



United States Department of Agriculture

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Dear Dr. Reyes Puerto:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Honduras' meat inspection system from April 9 through April 25, 2013. Enclosed you will find a copy of the final audit report that includes comments that you provided. Please disregard the previously submitted communication in which the report was erroneously identified as a draft final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-0676, or electronic mail at international.audit@fsis.usda.gov.

Sincerely,

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

Enclosure

HONDURAS
FINAL AUDIT REPORT

March 27, 2014
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from April 9 through April 25, 2013, to determine whether Honduras' food safety system governing the production of meat (MISH) remains equivalent to that of the United States (U.S.), with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled.

The audit focused on six system components: (1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. The FSIS auditor reviewed information provided by the Central Competent Authority (CCA) self-reporting tool (SRT) and reports provided by the CCA on the verification of corrective actions implemented by the MISH to address findings from FSIS's March 2010 audit and point of entry (POE) violations reported by FSIS.

The onsite verification portion of this audit included review of documents beyond those that MISH had previously submitted to FSIS and interviews and observations conducted at CCA headquarters, at two local government offices, at two government laboratories that perform microbiological and chemical residue analysis, and at the two cattle slaughter and fabrication establishments certified to export raw beef products to the United States.

The auditor found that the performance of the MISH has improved since the last audit conducted by FSIS in 2010. The findings reported for the 2010 FSIS audit had been corrected, and the MISH has introduced measures within the production processes that have effectively prevented recurrence of POE violations. FSIS POE records show that from September 13, 2012 through October 31, 2013, raw beef products shipped to the United States from the two certified establishments of Honduras were re-inspected, and no food safety violations were found. The onsite verification audit identified only minor concerns with the Sanitation, HACCP, and Residue Control Program components, which the CCA promptly and adequately addressed as reported in the corresponding sections of this report.

The results of this audit found that the equivalence criteria for the six components were met, and recent POE re-inspection of Honduran beef product results confirms that Honduras has maintained an average-performing equivalent food safety system.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an ongoing equivalence verification audit of Honduras' meat inspection system including onsite verification activities conducted from April 9 through 25, 2013.

Honduras is eligible to export meat products to the United States. From January 1 to October 31, 2013, certified Honduran establishments shipped 8,745,873 pounds of raw beef products to the United States that FSIS re-inspected and accepted. From January 1 to December 31, 2012, the volume exported to the United States was 15,007,238 pounds of the same product, of which FSIS rejected 42,000 pounds because of one POE violation related to food safety that occurred in September of that year.

FSIS conducted an onsite verification audit of Meat Inspection System of Honduras (MISH) from April 9 through April 25, 2013. During the audit, the auditor verified that the inspection system maintained requirements equivalent to those of FSIS, 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. 1901-1906)
- 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 this audit included all applicable legislation originally determined by FSIS as equivalent as part of the initial equivalence process and any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement.

II. AUDIT GOAL AND OBJECTIVES

FSIS's overall goal for the audit was to verify that Honduras' food safety system governing meat production continues to be equivalent to that of the United States, with the ability to produce and export products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six components of the program with the objective of determining if they are equivalent and can maintain the system's equivalence. The six equivalence components are the following: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Program; and (6) Microbiological Testing Programs. In addition, FSIS assessed the adequacy of the corrective measures that the CCA implemented to address findings of the 2010 ongoing equivalence audit and the adjustments made within the Honduran meat inspection system's components to prevent recurrence of POE violations.

III. AUDIT METHODOLOGY

For this equivalence verification audit, FSIS utilized its established four-phase process: planning, execution (onsite), evaluation, and feedback. Each phase is described below.

The first phase involved document and data analysis of previous audit findings and other available information. The FSIS auditor examined the six equivalence components of Honduras' meat inspection system, FSIS data on exported product types and volumes, as well as POE testing results and other data collected by FSIS since the last onsite audit. The FSIS auditor verified the documented corrective actions proffered by the CCA to address the findings of the 2010 audit that identified minor concerns with post-mortem inspection, HACCP, recordkeeping, and supervisory reviews twice per month.

Additional information reviewed by the FSIS auditor included the responses provided by the CCA via the self-reporting tool (SRT), outlining the current structure of the inspection system and identifying significant changes that have occurred since the last FSIS audit. The review also included reports provided by the CCA on the corrective actions that the sectors of the Honduran meat inspection system implemented to address POE violations reported by FSIS between the 2010 audit and September 2012.

The second phase was the onsite verification. FSIS verified the CCA's oversight activities through onsite document reviews, interviews, observations, and site visits. The auditor reviewed management, supervision, and administrative functions at the CCA headquarters and at the two inspection offices located at the two cattle-slaughter and fabrication establishments certified to export raw beef products to the United States. FSIS verified that the national system of inspection, verification, and enforcement was being implemented as required. Additionally, the two official laboratories that conduct microbiological and chemical residues analyses were audited to verify the adequacy of the oversight that the CCA provides to its technical support and to assess the technical and administrative controls maintained by managers at the laboratories.

During the onsite audit, the FSIS auditor paid particular attention to the extent to which government offices, establishments, and laboratories of the meat inspection system of Honduras interact at different levels 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 twice per month that ensure that the meat inspection system continues to operate in accordance with eligibility requirements specified in United States Code of Federal Regulations Title 9, Part 327, Section 327.2. During this ongoing equivalence verification audit, FSIS also assessed the corrective measures implemented by the CCA to address 2010 audit findings and different types of POE violations.

The third phase of the audit is evaluation. FSIS conducted an evaluation of all data collected onsite to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents. FSIS conducted an exit meeting with the CCA representatives to convey all findings and discuss next steps.

The final phase of the audit is feedback that begins with a draft audit report, which provides the CCA with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report. Then, the CCA develops an action plan to address any issues raised by the audit. These issues will be monitored by FSIS until resolution.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import eligibility requirements for Honduras state that the foreign food safety inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the system of meat inspection in the United States. The evaluation of this component included a review and analysis of documentation submitted by the CCA in the SRT, as well as onsite record reviews, interviews, and observations made by the FSIS auditor at government offices, establishments, and laboratories of the system.

In accordance with Honduran statute¹, the Servicio Nacional de Sanidad Agropecuaria (SENASA) serves as the CCA of the meat inspection system of Honduras. As such, it coordinates the functions of its sub-agencies that 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 Food Safety Division-Division de Inocuidad Alimentaria (DIA), which coordinates delivery of in-plant inspection, verification and certification services. DIA also develops and standardizes methodology needed for uniform enforcement of regulatory measures that apply to production, import, and export of meat products at establishments certified to export raw beef products to the United States. DIA officials evaluate raw beef slaughter and raw beef processing enterprises that seek eligibility to export to the United States, and ensure that they fulfill official requirements for: construction of facilities, food safety controls, and sanitary requirements stipulated in the regulations of the meat inspection system of Honduras, prior to granting eligibility.

Documents reviewed by the FSIS auditor that included the Meat Inspection Regulations (MIR), Manual of Procedures for the Inspection of Meat and Meat Products (MPIMMP), and the Guide for the Induction of Official Inspectors of Meat and Meat Products Establishments (GIOIMMPE) 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 oversight to slaughter establishments 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 Head of the DIA (HDIA). The HDIA reports to the Chief Veterinary Officer, who serves as the General Director of the CCA. The HDIA coordinates regulatory food safety activities nationwide, overseeing the functions of the LANAR, and the Meat Products Section Chief (MPSC) who manages delivery of regulatory oversight to meat and poultry establishments nationwide. The MPSC supervises the Official Veterinary Inspectors (OVI) stationed at slaughter and processing establishments that produce meat and poultry products for domestic and foreign markets.

The FSIS auditor reviewed documents maintained at the government offices and verified that CCA's regulatory directives and regulatory procedures are designed to enforce Honduras' laws that apply to the

¹ Chapter I, Article 2 of Honduras' Animal and Plant Health Law 157-94, as amended by Decree 344-2005, the Secretaria de Agricultura y Ganadería (SAG) of Honduras, designates the Servicio Nacional de Sanidad Agropecuaria (SENASA) as the government agency in charge of implementing regulatory oversight of the production activities of the dairy; fish and aquaculture; honey and feed; and meat industries of Honduras.

safe production of meat products for human consumption destined for domestic and international markets. The MIR, MPIMMP and the GIOIMMPE are the main sources of instructions that the CCA has distributed to the field. 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 establishments certified to export raw beef products to the United States were adequate.

FSIS verified that the DIA maintains daily presence at raw beef processing plants certified to export raw beef products to the United States, and inspectors stationed at the establishments exert the legal authority they possess to enforce the laws and regulations of the system. Additionally, records reviewed by FSIS, which are generated and maintained by DIA officials at headquarters and at the establishments, document that government officials conduct inspection and verification activities during each production shift to ensure that the daily implementation of food safety systems is adequate and to ensure that establishments meet United States' requirements.

Documents presented for review by the DIA demonstrate that, in accordance with the regulations of the system, establishments that are certified to export raw beef products are evaluated on a yearly basis, to ensure that they meet United States requirements. The FSIS auditor reviewed the DIA's operational procedures and verified that the MPSC conducts supervisory reviews of inspection personnel and assessments of the food safety programs maintained by certified establishments. OVIs, as veterinarians in charge, ensure effective delivery of inspection services, and supervise teams of veterinary auxiliaries (VA) at their duty stations. VA's conduct ante- and post-mortem inspection and verify every day those establishments are in compliance with food safety and other consumer protection regulatory requirements of Honduras' meat inspection system on every production shift.

The FSIS auditor observed activities at the different levels of the DIA and confirmed that official procedures are being implemented. Supervisory and in-plant officials document the results of regulatory activities. FSIS verified that in-plant inspection personnel staffing levels are consistent with protocols in the MIR. There were enough inspection personnel to deliver ante- and post-mortem inspection and verify tasks in the fabrication and other production areas of certified establishments.

CCA also provided documents that demonstrate that all individuals who work for the DIA – from the CCA to in-plant officials and laboratory personnel – are employees of the Government of Honduras (GOH) and are subject to administrative policies that apply to government officials. CCA provided information that indicates that funds required for operations of the DIA originate from national budget appropriations supplemented by payments made by establishments for additional DIA services. Establishments pay for inspection of exporting 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 GOH. 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 MIR stipulate that the CCA hires veterinarians who have become accredited to work in meat inspection and are active members in good standing of the College of Veterinarians of Honduras. CCA provides veterinary and non-veterinary personnel with on-the-job training at certified establishments 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 (SRM); and United States' requirements. In addition, the records show that as part of the corrective actions to address the POE violations, the CCA delivered additional training to its personnel on ante and post mortem inspection of livestock, verification, and recordkeeping activities; and analytical detection of veterinary drug residues and bacterial pathogens.

To address the recordkeeping findings reported during the 2010 ongoing verification audit, the CCA created and distributed new forms that included instructions for completion. The MPSC coordinated the implementation and evaluation of the corrective action and ensured that personnel under their supervision learned the new approach. FSIS reviewed records maintained by in-plant DIA officials and verified that they identify non-compliances, verified the adequacy of corrective actions, and maintained recordkeeping in accordance with the guidelines provided -- thus adequately correcting the shortcomings reported by FSIS auditors during the last audit of the meat inspection system of Honduras.

FSIS assessed the adequacy of regulatory activities being conducted at the two raw beef producing establishments. The FSISD auditor observed the conditions of the establishments and reviewed the documents to verify the implementation of regulatory oversight. Regulatory oversight at certified establishments is being conducted in an effective manner consistent with the Honduras requirements related to United States exports.

The FSIS auditor assessed the CCA's ability to provide oversight to its laboratories. The FSIS auditor interviewed laboratory personnel, observed operations at the laboratories, and reviewed operational procedures and personnel files with laboratory managers. The assessment revealed that the HDIA 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 that were introduced as part of the corrective actions implemented by the CCA to address POE violations reported by FSIS in 2010 and 2011. Further discussion of corrective actions implemented by the laboratories in response to POE violations involving microbial adulteration is presented within the microbiological sampling and chemical residue control sections of this report.

The records maintained by the HDIA and presented for review showed that DIA last audited the laboratories in January 2013. Findings reported for that audit included minor non-conformances related to maintenance of quality control protocols and recordkeeping. The laboratory managers presented documents demonstrating that CCA implemented corrective actions to remedy the reported non-

conformances. The CCA had also scheduled a third party audit of the laboratories to be conducted by the Costa Rican Accreditation Entity (ECA)² in April 2013.

The ongoing analysis of available data and onsite audit verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. FSIS concludes that the CCA continues to perform at an “average” level in meeting FSIS’ equivalence criteria for this component.

V. COMPONENT TWO: 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. 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, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to United States-eligible establishments.

FSIS’ evaluation of this component included an analysis of information that CCA provided in the SRT and information gathered during the onsite verification phase of the audit. The FSIS auditor verified that official inspection and verification activities were in accordance with the responses in the SRT and supporting documentation.

The CCA has developed a regulatory framework that is contained in the MIR and MPIMMP. These documents lay out requirements that apply to the design and construction of establishments and the pieces of equipment used in meat production for human consumption. They also mandate that, in accordance with Honduras’s legal³ requirements, producers adopt sanitary measures that ensure that meat products are safe, wholesome, properly labeled and properly packaged. Additionally, the MIR provide 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 certified establishments.

Onsite observations and reviews of government and establishment records conducted by FSIS demonstrate that from the point of receiving at the establishments, 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 DIA for humane handling and ante-mortem inspection of livestock.

The verification activities conducted by the FSIS auditor also included an assessment of the measures that the CCA and the establishments have implemented at the point of cattle-receiving in response to

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

³ Chapter I, Article 2 of Honduras’ Animal and Plant Health Law 157-94, as amended by Decree 344-2005

United States-POE violations related to chemical residues, *E. coli* O157:H7 and parasitic lesions in raw beef products reported by FSIS in 2010 and 2011, respectively. Corrective actions implemented consist of measures imposed by the CCA and revised production practices adopted by the establishments. The CCA prohibits slaughter of emaciated cattle for the production of raw beef for the export market. CCA requires that cattle suppliers provide official documents that attest to the origin and legal ownership of their animals. In addition, the establishments require an affidavit that discloses the type of macrocyclic lactones (ML) compounds (Doramectin and Ivermectin) 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 establishments 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 certified establishments, in accordance with the regulations of the DIA. Further observations made by FSIS confirmed that certified establishments provide adequately equipped inspection stations to government inspectors. The establishments also present properly and consistently identified heads, viscera, and carcasses for inspection, as required by Honduran regulations. Government inspectors were observed conducting post-mortem inspection in accordance with official procedures and United States requirements. As it pertains to the corrective actions that were implemented to improve detection of parasitic lesions caused by *Sarcocystis* during post-mortem inspection, the FSIS auditor verified that DIA inspectors were following the revised inspection procedures. These include palpation of the esophagus, diaphragm, and surfaces of the abdominal areas of all carcasses.

A team of inspectors identify suspect cattle and verify that all carcasses and parts are acceptable to be passed for human consumption. The inspectors work under the direct supervision of the OVI, who 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 personnel reviewed documents and observed during the audit indicate that in-plant DIA officials deliver ante- and post-mortem inspection of cattle at certified in a manner that is consistently equivalent to FSIS inspection.

CCA representatives, the MPSC, and OVIs conduct periodic reviews of the certified establishments 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 establishments' monthly and quarterly reviews, periodic performance reviews of DIA personnel, and records of evaluations of sanitary conditions at establishments. Additionally, FSIS observed supervisory officials as they evaluated the design and maintenance of the facilities, sanitary conditions of the premises, establishments' monitoring activities of food safety systems, as well as official verification activities and technical competence of in-plant officials. FSIS' review of records and their observations indicate that government officials periodically assess the functions of inspection personnel and establishments, examine document findings, verify adequacy of corrective actions, and provide guidance to establishments and instructions to officials to ensure uniform and continued compliance with the regulatory requirements of the system. In addition, the records show that during the time period in which implementation of corrective measures to resolve POE violations took place, DIA supervisory officials

increased the frequency of supervisory reviews to establishments and inspection personnel to ensure that corrective measures were done consistently and according to the instructions issued by the CCA.

The Honduran meat inspection system has 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 onsite verification activities indicate that CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. FSIS concludes the CCA continues to perform at an “average” level in meeting FSIS’ equivalence criteria for this component.

VI. COMPONENT THREE: SANITATION

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

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, MIR, MPIMMP, and samples of DIA’s daily in-plant sanitation monitoring records. The information reviewed indicates that the CCA has legal authority to require that operators develop and maintain sanitation programs to prevent direct product contamination of meat products and the creation of insanitary conditions. Furthermore, the MIR of the Honduran system requires that in-plant officials verify that plant sanitation programs are being adequately implemented.

FSIS verified that DIA’s verification and inspection functions were adequate by conducting observations of production activities; reviewing monitoring records for pre-operational and operational sanitation maintained by the establishment and in-plant inspection personnel; and by observing inspection personnel as they assessed the adequacy of the establishments’ sanitation programs. FSIS verification also included an assessment of the modified sanitary dressing procedures that were implemented in response to United States-POE violations involving the presence of *E. coli* O157:H7 and ingesta on raw beef products reported by FSIS in 2010 and 2012, respectively. The FSIS auditor observed that, as proffered in the corrective actions presented by the CCA, the establishments prevent gastric contents from spilling by tying both ends of the gastric system of slaughtered cattle. Furthermore, personnel assigned to the evisceration line have been provided with greater light intensity at their work stations to facilitate prevention and detection of spillages. Establishments also monitor adequacy of cattle dressing at a greater frequency in accordance with their revised sanitary dressing procedures. To prevent cattle from carrying fecal matter likely to contain *E. coli* O157:H7 into the slaughter floor, the establishment has implemented additional operational sanitation practices that consist of washing cattle with chlorinated water (50 ppm) to remove fecal matter from hides and hooves and washing the holding pens with a 15% acetic acid solution every 15 days.

DIA records reviewed onsite showed that inspection personnel verify that the establishments consistently follow 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 MIR and follow instructions contained in the MPIMMP to accomplish their tasks. Observations conducted at the two certified establishments of the Honduran system that export raw beef to the United States revealed that the overall construction and maintenance of their facilities meet equivalence requirements. However, during pre-operational inspection verification, the FSIS auditor noted several dead-end (capped) pipes that had been left in place after hand-wash sinks were relocated in the slaughter and deboning rooms. Stagnant water in the dead-end pipes could become a potential source of contaminants. This situation had the potential to create insanitary conditions. DIA officials documented the finding and immediately requested that the establishment implement corrective actions. In-plant DIA personnel verified that the corrective actions were adequate and recorded the results. Prior to the audit's conclusion, DIA provided a copy of the documentation generated to address the FSIS auditor's finding. The FSIS auditor reviewed the documents and confirmed that the corrective measures for the reported deficiency had been implemented in an acceptable manner, thus rendering the matter resolved.

The Honduran meat inspection system has 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 onsite verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for the Sanitation component. Therefore, FSIS concludes that the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT 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 the eligible establishments to develop, implement, and maintain HACCP programs. 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 submitted including MIR, MPIMMP, and copies of official monitoring records. Additionally, FSIS conducted onsite observations to assess the operations of the eligible establishments and government offices.

The auditor verified that DIA regulations mandate that establishments develop, implement, and maintain HACCP programs as well as pre-requisite programs to receive authorization from the CCA to produce meat products for human consumption. The CCA requires that establishments submit a copy of their current HACCP program and written pre-requisite programs for DIA's evaluation with their written request for initial approval to manufacture meat products for human consumption and then on a yearly basis thereafter. The FSIS auditor verified that DIA instructions require in-plant officials to verify the adequacy the establishments' implementation of their HACCP plan every day by reviewing records and performing measurements to monitor critical control points (CCP). On a monthly basis, the MPSC assesses selected aspects of the design and implementation of the establishments' HACCP programs, ensuring that they remain aligned with the seven principles of HACCP and in compliance with regulatory requirements of the meat inspection system of Honduras.

FSIS verified the adequacy of the corrective measures that the CCA and the establishments implemented within the HACCP component to address the findings of the last FSIS audit and to respond to the United States-POE violations reported by FSIS in 2010, 2011, and 2012. The FSIS auditor reviewed inspection and the establishments' records and conducted in-plant observations during production hours. The results of the verification showed that the CCA adequately verifies the implementation of establishments' HACCP plans, including verification activities; documentation of monitoring results, and corrective actions to address CCP deviations.

The CCA has modified the official HACCP verification activities to better ensure that the establishments adequately implement their HACCP plans and prevent recurrence of deviations from the critical limits of the CCP for zero tolerance for visible feces, ingesta and milk. Specifically, DIA increased the frequency of supervisory reviews performed by the MPSC to twice per month and doubled the frequency at which in-plant inspection personnel conduct daily verification of CCP monitoring. The establishments have reassessed their prerequisite program for sanitary dressing procedures and introduced practices that prevent spillage of contaminants from the gastric system onto the carcasses and increased the verification efforts to ensure that accidental contamination is prevented, detected and corrected. FSIS has not detected POE violations of this type in raw beef products from Honduras, since the time period of September 2012 to October 31, 2013.

The establishments have reassessed their HACCP programs and revised their hazard analyses to specify that prerequisite programs have been redesigned or incorporated into the processes to prevent recurrence of the presence of *E. coli* O157:H7, chemical residues of ML, and parasitic lesions in raw beef products as reported by FSIS in 2010 and 2011 POE violations. The CCA has also issued requirements that establishments have incorporated into their HACCP programs to ensure adequate prevention and control of hazards reasonably likely to occur in the slaughter processes. Consequently, establishments maintain prevention and control measures. Inspection personnel verify that prerequisite programs are adequately implemented, and that HACCP plans fulfill the CCA's requirements. FSIS re-inspection of Honduran beef products conducted at POE from March 2010 through October 31, 2013, has not detected *E. coli* O157:H7 or any of the six additional Shiga toxins producing *E. coli* in Honduran beef products. Likewise, chemical residue violations and parasitic lesions violations have not occurred since July 2011 and January 2011, respectively.

FSIS also observed and evaluated the design and execution of the HACCP programs at the two certified slaughter establishments. FSIS verified that DIA officials exert the legal authority they possess to ensure that establishments comply with the HACCP rules issued by the CCA. The FSIS auditor reviewed documents and records maintained by the establishment and government officials that document that supervisory government officials regularly visit the establishments to verify the adequacy of HACCP programs. In addition, the records document that the in-plant DIA official verifies daily, during each production shift, the adequacy of CCP monitoring procedures by reviewing establishments' HACCP records and by conducting hands on verification of adequacy of critical control points.

FSIS also verified that establishments maintain HACCP documents that include flow of product charts, written hazard analyses, and associated documents that support decisions to establish CCPs and critical limits. Additionally, the establishments also generate and maintain 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 systems.

FSIS' review of documents showed that establishments adequately monitor 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 establishments and government offices have responded to POE violations reported by FSIS in 2010, 2011, and 2012, by modifying HACCP plan verification activities, which, along with effective prerequisite programs implementation have prevented additional POE violations. The document analyses and onsite audit verification of the HACCP component indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. FSIS concludes that the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAMS

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residues Control Program. This component pertains to regulatory requirements for the inspection system to have a chemical residue control program that is organized and administered by the national government. An equivalent inspection system operates a residue control program that includes random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

FSIS assessed this component of the meat inspection system of Honduras by reviewing the Honduras National Residue Program 2013 (HNRP), interviewing LANAR personnel onsite, and conducting observations at the official chemical residue laboratory and two certified slaughter establishments. This evaluation made evident that 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 time period. The DIA officials collect tissue samples at the slaughter facilities 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 at above tolerance levels. The HNRP establishes tolerance levels for the analytes of interest according to the MIR, Codex Alimentarius recommendations; 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 MIR and the MPIMMP provide requirements and procedures that should be followed to implement the HNRP at the in-plant level. These instructions are supplemented by the standardized sample collection and handling protocols issued by the LANAR. The MIR specifies the compounds that are prohibited for use in food animals and designates the OVI as the official in charge of

collecting samples at the establishments. Records made available for FSIS review at the establishments, the LANAR, and CCA headquarters demonstrate that the MPSC verifies during supervisory visits that in-plant officials adhere to scheduled sampling protocols. Samples are adequately handled and shipped to the laboratory. LANAR tracks the samples and provides feedback to the in-plant OVI concerning adequacy of sample shipping and results of analysis.

The HNRP contains instructions to all sectors of the system -- government offices, establishments, and the laboratory -- on how to proceed when a violative result is reported. 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 IVO of this violation. The IVO will request the establishment to perform corrective actions and preventive measures in response to this violation. For this purpose, the IVO 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 IVO and CCA-SENASA would subsequently proceed to evaluate the adequacy of the proffered corrective actions, and the IVO would verify adequacy of its implementation.

Additional regulatory measures would include intensified sampling of meat products for analysis of the chemical compound identified in the violation. SENASA would duplicate the amount of samples to be collected for analysis, and normal sampling frequency would resume only after obtaining 16 negative consecutive results.

In May 2011, boneless raw beef trimmings that originated from a Honduran establishment tested positive for violative levels of ivermectin at a United States POE. FSIS notified the CCA of the violation and requested a report on the actions taken by the sectors of the Honduran meat inspection system to effectively correct and prevent recurrence of that type of violation. The CCA reported to FSIS that the violation derived from the fact that cattle suppliers had limited knowledge of proper use of veterinary drugs and had not adhered to the withdrawal period specified in the labels of the parasiticide they used to treat their cattle. Additionally, the CCA reported that the establishment in question had reassessed its HACCP program, as required by CCA and had revised the hazard analysis to include ivermectin as a chemical hazard reasonably likely to occur.

Accordingly, the identified hazard would be prevented by implementing a prerequisite program to verify that cattle suppliers adhere to good production practices and comply with prescribed withdrawal periods for veterinary drugs. The program also included measures to evaluate and classify cattle suppliers in accordance with their demonstrated ability to adhere to good production practices. Personnel from the establishment would evaluate the ranches to classify them as A or B suppliers and to determine the frequency of residue sampling their carcasses would undergo at the establishment. Carcasses derived from cattle from ranches classified as A, good performers, are sampled by the establishment once every 1,200 carcasses, and during the periods of the year when ivermectin is customarily used at greater frequency to control parasites in cattle, once every 400 carcasses. Conversely, carcasses from cattle supplied by B suppliers, poor performers, would be subject to test and hold for all their lots. Furthermore, as reported by the CCA, the program also would require that suppliers provide an affidavit that would attest that they met the establishment's specifications for cattle destined for slaughter.

In-plant officials would ensure that the establishments maintain records of cattle-receiving activities and as part of the corrective actions, verify every day that results of all monitoring activities are documented, and provided to DIA officials during ante-mortem inspection.

Pertaining to the corrective actions implemented by the CCA, FSIS reviewed records documenting that inspection personnel have verified that the establishment identified and removed the lot of product involved in the ivermectin violation from the human food chain. DIA officials then proceeded to follow established protocol and collected product for residue analysis for 16 consecutive production days. The samples were processed by the LANAR, and all were negative for the presence of ivermectin. Along with the modified sampling protocol, in-plant officials were instructed to remain vigilant and react accordingly when pathological signs and tissue changes were observed during ante-mortem and post-mortem inspection. In a joint effort with the establishments, the CCA implemented an additional measure to initiate an educational campaign designed to disseminate information related to proper use of veterinary drugs and the importance of compliance with withdrawal periods for animals presented for slaughter.

However, in July 2011, raw beef products from the same Honduran establishment again tested positive for violative levels of ivermectin and doramectin. As in the prior event, FSIS requested that the CCA provide a report of the corrective actions implemented by the Honduran meat inspection system. The cause of the problem was identified as a breach in the cattle-receiving protocol. A supplier presented for slaughter a group of animals, ten of which had been recently purchased from another rancher who had administered ivermectin to the cattle. During the CCA investigation, additional inadequacies were identified concerning the manner in which the establishment implemented the prerequisite program for receiving cattle. As a result, the CCA suspended the eligibility of the establishment to export raw beef products to the United States in August 2011. The suspension was lifted in September 2011. The CCA verified that the establishment could effectively implement its preventive measures, identification of product lot procedures, and traceability controls for all cattle presented for slaughter.

During this audit, FSIS verified the adequacy of the corrective measures that the CCA put into effect to address the POE violations related to the presence of ivermectin and doramectin in raw beef products. The FSIS auditor observed that establishment employees and inspection officials follow cattle-receiving protocols to prevent cattle that have not adhered to proper drug withdrawal periods from being slaughtered. DIA officials sample and test raw beef products eligible for export to the United States three times per month. Likewise, establishments sample raw beef products in accordance with established protocols for type A and B suppliers and have adjusted tissue sampling frequencies to respond to typical variations in use of parasitocides during the year. The analysis of the samples collected by the establishments is performed at their laboratory, and the results of the analysis are reported to the DIA officials.

The FSIS auditor verified at the LANAR that analysts had completed academic work and specialized training that qualified them to conduct the analytical methods for detection and quantification of ML, e.g., ivermectin, doramectin. The LANAR has responded to the increased demand for ML residue analysis services by purchasing new equipment and training analysts on the corresponding analytical methodology. The CCA also has developed joint outreach activities with establishments to educate ranchers on the proper use of different concentrations of ivermectin and their corresponding withdrawal periods.

FSIS reviewed results of testing conducted by the LANAR in 2012 and noted that the DIA collected and analyzed 1,447 raw beef samples, none of which were violative. In a similar manner, testing conducted by FSIS at United States' POE has not detected violative chemical residues in raw beef products produced by Honduran certified establishments up to the present. The observations conducted by FSIS of the operations at laboratories and establishments make evident that the corrective actions are being adequately implemented. In addition, the HNRP contains provisions for the sampling of tissues of slaughtered animals for the detection of residues that have been identified as potential contaminants. The HNRP however, does not include provisions for the CCA to exert its legal authority to take regulatory action against individuals who introduce violative meat or poultry products into the human food chain.

The CCA officials addressed the above-described finding by immediately drafting a ministerial decree to inform the public of the measures that the SAG of the GOH will institute to deter against the slaughter of animals with violative residues and the processing of adulterated products. Subsequently, FSIS received a copy of Ministerial Decree 330-2013, issued and signed by the Secretary of Agriculture and Livestock of Honduras, in the middle of May 2013. This decree restates the legal authority SENASA has to enforce food safety laws and prohibits delivery of cattle with respect to which there has not been adherence to withdrawal periods prescribed by veterinarians and drug manufacturers to slaughter establishments. In addition, the decree stipulates the regulatory measures that the government authorities will impose upon violators of the ministerial decree.

The Honduran meat inspection system has a chemical residue control program that is organized and administered by the national government to sample and analyze tissues of slaughtered cattle to detect chemical residues identified as potential contaminants. The document analyses and onsite audit verification of the Chemical Residues Control Program component indicate that the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological analysis programs that the CCA of the MISH organizes and administers to verify that meat products destined for export to the United States are unadulterated, 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 microbiological sampling and testing of raw beef products conducted by establishments and laboratories. FSIS also verified the adequacy of the corrective actions implemented by the sectors of the Honduran meat inspection system to address POE violations reported by FSIS in 2010, which related to the presence of *E. coli* O157:H7 in Honduran raw beef products.

The FSIS auditor verified that DIA officials follow standardized instructions for collection, handling, and shipping of samples to the official laboratory to verify the adequacy of pathogen control. Records

reviewed by the FSIS auditor showed that DIA officials verify that establishments adhere to their written program for sampling and testing of carcasses for generic *E. coli* and assess the results in accordance with MIR indicators of adequacy of sanitary dressing procedures. The microbiological laboratory of LANAR audits the establishments' laboratories annually and evaluates the proficiency of their analysts by using test samples on a monthly basis. FSIS reviewed audit reports and records maintained by the laboratory and inspection officials and observed that establishments adequately test and analyze carcass samples. They also confirmed that the results of such testing were within parameters associated with adequate process control.

The CCA also samples and tests raw beef carcasses for the presence of *Salmonella* at slaughter establishments certified to export raw beef products to the United States. DIA officials verify effectiveness of *Salmonella* controls by sampling and testing carcass surfaces. The regulatory measures included in their MIR correspond to the enforcement of pathogen reduction standards stated in 9 CFR 310.25(b). Officials sample designated areas of the carcass and send them to the LANAR. The MAL, in turn, analyzes the samples to detect and quantify *Salmonella* in the samples. FSIS reviewed results of testing and verified that the incidence of *Salmonella* on raw beef carcasses has remained below the performance standard. Furthermore, none of the certified establishments in Honduras have been suspended because of repetitive *Salmonella* positive results.

In reference to the *E. coli* O157:H7 and non-O157 STEC control program being implemented by the Honduran meat inspection system, the FSIS inspector reviewed and observed that the CCA requires establishments to include in their hazard analysis *E. coli* O157:H7 and the six non-O157 STEC strains identified by FSIS as biological hazards reasonably likely to occur in raw beef products. Accordingly, establishments must incorporate measures into their processes to prevent and control the identified hazards. Furthermore, the CCA requires that the establishments design and implement a program to sample and test products that verify the adequacy of the control measures. In accordance with Honduras' *E. coli* O157:H7 and non-O157 STEC control program, establishments are to collect raw beef samples from product identified as eligible for export to the United States and analyze the samples in their own laboratories using a screening method that has been approved and evaluated by the LANAR. In addition, the establishments' laboratories are to be audited by LANAR to verify their compliance with analytical methodology required for detection of *E. coli* O157 and non-O157 STEC and are to notify in-plant DIA of the results of their analyses. In accordance with the program, the laboratories must send all potential positives for *E. coli* O157:H7 to the LANAR for confirmation and consider 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 final results of the testing are obtained. The FSIS auditor reviewed the Honduras' *E. coli* O157:H7 and non-O157 STEC control program, establishments' records, and results of testing conducted in the last three months of production, as well as LANAR and DIA records. The documents' review made evident that LANAR had audited the establishments' laboratories, and that establishments' personnel follow established protocol when product tests positive for the presence of STEC. Additionally, in-plant government officials are notified of testing results, 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 slaughter establishments implement consistent and effective measures to maintain *E. coli* O157:H7 and non-O157 STEC under control. DIA in-plant officials collect samples of non-intact raw beef product in accordance with N-60 sampling protocol and send them to the MAL. As in the case of

establishment testing, each sub-lot of product that is tested by the government is held until LANAR reports the results of the analysis. The CCA program collects samples of non-intact raw beef products at U.S.-eligible establishments for *E. coli* O157:H7 and non-O157 STEC testing. Routine sampling includes 12 samples for *E. coli* O157:H7 and non-O157 STEC per month. However, during the rainy season, DIA officials collect 14 samples per month. FSIS reviewed records maintained by the MAL 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. The FSIS auditor further verified that analysts assigned to the STEC control verification program have been trained and successfully passed third party competency assessments.

In 2009, FSIS laboratory testing of raw beef products from one Honduran establishment at POE detected repeat *E. coli* O157 violations. As a result, FSIS delisted that establishment. Subsequently, in 2010, FSIS again detected repeat *E. coli* O157 POE violations in raw beef products shipped to the United States from the remaining certified Honduras establishment. As in the previous situation, FSIS assessed the risks inherent to the events and delisted that establishment.

In response to the actions taken by FSIS, the CCA of the Honduran meat inspection system investigated the likely root causes for the adulteration of raw beef products and provided FSIS with a report of the corrective and preventive measures that establishments and the DIA implemented. The CCA reported that establishments' dressing procedures had been modified to prevent carcass contamination caused by spillage of ingesta and fecal matter. They also reported that cattle-receiving procedures had been modified to prevent live cattle from tracking fecal matter on their hides and hooves into the slaughter rooms. The report also stated that establishments implemented preventive maintenance protocols for equipment needed to wash cattle at receiving. Employees assigned to perform critical dressing procedures had received training, and their work was monitored to ensure adequate and consistent dressing procedures to prevent contamination of carcasses by ingesta and fecal matter. Additionally, the establishments validated the adequacy of the corrective measures by sampling their products in accordance with the N-60 sampling method and obtaining negative results for the presence of *E. coli* O157. FSIS verified the adequacy of all measures proffered for implementation at the laboratories, establishments, and government offices and observed that personnel of all three sectors of the Honduran meat inspection system were adequately performing their duties and adhering to the protocols introduced by the CCA to prevent recurrence of *E. coli* O157 violations at United States' POE. Raw beef products from Honduran-certified establishments have not tested positive for the presence of *E. coli* O157 or other STEC at United States' POE since the last occurrence reported in 2010 through October 31, 2013.

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 onsite audit verification of the Microbiological Testing Programs component indicate that the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

X. CONCLUSIONS AND NEXT STEPS

Throughout the completion of the onsite verification audit, the CCA provided evidence to the FSIS auditor that the findings in the Sanitation and HACCP components had been addressed by establishments and government officials. FSIS reviewed the written reports and verified that the findings had been adequately addressed. Concerning the Residue Control Program component, in May 2013, the CCA provided FSIS with a copy of the Ministerial Decree issued by the government of Honduras to address the reported finding.

The auditor found that the performance of the meat inspection system of Honduras has improved since the last audit conducted by FSIS in 2010. Findings reported from the FSIS 2010 audit have been adequately corrected, and the Honduran meat inspection system has introduced measures at several steps of the production processes that have effectively prevented recurrence of POE violations. FSIS-POE records show that from September 13, 2012, through October 31, 2013, beef products shipped to the United States from the two certified Honduran establishments were re-inspected, and no food safety violations were found. The onsite verification audit identified only minor concerns with the Sanitation, HACCP, and Residue Control Program components, which the CCA promptly and adequately addressed. Thus, no further corrective actions are required, as reported in the corresponding sections of this report.

The results of this audit and recent FSIS- POE re-inspection of Honduran beef products support the conclusion that the CCA demonstrated that they continue to perform at an “average” level in maintaining their equivalence. The inspection program met the established core criteria for all six equivalence components.

APPENDICES

APPENDIX A: INDIVIDUAL FOREIGN ESTABLISHMENT AUDIT CHECKLISTS

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Empacadora Continental Barrio La Granja 12 Calle, Ave. Juan Pablo II San Pedro Sula, Honduras	2. AUDIT DATE 4/19/2013	3. ESTABLISHMENT NO. 12	4. NAME OF COUNTRY Honduras
	5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM		6. TYPE OF AUDIT <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) 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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		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.	X	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	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
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.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		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	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Honduras Slaughter Establishment No. 12

39. The FSIS auditor observed as the supervisory official evaluated the adequacy of pre-operational sanitation verification conducted by in-plant personnel. The officials demonstrated knowledge and ability to assess the effective implementation of the sanitation program. However, the FSIS auditor noted deficiencies in construction and maintenance of structures that required attention. The main pipe supplying hot water to the deboning room had accumulated corrosion on its surfaces. In some areas, paint had been applied to the corroded surfaces and flakes had started to form that could fall on products placed underneath. Also, there were several dead end pipes at several places in the slaughter room. A review of the SSOPs revealed that the establishment had developed measures to routinely evaluate the facilities and equipment, but had inadequately addressed the corrosion seen on the main hot water pipe and had not considered the presence of dead end pipes as a concern. Inspection personnel indicated that they had not assessed the status of the pipes and proceeded to document the findings and issued a request for corrective action to the establishment. These deficiencies were promptly corrected by the establishment and their acceptability verified by government inspectors.

15. The establishment has developed a HACCP plan and routinely monitors the adequacy of its implementation. Records are generated to documents results of monitoring and verification activities and actions are taken when deviations from the critical control limits occur. However, the corrective actions portion of the written HACCP plan does not address the need to segregate and evaluate affected product when a deviation occurs. Inspectors indicated that even when the plan did not indicate that product would be segregated and evaluated, the company documented corrective actions on a special form that included those actions. FSIS auditor reviewed corrective actions forms for the last three months and verified that in each instance in which a deviation occurred, the establishment isolated and assessed the acceptability of the product.

61. NAME OF AUDITOR
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Empacadora C&D Barrio El Hatillo Catacamas, Olancho Honduras	2. AUDIT DATE 4/16/2013	3. ESTABLISHMENT NO. 4	4. NAME OF COUNTRY Honduras
	5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM		6. TYPE OF AUDIT <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) 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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
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	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		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.	X	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	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
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.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		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	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. STEC control and verification	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Honduras Slaughter Establishment No. 4

58. The establishment conducts screening sampling of beef products to verify the adequacy of Shiga toxin producing *Escherichia coli* (STEC) control and prevention. The method of analysis used does not include a confirmatory step. Therefore, all positives are considered confirmed positive. On February 2, 2013, one product sample tested positive for STEC strain 026. The actions taken in response to that occurrence included the isolation of the involved product and its destruction under government supervision. FSIS auditor reviewed documents related to this event and confirmed that the establishment identified the affected lot of product, notified the in-plant veterinarian and documented steps taken to manage the occurrence. However, no record of the preventive actions that were to be implemented was made. The in-plant veterinarian (IPV) indicated that he would investigate to confirm if the preventive measures had been recorded in another document or if the establishment had not considered the need to develop preventive measures. In both instances, the IPV would document the finding to request that the establishment implemented a corrective action.

15. The hazard analysis conducted by the establishment determined that microbial growth on raw product would be prevented by a pre-requisite program that includes regular monitoring of the temperature of carcasses, fabricated products and chilling and processing rooms. Company employees and government officials monitor implementation of temperature controls and document their findings. Records reviewed by the FSIS auditor corresponding to the last three months of production showed that the temperature control program has worked effectively and no deviations had occurred. However, the documented hazard analysis conducted by the establishment at the carcass chilling step is not consistent with actual production practices. In the hazard analysis, the establishment indicates that the biological hazard, microbial growth, would not occur in the absence of the preventive measures provided by the temperature control program.

The establishment conducts continuous monitoring on line of a CCP to ensure that all carcasses are free of contamination derived from accidental contamination of the carcass with milk during udder removal, and ingesta and feces during dressing procedures. However, in the hazard analysis, at the removal of the udder step of the process, the biological hazards listed are the presence of neoplastic deformities and defects rather than bacterial pathogens.

In response to the occurrence of sarcocystis lesions in beef products imported from Honduras, the establishment was ordered to reassess its HACCP program. The establishment has implemented a sarcocystis prevention program that includes education of ranchers, husbandry practices and periodic technical supervision visits at the ranches supplying cattle for slaughter. However, the hazard analysis documents that sarcocystis is prevented in beef products by examining carcasses and fabricated products, a statement that is not consistent with the actual preventive practice being implemented.

The above described findings were promptly addressed by the CCA. Clarification to errors made during editing of documents and unclear statements were provided by the establishment and the CCA. Corrective actions were implemented and verified as acceptable by in-plant inspection personnel prior to the conclusion of the audit.

61. NAME OF AUDITOR
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

APPENDIX B: FOREIGN COUNTRY RESPONSE TO DRAFT FINAL AUDIT REPORT

SERVICIO NACIONAL DE SANIDAD AGROPECUARIA
SENASA

NOTA.DGS.DIA.513.2014

Tegucigalpa, M.D.C.,
May 30, 2014

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

Dear Doctor Syed:

I appreciate the remission of the draft final audit report on the Food Safety and Inspection Service (FSIS) on-site audit of Honduras' meat inspection system from April 9 through April 25, 2013. 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 Ganadería*
Licda. Ana Gómez-Especialista Agrícola USDA
Dr. Juan Ramón Velásquez-Coordinador DIA-SENASA
Archivo