this audit, FSIS verified that establishment employees and inspection officials follow cattle-receiving protocols to ensure that only cattle that have adhered to proper drug withdrawal periods are accepted for slaughter. The establishment has recognized chemical residues that were identified in the past in beef products, as chemical hazards reasonably likely to occur. From that perspective, a pre-requisite program is in place that ensures that suppliers follow authorized methods for the use of parasiticides. DIA officials collect and send the samples of tissues that include muscle, fat, and organs to the official laboratory.

The FSIS auditor verified at the LANAR that analysts assigned to the chemical residue laboratory, have completed academic work and specialized training that qualify them to conduct the analytical methods for detection and quantification of chemical residues in their scope of accreditation.

FSIS reviewed results of testing conducted by the LANAR in 2013 and noted that none of the raw beef samples was violative. In a similar manner, testing conducted by FSIS at United States' POE in calendar year 2013 and 2014, did not detect violative chemical residues in raw beef products produced by the Honduran certified establishment.

The observations conducted by FSIS of the operations at laboratories and the one establishment currently exporting to the United States show that the HNRP contains provisions for the sampling of meat and fat from slaughtered animals for the detection of residues that have been identified as potential contaminants, and to legally prohibit delivery of cattle which have not been adhered to established withdrawal periods prescribed by veterinarians and drug manufacturers, to the slaughter establishment.

The meat inspection system of Honduras has a chemical residue control program that is organized and administered by the national government to sample and analyze tissues that include muscle, fat, and organs of slaughtered cattle, to detect chemical residues identified as potential contaminants. The program has legal authority to prohibit the delivery of non-compliant cattle to the establishment and to take action when violations are detected. The document analyses and on-site audit verification of the Chemical Residue Control Program component indicate that this component of the system continues to perform at an average level.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The last equivalence component that the FSIS auditor reviewed was government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

FSIS reviewed the responses provided by the CCA in the Pathogen Reduction Standards section of its SRT that describe Generic *E. coli* and *Salmonella* sampling, as well as, Honduras' *E. coli* O157:H7 and non-O157 Shiga toxin producing *Escherichia coli* (STEC) control program. In

addition, FSIS assessed the daily implementation of the official microbiological sampling protocols at the one certified establishment and the testing of raw beef products conducted at the official laboratory.

Records reviewed by the FSIS auditor showed that DIA officials regularly verify that the establishment's written program for sampling and testing of carcasses for generic *E. coli* is implemented correctly, and that the results are used as indicators of adequacy of sanitary dressing procedures. The microbiological laboratory of LANAR audits the establishment's laboratory annually and evaluates the proficiency of its analysts by using test samples on a monthly basis. FSIS reviewed audit reports and records maintained by the laboratory and inspection officials and confirmed that the audited establishment adequately tests and analyses carcass samples and uses the sampling results to assess adequacy of process control.

The FSIS auditor verified that in-plant DIA officials collect samples of beef carcasses for the presence of *Salmonella* at the certified slaughter establishment. The government inspectors ship the samples to the official laboratory for analysis and the obtained results are assessed to verify the adequacy of the *Salmonella* controls maintained by the establishment. The CCA has adopted FSIS enforcement of pathogen reduction standards stated in 9 CFR 310.25(b). FSIS reviewed results of testing and verified that the incidence of *Salmonella* on raw beef carcasses has consistently met the performance standard.

The FSIS auditor observed that the CCA requires that the establishment include in their hazard analysis *E. coli* O157:H7 and the six non-O157 Shiga toxin producing *E. coli* (STEC) strains identified by FSIS as biological hazards reasonably likely to occur in raw beef products. Accordingly, the establishment has incorporated measures into its processes to prevent and control the identified hazards. Furthermore, the CCA requires that the establishment design and implement a program to sample and test products to verify the adequacy of the control measures. In accordance with Honduras' *E. coli* O157:H7 and non-O157 STEC control program, the establishment collects raw beef samples from each lot of product identified as eligible for export to the United States and analyzes the samples in its own laboratory using a screening method that has been approved and evaluated by the LANAR.

In addition, the establishment's laboratory is audited by LANAR to verify its compliance with analytical methodology required for detection of *E. coli* O157 and non-O157 STEC. The establishment laboratory must notify in-plant DIA officials of the results of their analyses. In accordance with the program, the laboratory sends all potential positives for *E. coli* O157:H7 to the LANAR for confirmation and considers all potential positives for non-O157 STEC as confirmed positive. In both instances, the lots of sampled product are segregated, held, and released after negative results of the testing are obtained. The FSIS auditor reviewed the Honduras' *E. coli* O157:H7 and non-O157 STEC control program, establishment's records, and results of testing conducted in the last three months of production, as well as LANAR and DIA records. The documents reviewed make evident that LANAR had audited the establishment's laboratory and that establishment's personnel follow established protocol when product tests positive for the presence of STEC. Additionally, product that tests positive is prevented from being shipped as raw product to the United States, and all actions taken are documented.

The CCA also implements its own official verification program. The official sampling and testing plan verifies that the slaughter establishment implements consistent and effective measures to maintain *E. coli* O157:H7 and non-O157 STEC under control. The protocol followed for *E. coli* O157:H7 verification includes a screening step that is followed by a confirmatory step. In the case of non-O157 STEC, the analytical protocol includes only the screening step. In that manner, all samples that show positive results in the screening step are considered confirmed positive. DIA in-plant officials collect samples of intact raw beef product in accordance with N-60 sampling protocol and send them to the official laboratory. As in the case of establishment testing, each lot of product that is tested by the government is held until LANAR reports the results of the analysis. The routine sampling program calls for 12 samples for *E. coli* O157:H7 and non-O157 STEC to be collected per month and during the rainy season, DIA officials collect 14 samples per month.

FSIS reviewed records maintained by the official laboratory to verify that samples are received in accordance with the instructions provided by the CCA and at the frequency stipulated in the STEC sampling program, as indicated above and confirmed that all parties adhere to established protocol. The FSIS auditor further verified that analysts assigned to the STEC control verification program have been trained and successfully passed third party competency assessments.

The microbiological testing programs component of the Honduran meat inspection system is organized and administered by the national government to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with Honduran regulatory requirements that are equivalent to United States requirements. The document analyses and on-site audit verification of Honduras' Microbiological Testing Programs component indicate that the CCA continues to perform at an average level.

## **X. CONCLUSIONS AND NEXT STEPS**

An analysis of the findings within each component did not identify any systemic deficiencies that represented an immediate threat to public health. An exit meeting was held on February 19, in Tegucigalpa with SENASA and DIA representatives. At this meeting, the preliminary observations from the audit were presented by the FSIS auditor. The CCA understood and accepted the observations.

The audit activities conducted revealed that past measures introduced by the CCA within the production processes have remained in effect, and continue to effectively prevent recurrence of POE violations. FSIS POE records show that in CY2013 and CY2014, raw beef products shipped to the United States from the certified establishment of Honduras were re-inspected, and no food safety violations were found. The on-site verification audit identified only minor observations with the Sanitation and HACCP components, which the Honduran CCA promptly and adequately corrected.

The ongoing analysis of available data and the results of the on-site audit verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for the six components of the meat inspection system. Furthermore, re-inspection

of beef products from Honduras; conducted by FSIS at POE shows that Honduran beef products continue to meet United States food safety standards. In conclusion, the Honduran meat inspection system is operating at an “average” level of performance.

**XI. ATTACHMENTS TO THE AUDIT REPORT**

Attachment A: Individual Foreign Establishment Audit Checklist

Attachment B: Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

|   |  |                           |   |
|---|--|---------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Empacadora C&D<br>Barrio El Hatillo<br>Catacamas, Olancho<br>Honduras | 2. AUDIT DATE<br>2/12/2015                       | 3. ESTABLISHMENT NO.<br>4 | 4. NAME OF COUNTRY<br>Honduras  |
|   | 5. NAME OF AUDITOR(S)<br>Francisco Gonzalez, DVM |                           | 6. TYPE OF AUDIT<br><input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT |

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

| Part A - Sanitation Standard Operating Procedures (SSOP)<br>Basic Requirements   | Audit Results | Part D - Continued Economic Sampling                    | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP  |               | 33. Scheduled Sample                                    |               |
| 8. Records documenting implementation.   |               | 34. Species Testing                                     |               |
| 9. Signed and dated SSOP, by on-site or overall authority.   |               | 35. Residue   |               |
| <b>Sanitation Standard Operating Procedures (SSOP)<br/>Ongoing Requirements</b>  |               | <b>Part E - Other Requirements</b>                      |               |
| 10. Implementation of SSOP's, including monitoring of implementation.  |               | 36. Export  |               |
| 11. Maintenance and evaluation of the effectiveness of SSOP's.   |               | 37. Import  |               |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.                                 |               | 38. Establishment Grounds and Pest Control              |               |
| 13. Daily records document item 10, 11 and 12 above.   |               | 39. Establishment Construction/Maintenance              |               |
| <b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>  |               | 40. Light   |               |
| 14. Developed and implemented a written HACCP plan .   |               | 41. Ventilation   |               |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.          |               | 42. Plumbing and Sewage                                 |               |
| 16. Records documenting implementation and monitoring of the HACCP plan.   |               | 43. Water Supply  |               |
| 17. The HACCP plan is signed and dated by the responsible establishment individual.  |               | 44. Dressing Rooms/Lavatories                           |               |
| <b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>   |               | 45. Equipment and Utensils                              |               |
| 18. Monitoring of HACCP plan.  |               | 46. Sanitary Operations                                 | X             |
| 19. Verification and validation of HACCP plan.   |               | 47. Employee Hygiene                                    |               |
| 20. Corrective action written in HACCP plan.   |               | 48. Condemned Product Control                           |               |
| 21. Reassessed adequacy of the HACCP plan.   |               | <b>Part F - Inspection Requirements</b>                 |               |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | X             | 49. Government Staffing                                 |               |
| <b>Part C - Economic / Wholesomeness</b>   |               | 50. Daily Inspection Coverage                           |               |
| 23. Labeling - Product Standards   |               | 51. Enforcement   |               |
| 24. Labeling - Net Weights   |               | 52. Humane Handling                                     |               |
| 25. General Labeling   |               | 53. Animal Identification                               |               |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)  |               | 54. Ante Mortem Inspection                              |               |
| <b>Part D - Sampling<br/>Generic E. coli Testing</b>   |               | 55. Post Mortem Inspection                              |               |
| 27. Written Procedures   |               | <b>Part G - Other Regulatory Oversight Requirements</b> |               |
| 28. Sample Collection/Analysis   |               | 56. European Community Directives                       |               |
| 29. Records  |               | 57. Monthly Review                                      |               |
| <b>Salmonella Performance Standards - Basic Requirements</b>   |               | 58. STEC control and verification                       |               |
| 30. Corrective Actions   |               | 59.   |               |
| 31. Reassessment   |               |   |               |
| 32. Written Assurance  |               |   |               |

## 60. Observation of the Establishment

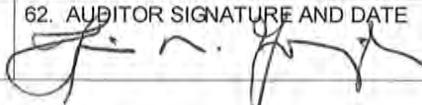
## Honduras Slaughter Establishment No. 4

22. The establishment's response to a deviation of the critical control point for zero tolerance for fecal matter, milk and ingesta on the surfaces of the carcasses reported by in-plant personnel did not document how the product affected by the deviation was prevented from entering commerce. Further review of records demonstrated that the establishment implemented corrective actions in accordance with the HACCP plan to reestablish control, segregate and identify the affected product and restore sanitary conditions including product disposition. However, inspection personnel had not noticed that the response to the reported non-compliance was incomplete.

46. During pre-operational sanitation verification, the FSIS auditor observed that proper storage of chemical compounds was not being fully implemented in accordance with government requirements. The auditor observed two containers, one labeled and another one without identification that had been left in the production areas.

61. NAME OF AUDITOR  
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

 Jan 2/12/2015

**SERVICIO NACIONAL DE SANIDAD AGROPECUARIA  
SENASA**

**NOTA.DGS.DIA.512.2015**

Tegucigalpa, M.D.C.,  
May 20, 2015

Doctor  
**SHAUKAT H. SYED**  
Director  
International Audit Staff  
Office of Internal Affairs  
FSIS-USDA  
Washington, USA

Dear Doctor Syed:

Thank you for sending the draft final audit report regarding the Food Safety and Inspection Service (FSIS) on-site audit of Honduras' meat inspection system from February 10 through February 19, 2015.

On this regard I would like to inform you that we have reviewed the information and we have no comments to the report.

Sincerely,

  
**DR. JOSE LIZARDO REYES PUERTO**  
General Director

cc: *Ing. Jacobo Paz Bodden-Secretario de Estado Agricultura y Ganaderia*  
*Licda. Ana Gómez-Especialista Agrícola USDA*  
*Dr. Juan Ramón Velásquez-Coordinador DIA-SENASA*  
*Dr. Manuel Soto-Jefe de Sección de Carnes y Productos Cárnicos*  
*Archivo*