



United States Department of Agriculture

Food Safety and  
Inspection Service

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

MAY 26 2015

Dr. Josè 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. Reyes:

The Food Safety and Inspection Service (FSIS) conducted an initial equivalence audit of Honduras' poultry inspection system from September 16 – 22, 2014. The objective of the audit was to verify whether Honduras' inspection system for poultry slaughter meets an equivalent level of protection as FSIS' meat inspection system. As you know, a positive equivalence determination is required for Honduras to export raw poultry products to the United States. Enclosed is a copy of the final audit report.

As the next step in its equivalence process, FSIS will develop a proposed regulation to propose to add Honduras to the list of countries in the United States Code of Federal Regulations that are eligible to export raw poultry products to the United States. The proposed rule will be published in the United States *Federal Register*. This proposal will include a 60-day comment period. After the comment period, FSIS will analyze, consider and respond to comments in developing a final rule.

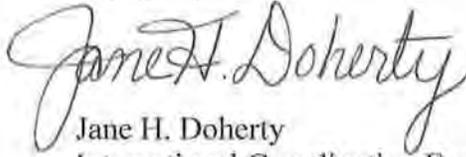
If the rule becomes final, Honduras will provide FSIS with a list of certified establishments that have been determined to be in compliance with FSIS requirements and, therefore, eligible to export raw poultry products to the United States. FSIS cannot provide a specific date at this time, but FSIS is committed to work closely with Honduras as the rulemaking process moves forward.

It is important to note that FSIS only determines the equivalence of a country's poultry slaughter inspection system from a human health perspective. USDA's Animal and Plant Health Inspection Service (APHIS) determines the eligibility of animal products to enter the United States based on the animal disease status of exporting countries. Consequently, Honduras will have to comply with APHIS import requirements prior to exporting raw poultry to the United States.

Dr. Jose Lizardo Reyes Puerto  
Page 2

If you have any questions, please contact the Director of the International Equivalence Staff, Dr. Andreas Keller, via telephone at (202) 690-5646, via facsimile at (202) 720-7990, or via e-mail at [andreas.keller@fsis.usda.gov](mailto:andreas.keller@fsis.usda.gov).

Sincerely,

A handwritten signature in cursive script that reads "Jane H. Doherty". The signature is written in black ink and is positioned above the printed name and title.

Jane H. Doherty  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN INITIAL EQUIVALENCE FOLLOW-UP AUDIT

CONDUCTED IN

HONDURAS

September 16 - 22, 2014

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

Food Safety and Inspection Service  
United States Department of Agriculture

## **Executive Summary**

This report describes the outcome of an initial equivalence follow-up audit of Honduras' poultry inspection system conducted by the Food Safety and Inspection Service (FSIS) from September 16 to 22, 2014. The objective of the audit was to verify whether Honduras employs a poultry inspection system equivalent to that of the United States (U.S.), with the ability to produce poultry products that are safe, wholesome, unadulterated, and properly labeled.

This follow-up audit focused on the ability of the National Plant and Animal Health Service (SENASA), the Central Competent Authority (CCA), to implement effective inspection and control programs related to the production and exportation of poultry products to the United States. The auditor focused on performance within the following six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs. This audit was necessary to assess the effectiveness of the implementation of the corrective action plan proffered by Honduras in response to the findings related to the previous FSIS initial equivalence on-site audit conducted from June 8 to 15, 2009.

Subsequent to the initial equivalence audit conducted in June 2009, Honduras submitted its corrective actions to address FSIS findings. Through analysis of these corrective actions, FSIS concluded that the submitted corrective actions adequately addressed the findings of the 2009 audit. In conjunction with the results of the 2014 follow-up audit, FSIS has concluded that the CCA has adequately addressed all identified issues of concern and is able to meet the FSIS equivalence criteria and requirements related to all six components. Therefore, FSIS will move forward with proposing a rule to list Honduras as a country eligible to export poultry product to the United States.

## TABLE OF CONTENTS

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

## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
IES	International Equivalence Staff
FSD	Food Safety Division
GMP	Good Manufacturing Practices
LANAR	<i>Laboratorio Nacional de Analisis de Residuos</i> , National Laboratory of Residue Analysis
OVI	Official Veterinary Officer
OVS	Official Veterinary Supervisor
SENASA	<i>Servicio Nacional de Sanidad Agropecuaria</i> (SENASA), Ministry of Agriculture and Livestock
SOV	Official Veterinary Supervisor
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
QMS	Quality Management System
VI	Veterinary Inspector

## **1. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an equivalence on-site audit of Honduras' poultry inspection system in 2009. The Agency conducted a follow-up audit to verify that Honduras made necessary changes to its inspection system following that the 2009 audit. The follow-up audit began with an entrance meeting on September 16, 2014 in Tegucigalpa, Honduras, with the participation of the FSIS auditor and representatives from the *Servicio Nacional de Sanidad Agropecuaria* (SENASA), which is the CCA in Honduras. The FSIS auditor was accompanied by representatives from SENASA at the central and regional levels throughout the audit.

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

The objective of the FSIS 2014 initial equivalence follow-up audit was to verify whether the control exercised by the CCA over the implementation of the corrective action plan proffered in response to the findings of the FSIS audit conducted from June 8 to 15, 2009 was adequate. The audit was also designed to determine whether the food safety system governing poultry inspection is equivalent to that of the United States' inspection system. Before conducting the audit, the auditor reviewed the proffered corrective action plan and supporting documents provided by the CCA in response to the 2009 FSIS audit findings. These documents included descriptions of the new control measures and procedures adopted by the Honduran CCA.

The audit focused on the CCA's performance in addressing six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs. Because some of the findings FSIS made during the 2009 audit pertained to microbiological testing and the government's oversight of the laboratory system, these findings are addressed in this report under both the government oversight and microbiological testing program equivalence components.

FSIS assessed the administrative functions of the CCA through review of records and interviews of officials conducted at the CCA headquarters in Tegucigalpa. FSIS evaluated the implementation of the management control system established to ensure that the national inspection system and verification and enforcement strategies operate as intended. FSIS conducted further assessments through observations, interviews, and document review at the government laboratories and at one local inspection office located within one slaughter establishment. FSIS reviewed the administrative functions of the local inspection office as part of the audit of the establishment.

At this point there is only one slaughter establishment that intends to export raw poultry product to the United States. This establishment was audited by FSIS to assess the CCA's ability to provide effective government oversight and consistent inspection measures to meet equivalence criteria.

The auditor paid particular attention to the extent to which industry and government interact to meet the equivalence standards and other requirements; to control hazards, and to prevent non-compliances that could pose risk to the public health. The auditor verified that the CCA provides

oversight through supervisory reviews conducted in accordance with the requirements of 9 CFR 327.2. The outcome of the review was used to determine the effectiveness of the coordination between the different components of the CCA.

Furthermore, the FSIS auditor conducted a review of the government’s official *Laboratorio Nacional de Analisis de Residuos* (LANAR), which supports the microbiological testing program as well as verification of the residue control program. The review was intended to verify that the laboratories that are part of the LANAR perform microbiological and residue testing using analytical methods that are equivalent to the ones used by the FSIS.

### Audit Scope Summary

Competent Authority Visits		No	Locations
Competent Authority	Central	1	▪ Tegucigalpa
	Local office ( <i>In-plant Level</i> )	1	▪ Reviews were conducted as part of the establishment reviews at San Pedro Sula.
Government Laboratories ( <i>Microbiological testing programs and Residue testing programs</i> )		1	▪ National Laboratory of Residue Analysis – LANAR (Tegucigalpa)
Poultry Slaughter Establishment		1	▪ San Pedro Sula

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

This initial equivalence follow-up audit verified whether Honduras maintains requirements equivalent to the following U.S. laws and regulations:

- The Poultry Products Inspection Act (21 U.S.C. 451 et. seq.)
- The Poultry Products Inspection Regulations (9 CFR parts 381 et. seq.)
- The Food Safety and Inspection Service Regulations (9 CFR, Chapter III, Subchapter A, Part 416 and Part 417)

The audit standards included all applicable regulations and procedures originally determined to be equivalent by the FSIS during the initial document review process. The legislation and regulations review included:

- The Phytosanitary Law (Animal Health Law) No. 157-94
- The Phytosanitary Law No. 157-94 as modified by Decree No. 344-2005, Guidelines for Procedures for the Inspection of Meat Products (DIA-GIPA-05)
- Regulations on the Inspection, Slaughter, and Industrial Treatment of Poultry Products (Agreement No. 552-05), and the SENASA Law Order No. 558-01

### 4. BACKGROUND

In November 2003, Honduras submitted an initial equivalence application and requested that

FSIS conduct a review of the Honduran poultry slaughter inspection system to establish eligibility to export raw poultry to the United States.

Following the document review process, FSIS conducted the first initial equivalence on-site audit of Honduras' poultry slaughter system in November 2005.

The audit identified findings in the following equivalence components:

- *Government Oversight:* The establishment did not provide a helper for each SENASA post-mortem inspector. The CCA did not properly stage the required number of post-mortem inspectors at the evisceration line.
- *Sanitation:* During pre-operational sanitation verification inspection procedures, all shackles checked within a 15 foot section of the slaughter line were observed with protein residue, fat particles from the previous day's production, and dried paint droplets.
- *HACCP:* Records documenting actions taken in response to a deviation from a critical limit did not include measures to prevent recurrence of the deviation. Records were not available documenting actions taken in response to a deviation from the critical limit for temperature in the fresh poultry cooler.

The CCA provided corrective actions that addressed all of these audit findings, either at the time of the finding, or subsequent to the distribution of the Final Audit Report, on March 7, 2006.

In June 2009, FSIS conducted a second initial equivalence on-site audit. The auditor verified that the proffered corrective actions from the 2005 audit were implemented effectively, and the auditor determined that the corrective actions were acceptable.

#### FSIS 2009 Audit of Honduras' Poultry Slaughter Inspection System

The 2009 audit, however, identified findings in the following equivalence components:

##### *Sanitation:*

- The establishment uses three private wells for its water supply. Honduran legislation requires that a chemical analysis of the water potability be conducted every six months. However, the auditors found that a chemical analysis of the potability of the establishment's water supply had only been conducted once a year.
- There were several holes, approximately one inch in diameter, in the ceiling above the poultry chilling tank.
- A production line employee's work clothing routinely came into contact with product and food contact surfaces.

##### *Hazard Analysis and Critical Control Point System:*

- The establishment did not follow the frequency of their verification procedures as written in the establishment's HACCP plan.
- The establishment's verification records did not document the type of verification procedures it conducted or the results of the verification procedures.
- Establishment monitoring records did not include the initials of the responsible establishment employees making the entries.

*Microbiological Testing Programs:*

- Some of SENASA's laboratory sample tracking records were signed and initialed by a supervisor, indicating supervisory review, before the sample analysis had concluded. Moreover, not all records were signed and initialed. These findings suggest that supervisory oversight in the laboratory was not conducted appropriately.
- Some of SENASA's laboratory temperature monitoring logs did not have corrective action information documented when there was a deviation from the set temperature on incubators.

The CCA provided a corrective action plan that adequately addressed all of the previous audit findings. The proffered corrective actions included new regulations, procedures, implementation measures, and verification activities that were designed to ensure uniformity in conducting the official inspection activities. Consequently, FSIS decided to conduct a follow-up audit to assess the effectiveness of the implemented corrective action measures. This follow-up audit focused primarily on verifying the implementation of the corrective actions taken to address the previous audit findings rather than the aspects of the inspection system that were determined to be meeting the FSIS equivalence criteria.

## **5. GOVERNMENT OVERSIGHT**

The first of the six components reviewed by the FSIS auditor was Government Oversight. This component addresses the requirement for the inspection system to be organized and administered by the national government and employ standards equivalent to those of the federal system of poultry inspection in the United States. FSIS evaluated and verified whether Honduras met these requirements through interviews of government officials and reviews of inspection records. The auditor assessed the CCA's ability to effectively communicate requirements throughout the inspection system

The director of SENASA is the Chief Veterinary Officer (CVO), and SENASA administers the Honduran poultry inspection regulations. The in-plant inspection of poultry and poultry products is conducted by the Food Safety Division (FSD). The Phytosanitary Law No. 157-94 grants SENASA-FSD the authority to certify and decertify an establishment's eligibility to export product to the United States. The salaries of official inspection personnel are paid directly by the national government from allocations that are established in SENASA's budget. All inspection personnel that are assigned to establishments are either permanent employees of the government of Honduras, or they are contractually employed by the government of Honduras.

The SENASA-FSD's veterinary officials are responsible for the oversight and administration of the hiring, the training, the assigning, and the overseeing of inspection personnel. This training program includes training in HACCP, SSOP, animal welfare, and food chemistry, as well as, ante-mortem inspection and post-mortem inspection procedures. Veterinary and non-veterinary government inspectors are required to attend inspection training courses before they are assigned to an establishment. There are also requirements for training in the field before being assigned to a slaughter or processing establishment that are described in *Guidelines for Procedures for the Inspection of Meat Products* (DIA-GIPA-05). The auditor obtained and verified the accuracy of this information during the previous audit in 2009 and re-verified the accuracy of this information during this verification audit.

The Official Veterinary Inspector (OVI) is present in the establishment carrying out inspection duties whenever the establishment is operating. The OVI conducts inspection on a daily basis and is on the line during slaughter operations and records his or her observations on the "Weekly Analysis Schedule/CIS-01" form. This form requires the OVI to verify aspects of the establishment's SSOP, SPS, Good Manufacturing Practices (GMP), HACCP, and other programs, including sampling procedures, analytical results of laboratory testing, and equipment calibration. The auditor reviewed samples of the CIS-01 form and verified that these inspection tasks are conducted as described.

The requirement for periodic supervisory visits is mandated in the *Guidelines for Procedures for the Inspection of Meat Products* (DIA-GIPA-05). SENASA relies on periodic supervisory visits, performed at least on a quarterly basis (as determined by the CCA) by the Official Veterinary Supervisor (SOV) to verify whether inspectors conduct necessary inspection activities in the establishment. The reviewing official uses a checklist while conducting reviews, and if he or she finds non-compliance during one of these visits, the official issues a Corrective Action Demand (DAC). The next supervisory visit includes a more targeted focus on the effectiveness of the corrective action. The auditor verified the regular performance of these visits by randomly selecting six months of records for review. These documents, titled "SI-PA-05", documented the procedures followed by the supervisor and included examples of procedures taken after non-compliances were found.

The information gathered during this follow up audit demonstrates that the SENASA-FSD has ultimate control and supervision over the official activities of all program employees or licensees.

As established in Order No. 588-01, Article 16, the SENASA-FSD also has direct oversight over the activities of the National Laboratory of Residue Analysis (LANAR), the official government laboratory that provides sample analysis for chemical and microbiological testing of meat and poultry products. Honduras has employed a private laboratory in Costa Rica, LAMBDA, to confirm and quantify antibiotic chemical residue samples that return a violative result for antibiotics. SENASA has provided documentation that demonstrates their adequate oversight of the laboratory, the capability of the laboratory to perform the necessary analyses, accreditation, and direct reporting of analytical results to SENASA.

The auditor reviewed records for oversight of both laboratories and verified that there is effective

government oversight at both. The activities of the LANAR and LAMBDA laboratories are discussed further in the Chemical Residue Program and Microbiological Testing sections below.

SENASA requires that all establishments that intend to become eligible for U.S. export to develop and implement product recall procedures that will be incorporated into their production system. SENASA provides direct government oversight of recall systems and verifies that the systems have been effectively implemented. There are specific criteria that establishments must incorporate into their recall system. For example, establishments are responsible for identifying the need for a recall and for defining the classification of the recall. The SENASA inspector in the plant is consulted on the recall classification, and must agree with the classification for the establishment to proceed.

The establishment is responsible for informing the public of product that is to be recalled. The public is informed by means of radio, television, and print media. When the decision is made that a recall is necessary, SENASA is immediately informed, and SENASA remains aware of proceedings throughout the recall process. SENASA is made aware of the identity of the product to be recalled, the reason for the recall, and the volume of the product, geographic distribution, communications between the company and all interested parties, as well as the contact information for the company's recall coordinator. SENASA reviews all recall records on a monthly basis as part of their routine verification activities as described in the "Official Monthly Plan" (DIA-CMAI-12). It verifies that all retailers or facilities that received adulterated or misbranded product were notified, and that misbranded or adulterated product was properly disposed of. SENASA's verification of recall records are included in PART XIII - Procedures for the Recall of Products in the Guide for the Inspection of Poultry Products (DIA-GIPA-05).

The one audited establishment that is seeking export eligibility has developed a computer based recall system that uses the same recall classification as that used by FSIS, i.e., Class 1, 2, and 3, and uses the criteria established by FSIS. This program uses a unique barcode that is capable of tracing backwards to identify the farm from which the poultry originated, as well as where the finished product to be recalled was sent.

The auditor discussed this program with the Coordinator of the FSD at SENASA headquarters in Tegucigalpa and was given an abbreviated demonstration of the program in the establishment. The auditor was informed that, at that point in 2014, the recall system had been simulated once and had actually been put into effect once for product that had been exported to Guatemala. The auditor reviewed SENASA's verification records and concluded that this program is implemented and functioning as documented.

FSIS has concluded that Honduras' poultry inspection system meets the equivalence requirements for this component.

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

The second of the six equivalence components that the FSIS auditor reviewed was Statutory

Authority and Food Safety Regulations. The inspection system must be organized and administered by the national government of the foreign country. The system must provide for ante-mortem inspection of birds; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; and periodic supervisory visits to the inspection system.

The headquarters in Tegucigalpa and one local inspection office in San Pedro Sula were audited in order to review the legislation associated with this component.

The FSIS review of the oversight activities carried out at the headquarters and at a regional office determined that the CCA has a single set of rules, that the CCA has legal authority and responsibility to enforce inspection regulations, and that the CCA enforces requirements that ensure that adulterated or misbranded products are not exported to the United States.

The primary laws for regulating poultry inspection in Honduras are the *Phytosanitary Law* (Animal Health Law) No. 157-94, which was later modified by Decree No. 344-2005; *Guidelines for Procedures for the Inspection of Meat Products* (DIA-GIPA-05); Regulations on the Inspection, Slaughter, and Industrial Treatment of Poultry Products (Agreement No. 552-05); and the SENASA Law Order No. 558-01. These laws provide the operational and regulatory authority to SENASA. The FSIS review of specific regulations based on these laws concerning the registration of slaughter establishments, inspection activities, and import-export requirements verified that the CCA has a clear legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded poultry products are not exported.

Honduras' requirements for ante-mortem and post-mortem inspection procedures are conducted as required in the *Regulations on the Inspection, Slaughter, and Industrial Treatment of Poultry Products* (Agreement 552-05), Chapter VII, Articles 111 and 112. The *Guidelines for Procedures for the Inspection of Meat Products* (DIA-GIPA-05) is a form that provides instruction to field personnel. It re-states and elaborates upon the requirements cited above, as well as describes the requirements for establishment construction, facilities, and equipment. Inspection personnel are required to condemn poultry carcasses or poultry products that fail to meet inspection standards according to this legislation and these inspection guidelines. These regulations also provide a specific description of the condemnation bins, detailing how they are marked to differentiate them from containers intended for edible product. After reviewing these documents, the auditor concluded that they provide detailed instructions on how inspection officials are to perform these inspection tasks.

The 2009 audit verified that SENASA has the legal authority and the regulatory framework to impose regulatory requirements related to good commercial practices, ante-mortem and post-mortem inspection, control over the establishment construction and processes, and measures to ensure that supervisory reviews emphasize the oversight related to competence of the inspection program personnel related to essential inspection components.

The 2014 FSIS audit verified that SENASA retains the necessary legal authority and regulatory framework to maintain Honduras' poultry inspection system.

FSIS has concluded that Honduras' poultry inspection system continues to meet the equivalence requirements for this component.

## 7. SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. This component requires that the inspection system include measures that address the sanitation operation requirements, the sanitary handling of products, as well as the development and implementation of Sanitation Standard Operating Procedures (SSOPs). Honduras' poultry inspection system requires that all official establishments meet all of the sanitation requirements.

In the 2009 audit the auditor reviewed Honduras' requirements for sanitation, described in Agreement 552-05, and the inspector's tasks relative to these requirements, which are defined in DIA-GIPA-05. That review verified that the CCA's sanitation requirements were equivalent to those implemented and enforced by FSIS in 9 CFR Part 416 – Sanitation.

The 2009 audit resulted in the following finding:

1. A review of the establishment's production practices showed that a production line employee's work clothing routinely came into contact with product and food contact surfaces. As described in *Guidelines for Procedures for the Inspection of Meat Inspection* (DIA-GIPA-05), the official veterinary inspector or the inspector's assistants, have authority to request the change of clothing whenever it seems necessary to prevent the creation of an insanitary condition. Neither inspection personnel nor establishment management instructed the employee to change his work clothing before returning to the production line either by inspection personnel or the establishment management.

Honduras provided a corrective action that addressed this finding and assigned a specific employee to ensure that the establishment's Good Manufacturing Practices (GMP) are enforced appropriately. This monitoring activity is designed to prevent such an occurrence and is recorded on the form FCC BPMS A5-01-07. SENASA's OVI verifies that these activities are carried out in order to ensure that cross contamination is avoided. This verification act is recorded on the CIS-01 form and is verified during the periodic supervisory visits. This supervisory activity is recorded on the DIA-HA-05-08 form.

During the 2014 verification audit the auditor reviewed 6 months of DIA-HA-05-08 forms. The review of this documentation verified that the corrective actions are being enforced as documented.

2. The 2009 audit showed that the establishment uses three private wells for its water supply. According to Article 61 of DIA-GIPA-05, the equipment or sinks used to wash poultry or poultry products must be equipped with potable cold and/or hot water. Article 68 of DIA-GIPA-05 states that every six months the plant must conduct a chemical analysis that allows SENASA to evaluate the potability of the water. This requirement is repeated in Agreement 552-05, with the addition of meeting the equivalent requirement

of importing countries. The potability of the water supply had been tested once a year by the establishment.

Honduras provided a corrective action that addressed this finding. To verify potability of the water supply, SENASA collects microbiological samples every three months and chemistry samples every six months. If the analysis of any sample returns a violative level, the government inspector issues a Corrective Action Demand (DAC) and collects samples for three consecutive months. These samples are submitted to the LANAR for analysis. If any of these follow-up samples are violative, then the establishment cannot use the water supply for production purposes until it can show that the water supply meets potability standards. The results of these chemical analyses are documented on form IRA-31.

During this verification audit the auditor reviewed six months of documentation and verified that the corrective actions are being implemented as documented.

3. The 2009 audit identified that the ceiling above the poultry chilling tank had several holes approximately one inch in diameter. In DIA-GIPA-05 Part II, Construction, Article 60, Number 23 it is mandated that the ceilings, and other suspended installations must be designed, constructed, and finished in such a manner that they block the accumulation of dirt, reduce, and block condensation and the formation of undesired mold and particles. Article 71 of Agreement 552-05 stipulates that the ceiling must be of impermeable, easy to clean material.

Honduras provided a corrective action that addressed this finding. As a temporary fix, the establishment filled the holes with silicon until replacement panels could be acquired. The replacement panels were obtained and put in place within a few days. The OVI began performing monthly verifications of the overall SPS condition of the establishment and recording this verification on CIS-01 form Section A: SSOPs, SPS #4 "Evaluation of Internal Structures (Walls, Doors, Floors, Ceilings and Others)".

During the 2014 verification audit the auditor reviewed six months of documentation and observed the ceiling above the chiller during pre-operational inspection. The auditor found that the verification activities performed by the OVI are being conducted as documented, and the ceiling has been repaired in good order. The auditor verified that the overall construction and maintenance of the establishment met the standards of the Honduran regulations that FSIS has determined to be equivalent.

The auditor verified that the SENASA-FSD's verification and inspection functions were appropriately performed by observing pre-operational and operational production activities; by 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 establishment's sanitation programs. The auditor reviewed the SENASA-FSD records to verify that inspection personnel ensure that the establishment consistently follows its sanitation program by identifying sanitary deficiencies, requiring corrective actions when necessary, and verifying their implementation and effectiveness.

Thus, the auditor found that the establishment's corrective actions had improved its sanitary procedures and environment. Overall, sanitary conditions are maintained in the establishment, and the production of poultry products is conducted in a manner that prevents direct contamination of product.

FSIS has concluded that Honduras' poultry inspection system meets the equivalence requirements for this component.

## **8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM**

The fourth of the six equivalence components that the FSIS auditor reviewed was the Hazard Analysis and Critical Control Point (HACCP) system. This component addresses the inspection system's ability to ensure that each official establishment develops, implements, and maintains an effective HACCP system. The FSIS assessment showed that SENASA met the requirements for this component.

FSIS audited the headquarters in Tegucigalpa and local inspection office in San Pedro Sula to review the legislation associated with this component, as well as to assess the CCA's ability to effectively communicate these requirements throughout the inspection system. The auditor reviewed Honduras' procedures for implementation and maintaining a HACCP plan, including verification procedures as described in *Guidelines for Procedures for the Inspection of Meat Products* (DIA-GIPA-05), *Regulations on the Inspection, Slaughtering and Industrialization of Poultry and By-Products*, Phytozoosanitary Law Decree No. 344-2005, and SENASA Law 588-01.

During the 2009 audit, the auditors reviewed Honduras' procedures for implementing and verifying a HACCP plan in both headquarters and a local inspection office. The auditors reviewed Honduras' inspection instructions and HACCP related inspection records maintained by the local inspection office having regulatory oversight of the audited establishment. The auditors also observed how inspection personnel implement and verify establishment compliance with the HACCP equivalence component. This record review and interview of the inspection personnel resulted in the identification of three non-compliances for the HACCP component:

1. In 2009, the frequency of verification procedures was not followed as written in the establishment HACCP plan.

Honduras provided a corrective action that addressed this finding. Honduras required that the establishment reassess its HACCP plan and determine whether the frequency of the verification procedures identified in the plan was appropriate to manage the specified hazards. The reassessment included the establishment's Quality Management review of the history of HACCP verification frequencies and has assured SENASA that the prescribed verification frequencies will be followed. The SENASA inspection performs verification of the establishment's HACCP plan to ensure that the plan is being followed, and that verification procedures are being followed as stated by the establishment.

During the 2014 verification audit the auditor reviewed the establishment's HACCP plan and SENASA's verification of the plan as well. This review verified that the prescribed frequency of

verifications was being followed.

2. In 2009, verification records did not document the type of the verification procedures and the results of the verification.

Honduras provided a corrective action that addressed this finding. The establishment modified its verification records so that the type of verification procedures that were conducted as well as the results of those verifications are included.

During the 2014 verification audit the auditor reviewed three months of verification records. This review verified that the HACCP verification records were modified as documented. The auditor verified that the inspectors were performing the appropriate verification tasks, recording the results of those tasks, documenting violations, and the follow up activities taken to resolve those violations.

3. In 2009, monitoring records did not allow for the responsible establishment employees verifying the records to identify themselves.

Honduras provided a corrective action that addressed this finding. The establishment has reformatted its monitoring records and now includes an entry for the establishment employees to identify themselves by signing their names. This reformatted document now allows for the responsible employees to acknowledge their verification of the record. The SENASA inspectors are aware of the revision to this document. The SENASA inspectors are verifying that establishment employees perform their HACCP plan monitoring activities at the prescribed frequencies and are identifying themselves as having performed their monitoring activity.

During the 2014 verification audit the auditor reviewed three months of records and verified that the records had been reformatted as described, and that the responsible employees were identifying themselves as having verified the records. The auditor confirmed that the SENASA inspectors are verifying that the establishment employees are identifying themselves as having performed the HACCP plan monitoring activities as required by SENASA.

Overall, the HACCP program is effectively implemented in this establishment, and the documentation substantiates the auditor's determination. Records reviewed showed that oversight of the HACCP plan is regularly maintained by the establishment and verified by the government inspector assigned to the establishment.

FSIS concluded that Honduras' poultry inspection system meets the equivalence requirements for this component.

## **9. CHEMICAL RESIDUE PROGRAMS**

The fifth of the six equivalence components the FSIS auditor reviewed was Chemical Residues. The inspection system is required to have a chemical residue control program that is organized and administered by the national government. To be equivalent to FSIS's program, the residue control program needs to include random sampling of meat, internal organs, and fat of carcasses for chemical residues identified by either the exporting country's meat inspection authorities or

by FSIS as potential contaminants. The program must include an effective enforcement action that addresses handling and disposition of contaminated product and measures to deter repeat violators.

To assess Honduras' ability to meet the equivalence requirement of this component, the FSIS auditor conducted a review of the SENASA headquarters in Tegucigalpa and the LANAR laboratory. The FSIS auditor interviewed the CCA officials and reviewed the testing methods, enforcement strategies, and communication tools used within the laboratory system.

The 2014 verification audit confirmed that Honduras performs chemical residue samplings and analyses using internal organs, muscle, and fat as appropriate matrices to detect chemical residues that are of concern. The auditor reviewed analytical records to verify that Honduras's chemical residue program is equivalent. The auditor conducted interviews at the CCA to get a complete understanding of the steps it takes to ensure that the chain of custody of samples is documented, and that if there is evidence of sample tampering, the sample is rejected. The auditor also verified these steps as described during the audit of the LANAR laboratory. This verification audit confirmed that all of the above activities are being performed as documented.

LANAR has implemented a Quality Management System (QMS) to regulate the activities of the laboratory. The QMS is a computer based program that applies a unique code to each sample that guarantees that the analytical results are reported accurately. This sequence of events begins with the receipt of the sample to be analyzed and is traced throughout the entire process of analysis. The analysts input information about the sample as it moves through each individual area of responsibility. Only the LANAR management can access the program such that the entire process of reception and analysis can be overseen and documented as completed.

Additionally, paper based records are maintained by each section of the laboratory that show that analytical activities have been completed, and that the sample has then moved to the next section of the laboratory. While performing the audit of the LANAR laboratory, the auditor performed a walkthrough of the laboratory to observe the processes for the receiving of an actual sample for analysis. During the walkthrough the auditor followed every step that is taken throughout receiving, sample processing, and analysis. The auditor verified that each step of the process is accurately recorded as described.

The auditor reviewed a selection of records verifying the proficiency testing of laboratory technicians. The laboratory verifies the analysts' proficiencies on at least a yearly basis. Analysts are given blind check samples to analyze while running normal analyses, so they never know when they are being tested for proficiency. The auditor's review verified that the laboratory technicians are tested as described and are proficient in their analytical capabilities. The auditor checked these records during the audit of the LANAR laboratory as well.

The LAMBDA lab in Costa Rica is under contract with SENASA. The LAMBDA laboratory performs analyses to detect violative levels of antibiotics for SENASA. The LAMBDA laboratory is ISO 17025:2005 accredited to perform this analysis. The LAMBDA laboratory immediately notifies SENASA of any violative results via email. No other entity is involved in the notification of these analytical testing results. The auditor reviewed the accuracy of

SENASA documents reporting the most recent violative analytical results and records verifying the ISO 17025 accreditation of the laboratory as well as proficiency records of the analysts at the laboratory.

SENASA audits the LAMBDA laboratory at least once a year. The auditor reviewed records of SENASA's most recent audit (June 19, 2014) and verified that SENASA maintains oversight of laboratory activities as they relate to Honduras' antibiotic analyses.

Based on review of the official and private laboratory documents maintained at headquarters and in the LANAR laboratory, the auditor verified that official oversight of both laboratories is maintained. The auditor verified that all records are maintained appropriately, and that chain of custody is maintained throughout.

During preparatory review for this verification audit, the auditor noted that Honduras does not account for sampling and analysis for arsenicals in its National Residue Program. The auditor asked SENASA for an explanation for the absence of this chemical. SENASA explained that up until 2012 there were samplings for arsenic being conducted. SENASA has researched this issue and has shown that there has never been a quantifiable result for this chemical. Further, in 2005 there was one arsenical that was approved (Roxarsone) for use in Honduras. This drug was approved for a three year period. The approval period ended in 2008, and since then there have been no additional requests for the approval of Roxarsone or any other arsenical. SENASA's supervisory visits to feed producing plants have verified that there are no arsenicals used in the production of feed for poultry. For these reasons, Honduras no longer includes arsenicals in their annual chemical residue program.

Additionally, during preparatory review, it was noted that Honduras has listed only seven antibiotics in its residue testing program. SENASA explained that while the analytical method has the ability to detect several families of antibiotics, only the top seven used are reported in its national program. Overall Honduras does conduct surveillance of other antibiotics used. If a different antibiotic returns violative levels at rates higher than any of the current top seven reported, that antibiotic will become one of the top seven identified in the residue program.

FSIS concluded that Honduras' poultry inspection system meets the equivalence requirements for this component.

## **10. MICROBIOLOGICAL TESTING PROGRAMS**

The sixth, and last, equivalence component that the FSIS auditor reviewed was the Microbiological Testing Program employed by the CCA. This component pertains to the regulatory requirement that the inspection system have a microbiological testing program that is organized and administered by the national government. The sampling and testing program must verify that establishments have food safety systems that produce poultry products intended for export to the U.S. that are safe, wholesome, and unadulterated. In particular, the microbiological testing program needs to include:

- Provisions for the establishments' sampling and testing program for generic *E. coli* or indicator organism. The testing results are to be used to verify the establishments' slaughter processing and dressing controls.
- Provisions for inspector *Salmonella* and *Campylobacter* sampling and a testing program in raw product, which includes *Salmonella* and *Campylobacter* performance standards. The inspection system should achieve pathogen reduction by ensuring that all slaughter establishments meet the *Salmonella* and *Campylobacter* Performance Standards.

During the 2009 audit, the auditors interviewed SENASA personnel and reviewed relevant laboratory records including analyst qualifications, sampling protocols, testing methods, test reporting procedures, enforcement strategies, and communication tools. During the audit of the LANAR laboratory the following finding was noted:

- Some of the laboratory tracking records were signed and initialed by a supervisor indicating supervisory review before the sample analysis process had concluded.

Honduras has provided a corrective action that addressed this finding. The QMS system that is implemented for the chemical residue analysis is also implemented for microbiological analysis. The auditor reviewed records at each step verifying that this system works in the same manner as that described in the Chemical Residue section of this report.

- Some of the temperature monitoring logs in the laboratory did not have corrective action information documented when there was a deviation from the set temperature in incubators. The CCA notified the auditors that the proper corrective action was taken and recorded. The auditors were not able to verify this claim based on document review.

Honduras has provided a corrective action that addressed this 2009 finding. The LANAR laboratory only considers temperature violations as such whenever there are samples inside the incubators. LANAR now identifies in its daily records when there are samples inside the incubators when performing temperature monitoring activities. SENASA verifies that this process works during its annual audit to ensure that the results are being recorded accurately.

The 2014 verification audit verified that the corrective actions have been implemented as documented.

SENASA monitors the establishment's generic *Escherichia coli* (*E. coli*) requirements for poultry. SENASA has implemented generic *E. coli* requirements consistent with the FSIS regulations. The auditor verified that the CCA's testing program has been implemented as documented.

SENASA has regulatory requirements including sampling and enforcement strategies for testing programs related to *Salmonella* species. The inspection personnel follow the FSIS sampling protocol, which includes testing frequency, carcass rinse sample collection, and the delivery of samples to the laboratory. The sample analysis is performed using the *Salmonella* method as described in the FSIS Microbiological Laboratory Guidebook for isolating and identifying *Salmonella* in meat and poultry products. The LANAR laboratory reports the test results to

SENASA.

Currently, SENASA has implemented *Salmonella* and *Campylobacter* performance standards for raw chicken carcasses that are consistent with 9 CFR 381.94 and FSIS Directive 10250.1 respectively. These standards ensure that Honduran slaughter establishments are maintaining consistent process controls verifiable by SENASA through moving sample collection windows.

In the event that an establishment exceeds either of these standards during a sampling window the establishment must take corrective actions. After the corrective actions are implemented, the sampling window starts again. Should there be a second deviation for either performance standard during this sampling, the establishment is required to reassess its HACCP system for raw chicken product. After the reassessment is completed a third sampling window begins. A third failure for either performance standard will result in a suspension of inspection services, effectively stopping the establishment's activities. During this time, the establishment must conduct an investigation to determine the cause of the failures.

After the establishment has identified the root cause of the sample failures and verified that the causes have been addressed, it must provide written verification to the inspection service that the deficiencies have been corrected. After these steps have been taken, the establishment may begin operations again, and government inspection will return. The auditor reviewed documentation at the CCA headquarters, at the LANAR laboratory, and at the establishment. The auditor verified that SENASA's verification activities are taking place as documented, and that the process controls are sufficiently maintained by the establishment.

The 2014 verification audit confirmed that Honduras performs microbiological samplings and analyses to detect pathogens that are of concern. The auditor verified this through the review of analytical records. The auditor also interviewed the CCA to get a complete understanding of steps taken when samples are received at the laboratory to ensure chain of custody and to verify that if there is evidence of sample tampering, the sample is rejected. The auditor also verified these steps during the audit of the LANAR laboratory.

FSIS concluded that Honduras' poultry inspection system meets the equivalence requirements for this component.

## **11. EXIT MEETING**

An exit meeting was held on September 22, 2014, at SENASA headquarters in Tegucigalpa and was attended by representatives from SENASA and the LANAR laboratory. During this meeting, FSIS presented the observations of the audit, confirmed that all corrective actions from the 2009 audit were implemented as described and reported that there were no additional findings.

## **12. CONCLUSIONS**

The 2014 follow-up audit verified that SENASA has appropriately implemented the corrective action plan proffered in response to the findings of the FSIS audit conducted from June 8 to 15, 2009. FSIS has verified that SENASA exercises adequate control over the execution of inspection programs. The audit did not identify systemic findings that would adversely impact

Honduras' poultry inspection system's ability to meet the equivalence criteria and other FSIS import requirements.

### **13. ATTACHMENTS TO THE AUDIT REPORT**

Honduras' response to the FSIS audit report



SERVICIO NACIONAL DE SANIDAD AGROPECUARIA  
SENASA

NOTA.DGS.DIA.150.2015

Tegucigalpa, M.D.C., March 23, 2015

PhD  
**ANDREAS KELLER**  
Director  
International Equivalence Staff (IES)  
OPPD, FSIS, USDA  
Washington, D.C.

Dear Doctor Keller:

Please find the attached SENASA's comments to the draft final audit report of the assessment conducted by the Food Safety and Inspection Service (FSIS) to the Honduras' poultry slaughter inspection system in the period from September 16-22, 2014 to verify whether the system could be determined equivalent to FSIS' inspection system in order to export raw poultry products to the United States. The attached document contains minor corrections to the report; however, SENASA has no major comments on the document and we expect that the final audit report be submitted soon.

I would like to take the time to thank the support you and your team have provided to conclude this technical process and hope to continue our joint collaboration. At the same time I would like to reassure our commitment in maintaining our inspection system as it has been evaluated by FSIS in order to guarantee the safety and wholesomeness of our products.

Finally, I will appreciate your efforts into moving forward with the final rule process to list Honduras as a country eligible to export poultry products to the United States, which we hope to complete in the short term.

Sincerely,

**DR. JOSÉ LIZARDO REYES PUERTO**  
General Director of SENASA

cc: *Ing. Jacobo Paz-Secretario de Estado Agricultura y Ganadería*  
*Dr. Juan Ramón Velázquez-Coordinador DIA SENASA*  
*Licda. Ana Gómez-Especialista Agrícola FAS USDA Embajada EE.UU. en Honduras*  
Archivo

## 1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an initial equivalence on-site follow-up audit of Honduras' poultry inspection system in 2009. This follow-up audit was conducted to verify that Honduras made necessary changes to its inspection system following that audit. The follow-up audit began with an entrance meeting on September 16, 2014 in Tegucigalpa, Honduras, with the participation of the FSIS auditor and representatives from the ~~Secretaría de Agricultura y Ganadería~~ **Servicio Nacional de Sanidad Agropecuaria (SENASA)**, which is the CCA in Honduras. The FSIS auditor was accompanied by representatives from SENASA at the central and regional levels throughout the audit.

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

The audit standards included all applicable regulations and procedures originally determined to be equivalent by the FSIS during the initial document review process. The legislation and regulations review included:

- The Phytosanitary Law (Animal Health Law) No. 157-94
- The Phytosanitary Law No. 157-94 as modified by Decree No. 344-2005, Guidelines for Procedures for the Inspection of Meat Products (DIA-GIPA-05)
- Regulations on the Inspection, Slaughter, and Industrial Treatment of Poultry Products (Agreement No. 552-05), and the SENASA Law Order No. 558-01
- ~~Traceability and Recall Program PTR A5-12-13.~~

SENASA requests this document to be deleted from the list of regulatory audit standards since this document PTR-A5-12-13 is the Traceability and Recall Program implemented by the establishment. SENASA assessed the design of the program and routinely verifies it's implementation.

## 5. GOVERNMENT OVERSIGHT

Since the 2009 audit, ~~Honduras~~ the establishment has developed a computer based recall system that is directly approved and overseen by SENASA. This system is described in a document titled "Traceability and Recall Program PTR A5-12-13." The establishment is responsible for identifying the need for a recall, and for defining the classification of the recall. The SENASA inspector in the plant is consulted on the recall classification, and must agree with the classification for the establishment to proceed. The classification is the same as that used by FSIS, i.e., Class 1, 2, and 3, and uses the same criteria established by FSIS. This program uses a unique barcode that is capable of tracing backwards to identify the farm from where the poultry originated, as well as where the finished product to be recalled was sent.

The primary laws for regulating poultry inspection in Honduras are the *Phytosanitary Law* (Animal Health Law) No. 157-94, which was later modified by Decree No. 344-2005; *Guidelines for Procedures for the Inspection of Meat Products* (DIA-GIPA-05); *Regulations on the Inspection, Slaughter, and Industrial Treatment of Poultry Products*

(Agreement No. 552-05); and the SENASA Law Order No. 558-01. These laws provide the operational and regulatory authority to SENASA. The FSIS review of specific regulations based on these laws concerning the registration of slaughter establishments, inspection activities, and import-export requirements verified that the CCA has a clear legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded poultry products are not exported.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Pollo Rey - Santa Cruz	2. AUDIT DATE 9/18/14	3. ESTABLISHMENT NO. A-5	4. NAME OF COUNTRY Honduras
5. NAME OF AUDITOR(S) David Smith		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		
<b>Sanitation Standard Operating Procedures (SSOP) 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		
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.			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 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.		
30. Corrective Actions			59.		
31. Reassessment					
32. Written Assurance					

60. Observation of the Establishment

No findings observed in this establishment

61. NAME OF AUDITOR

62. AUDITOR SIGNATURE AND DATE