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Food Safety
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Service

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Dear Dr. Amador:

The Food Safety and Inspection Service (FSIS) conducted an on-site initial equivalence audit of Honduras' poultry slaughter inspection system June 8-15, 2009. FSIS submitted a draft poultry slaughter audit report to Honduras on January 13, 2012. In response, Honduras proposed corrective actions on March 13, 2012. The final audit report has been amended to include Honduras' proposed corrective actions, in the body of the report, which address the areas of non-compliance FSIS identified within Honduras' poultry slaughter inspection system. Enclosed is a copy of the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, via facsimile at (202) 720-7990, or via e-mail at InternationalEquivalence@fsis.usda.gov.

Sincerely,

Dr. Andreas Keller
Director
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Office of International Affairs

Enclosure

NOV 01 2012

FINAL REPORT OF AN INITIAL EQUIVALENCE ON-SITE

AUDIT CONDUCTED IN HONDURAS

JUNE 8 - 15, 2009

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 on-site audit of Honduras' poultry inspection system conducted by the Food Safety and Inspection Service (FSIS) from June 8 through 15, 2009. The issuance of this report has been delayed, as a result of a formal instruction by the U.S. Department of State, due to political instabilities in the government of Honduras, which began shortly after the conclusion of this audit. These have since been resolved.

This was an initial equivalence audit with an emphasis on process controls exercised by the Central Competent Authority (CCA) over Honduras' poultry inspection system and corrective actions proffered and implemented by the CCA in response to the previous FSIS initial equivalence on-site audit of Honduras' poultry inspection system conducted in 2005. The audit objective was to ensure that Honduras has an inspection system for slaughtering poultry equivalent to the United States' (U.S.) inspection system with the resultant capacity to produce poultry and poultry products that are safe, unadulterated and properly labeled.

The auditors confirmed that all prior findings related to the 2005 audit were appropriately addressed. Furthermore, the auditors concluded that the CCA was able to meet all of the FSIS requirements for all of the equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) HACCP and (6) Microbiological Testing Programs.

However, the current audit resulted in the identification of the following findings which are of concern:

- The CCA was unable to demonstrate adequate oversight and control over the establishment's sanitation practices.
- The CCA was unable to provide adequate oversight and verification of the LANAR laboratory's record keeping procedures.

The nature of these findings is further elaborated on in the Sanitation and Microbiological Testing Programs sections of this report.

Equivalence component (5) Chemical Residues Programs, was not audited during the on-site audit; however documentation available at the time, which pertained to the chemical residues program implemented for analysis of meat samples, was evaluated and used to determine that the requirements for this component were met. This is further elaborated on in the Chemical Residues Programs section of this report.

This final report has been amended on August 15, 2012 to incorporate Honduras' corrective actions in response to the findings in the draft final audit report. Honduras' proposed corrective actions have been inserted into the individual components of the report, which address the non-compliances identified within their food safety system.

FSIS recommends moving forward with the rulemaking process for Honduras' poultry slaughter system equivalence.

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 SYSTEM
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 (SENASA)
CFR	United States Code of Federal Regulations
<i>E. coli</i>	<i>Escherichia coli</i>
FSD	Food Safety Division
FSIS	Food Safety and Inspection Service
GMP	Good Manufacturing Practices
LANAR	<i>Laboratorio Nacional de Analisis de Residuos</i> , National Laboratory of Residue Analysis
OVI	Official Veterinary Inspector
OVS	Official Veterinary Supervisor
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
SAG	<i>Secretaria de Agricultura y Ganaderia</i> , Ministry of Agriculture and Livestock
<i>Salmonella</i> spp.	<i>Salmonella</i> species
SENASA	<i>Servicio Nacional de Sanidad Agropecuari</i> , National Service of Plant and Animal Health
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an audit of Honduras' poultry inspection system from June 8 through June 15, 2009. Honduras is currently eligible to export meat product to the United States. The last FSIS audit of Honduras' meat inspection system was conducted from March 2 to 23, 2010.

This audit began with an entrance meeting held on June 8, 2009 in Tegucigalpa with the participation of representatives from the Central Competent Authority (CCA) – the Department of Agriculture and Livestock (*Secretaria de Agricultura y Ganaderia - SAG*), National Plant and Animal Health Service (SENASA) Food Safety Division (FSD) and two auditors from FSIS' Office of International Affairs (OIA), International Equivalence Staff (IES) and International Audit Staff (IAS).

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was an initial equivalence audit with emphasis on process controls exercised by the CCA over Honduras' poultry inspection system, and corrective actions proffered and implemented by the CCA in response to the previous initial equivalence on-site audit conducted by FSIS in 2005.

The audit objective was to ensure that Honduras' food safety system governing poultry slaughter is equivalent to that of the United States, with the resultant capacity to produce poultry products, which are safe, unadulterated, and properly labeled. In pursuit of this objective, FSIS conducted a comprehensive document review which included an analysis of the inspection documents submitted by Honduras to demonstrate their inspection system's structure as it relates to the inspection of slaughtered poultry, and their response to the 2005 on-site audit findings, in advance of its second initial equivalence on-site audit of Honduras.

The FSIS auditors were accompanied throughout the entire audit by representatives from the CCA, and the local inspection office in San Pedro Sula. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point System (HACCP), (5) Chemical Residues Programs, and (6) Microbiological Testing Programs.

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

There was only one establishment seeking certification for U.S. export at the time of the audit. During the establishment visit, particular attention was paid to the extent to which

industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 381.196.

Additionally, the microbiological aspect of the government laboratory was audited to verify the CCA's ability to provide adequate technical support to the inspection system. This government laboratory provides analytical support for both microbiological and chemical residue sample analyses for products produced under the purview of the Honduran government.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	Tegucigalpa
	Local Office	1	San Pedro Sula
Laboratory		1	Government Microbiology Laboratory: Tegucigalpa
Poultry Slaughter Establishment		1	San Pedro Sula

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- The Poultry Products Inspection Act (21 U.S.C. 451 et. seq.)
- The Poultry Products Inspection Regulations (9 CFR Part 381 et. seq.)
- HACCP Regulations (9 CFR Part 417 et. seq.)
- Sanitation Regulations (9 CFR Part 416 et. seq.)

The audit standards applied during the review of Honduras' poultry inspection system included all applicable legislation submitted to FSIS and determined, by the reviewers, to be equivalent to FSIS' requirements, which have been adopted by SENASA.

4. BACKGROUND

In November 2003, Honduras submitted an initial equivalence application and requested that FSIS conduct a review of Honduras' poultry slaughter system, to establish eligibility to export raw poultry products 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 for 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, all shackles checked in a 15 foot section 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, which 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. FSIS determined that due to the passage of time that had occurred, it would be necessary to conduct a second on-site, initial equivalence audit before proceeding with Honduras' submission. While the audit team was in Honduras for this audit, the corrective actions proffered from FSIS' 2005 audit were verified, and determined by the auditors to be acceptable.

5. GOVERNMENT OVERSIGHT

The first of the six equivalence components that the auditors reviewed was Government Oversight. FSIS import eligibility requirements oblige that the foreign inspection system be organized and administered by the national government and provide standards equivalent to those of the U.S. system.

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 Order No. 588-01. These laws provide the operational and regulatory authority to carry out Honduras' poultry inspection system. FSIS' review of specific regulations based on these laws concerning the registration of slaughter establishments, inspection activities, and import/export requirements indicated that the CCA has a clear legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported.

The CCA maintains the legal authority and the responsibility to enforce all applicable laws and regulations governing Honduras' requirements for poultry slaughter inspection. The authority to enforce Ministry of Agriculture and Livestock (SAG) inspection laws is granted to the National Plant and Animal Health Service (SENASA) by the Phytosanitary Law No. 157-94, modified by Decree 344-2005. The inspection of poultry and poultry products is conducted by the Food Safety Division (FSD) through the *Regulations on the Inspection, Slaughter, and Industrial Treatment of Poultry Products* Agreement No. 552-05.

The auditors confirmed that SENASA-FSD maintains ultimate control and supervision for establishments, which would be considered as eligible to export poultry and poultry products as stated in the Phytosanitary Law No. 157-94. This law also provides

SENASA with direct control over inspection activities at exporting establishments and the authority to certify and/or decertify establishments for export to the United States. The salaries of official inspection personnel are paid directly by the national government via allocations that are established in its budget. All inspection personnel 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 veterinary officials are responsible for the oversight and administration of the hiring, training, assigning, and overseeing of inspection personnel. This 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. The auditors obtained this information during the audit, which verified information supplied by the CCA in a data collection tool used for collecting information from foreign countries regarding their inspection systems called the Self-Reporting Tool (SRT). 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).

As established in Order No. 588-01, Article 16, SENASA-FSD also has direct oversight of the government of Honduras' National Laboratory of Residue Analysis (LANAR). This is an official government laboratory, which provides sample analysis for chemical and microbiological testing of meat, and meat products, which are exported to the United States. This laboratory would provide the same services for poultry product to be exported to the U.S. should Honduras' poultry slaughter system be determined equivalent.

Based on review of the official inspection and laboratory documents maintained at headquarters, and local inspection offices, the auditors concluded that Honduras' legislation, guidance documents, and instructions were properly disseminated from the CCA headquarters to all inspection and laboratory personnel by e-mail.

The auditors did note that there were implementation and record keeping non-compliances regarding the CCA oversight of the poultry inspection system. These findings pertain to the government oversight aspect of the HACCP, Microbiological Testing Program, and Sanitation components that were evaluated during this audit. The CCA did not identify or document these non-compliances through its routine inspection verification activities or during its periodic supervisory reviews.

While the detailed descriptions of these findings can be found in the HACCP, Microbiological Testing Program, and Sanitation components of this report, the nature of the findings are more reflective of aspects of government oversight. For this reason, FSIS has considered these findings as more applicable to the Government Oversight component and is reporting them as such.

None of these findings by themselves was a serious failure of this component, and as such, FSIS has determined that Honduras' poultry inspection system has met the requirements of the Government Oversight component. However when taken together, the cumulative effect of the findings observed during the audit is of concern relative to Honduras' ability to maintain oversight and control of their poultry inspection system. Honduras has provided corrective actions that address the findings described in the sections of this report that pertain to Sanitation and Microbiological Testing Programs and prevent their recurrence. While the findings specific to the HACCP program did not arise to the level which would necessitate providing corrective actions, corrective actions were proffered.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditors 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 official establishments.

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 auditors also assessed the CCA's ability to effectively communicate these requirements throughout the inspection system.

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 No 552-05, Chapter VII, Articles 111 and 112. The *Guidelines for Procedures for the Inspection of Meat Products* (DIA-GIPA-05) is a form, which provides instructions to field personnel, which re-states and elaborates upon these requirements, 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 Honduran legislation, and these inspection guidelines. This legislation also provides a specific description of the condemnation bins, detailing how they are marked to differentiate them from containers intended for edible product. A review of these documents indicated that they provide detailed instructions on how inspection officials are to perform these inspection tasks.

The Official Veterinary Inspector (OVI) is present in the establishment carrying out inspection duties whenever the establishment is operating. The OVI assesses the performance of the inspection system on a daily basis and records their observations in the "Weekly Analysis Schedule/CIS-01" form. This form requires the OVI to verify aspects of the establishment's Sanitation Standard Operating Procedures (SSOP),

Sanitation Performance Standards (SPS), Good Manufacturing Practices (GMP), HACCP, and other programs including sampling procedures, analytical results of laboratory testing, and equipment calibration. The auditors 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). The CCA relies on periodic supervisory visits, performed monthly by the Official Veterinary Supervisor (OVS) to verify the compliance of inspection activities in the establishment. The auditors verified that this supervisory procedure is occurring by reviewing documents that are used by the OVS whenever these visits occur (Form AV-01-06 and SI-PA-05).

On June 8, 2007, FSIS informed exporting countries of a change in policy regarding the requirement for species verification. This change in policy enabled countries to choose to continue to perform species verification as they had been doing, adopt product formulation checks, or to submit an alternative proposal for an equivalence determination. Honduras will need to confirm what their intentions are for satisfying this requirement as it relates to the slaughter of poultry.

As indicated previously, one establishment intending to export to the U.S. was audited. During the audit, FSIS reviewed relevant procedures and records maintained by the local inspection offices, and observed how inspection personnel carried out their responsibilities related to verification and enforcement.

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

HONDURAS' PROPOSED CORRECTIVE ACTIONS

SENASA has reviewed information for species verification, and will be implementing the AOAC approved ELISA-TEK® Raw Meat Species Kit.

7. SANITATION

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

The auditors reviewed Honduras' requirements for sanitation, which are described in Agreement 552-05, and the inspector's tasks relative to this regulation are defined in DIA-GIPA-05. This review concluded that there were no significant differences between the CCA's sanitation requirements and those implemented and enforced by FSIS in 9 CFR Part 416 – Sanitation.

One establishment intending to export poultry products to the U.S. was audited to assess the CCA's ability to implement the inspection system's requirements for sanitation. The

auditors reviewed the CCA's inspection instructions and inspection records maintained by the local inspection offices overseeing this establishment. This review resulted in the following findings:

- A review of the establishment's production practices indicated that the production line employees work clothing routinely came into contact with product and food contact surfaces. During the course of the audit of the establishment, one of the production line employees was observed entering a restroom facility without removing or changing his work apron before or after going to the restroom. As described in *Guidelines for Procedures for the Inspection of Meat Products* (DIA-GIPA-05) the official veterinary inspector, or the inspection assistants, have authority to request the change of clothing whenever it seems necessary to prevent the creation of an insanitary condition. This production-line employee was not instructed to change his work clothing before returning to the production line either by inspection personnel or the establishment management.
- 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 the poultry products or by-products must be equipped with potable cold and/or hot water. Article 68 of DIA-GIPA-05 states 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 has been tested once a year by the establishment. This finding is a concern because the CCA was not enforcing the Honduran legislation and FSIS regulations.
- There were several holes, approximately one inch in diameter, in the ceiling above the poultry chilling tank. In DIA-GIPA-05 Part II, Construction, Article 60, Number 23 it is mandated that the ceilings, false 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, fireproof and easy to clean material.

HONDURAS' PROPOSED CORRECTIVE ACTIONS

The establishment has implemented specific corrective actions to address these findings.

The finding of an employee entering a restroom facility without removing or changing his work apron before or after going to the restroom has been addressed. There has been a specific employee assigned to ensure that the establishment's Good Manufacturing Practices (GMPs) are enforced appropriately. These GMPs include the verification of personnel removing their uniform when entering the restroom facility. This monitoring activity is recorded on the form FCC BPMs A5-01-07. SENASA's Official Veterinary

Inspector (OVI) verifies these activities in order to ensure that cross contamination is avoided. This verification activity is recorded on the CIS-01 form. This activity is also verified during the OVS' periodic supervisory visits. This supervisory activity is recorded on the DIA-HA-05-08 form.

Additionally, the establishment requires color coded uniforms as a means of preventing cross contamination. Specific areas of the establishment are designated with a specific colored uniform, and personnel in those areas must wear the appropriate colored uniform for the area in which they work. The establishment's corrective action was the provision of training for their employees. This training was conducted on June 28, 2009, and enforced the need to wear the appropriate uniform for the area of the establishment that the employee is working in.

The establishment has addressed the audit finding of water potability analysis by collecting samples on a semi-annual basis. The sampling schedule is verified by the OVI to ensure that the sampling occurs as scheduled. The OVS verifies these schedule checks during the periodic supervisory visits, and records this activity on the AV-01-06 form. The samples are submitted to the LANAR laboratory for analysis. There have been no deficiencies in water potability since this semi-annual sampling began in 2010.

The establishment scheduled the repair of the ceiling on June 19, 2009 and it was completed by June 27, 2009. The OVI has performed monthly verifications on the establishment's overall SPS condition of the establishment. These verifications are recorded in the CIS-01 form Section A: SSOPs, SPS #4 "Evaluation of Internal Structures (Walls, Doors, Floors, Ceilings and Others)".

To ensure that official controls are properly enforced, SENASA has scheduled semi-annual training for Official Inspectors assigned to poultry establishments. This training focuses on regulatory requirements, official inspection procedures as specified according to the DIA-GIPA-05. This first segment of this training occurred May 2-4, 2012, and will continue September 5-7, 2012.

After analysis of the CCA's corrective actions, FSIS has concluded that Honduras' poultry inspection system meets the requirements for this component.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

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

The headquarters in Tegucigalpa and local inspection office in San Pedro Sula were audited 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 auditors reviewed Honduras' procedures for implementing 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 Products and By-Products, Phytosanitary Law Decree No 344-2005, and SENASA Law 588-01.

This review concluded that the CCA has adequate procedures to implement the necessary HACCP requirements, and that these procedures are very similar to those utilized by FSIS in 9 CFR Part 417.

One establishment intending to export poultry products to the U.S. was audited to assess the CCA's ability to implement the inspection system's HACCP requirements.

The auditors reviewed Honduras' procedures for implementing and verifying a HACCP plan in both headquarters and a local inspection office. In addition, a poultry slaughter establishment intending to export poultry products to the U.S. was audited to assess the CCA's ability to implement the inspection system's HACCP requirements. 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:

- Frequency of verification procedures was not followed as written in the establishment HACCP plan.
- Verification records did not document the type of the verification procedures and the results of the verification.
- Monitoring records did not include the initials of responsible establishment employee(s) making the entries.

While all of the findings specific to this component are of significance to the audit they do not warrant failure of the overall requirements for this component.

HONDURAS' PROPOSED CORRECTIVE ACTIONS

On June 17, 2009 the establishment reassessed its HACCP plan. The HACCP plan reassessment rectified all of the findings described above. This reassessment included a modification of the establishment's verification records so that the opportunity to record the type of verification procedures that were conducted as well as the results of those verifications is included. The HACCP reassessment also included a reformatting of monitoring records. These records now include an entry for the establishment employee to sign their initials showing their verification of CCPs. The establishment's Quality Management has reviewed the history of the establishment's HACCP verification frequency and has assured SENASA that the prescribed verification frequencies will be followed.

To prevent deficiencies of this nature from occurring again, SENASA included these aspects of government inspection activities and verification in their semi-annual training described in the above "Sanitation" section of this report.

After analysis of the CCA's corrective actions, FSIS has concluded that Honduras' poultry inspection system meets the requirements for this component.

9. CHEMICAL RESIDUES PROGRAMS

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

The residue activities of the LANAR laboratory were not evaluated during this audit. This decision was made based on the following factors: Honduras is eligible to export meat and meat product to the United States; the chemical residue samples collected for meat and meat products are analyzed by the LANAR laboratory just as they are for poultry and poultry products; the government oversight of LANAR is under the same structure, and provided by the same personnel for poultry as for meat.

Prior audit reports of Honduras' meat inspection system since 2005 were reviewed and, except for the 2007 audit, there had been no deficiencies observed in Honduras' Chemical Residues Program. In 2007, there was a finding of two compounds which analyses were not completed within the time frame established in the laboratory's quality control manual. Additionally, FSIS' Automated Import Inspection System (AIIS) database was consulted for chemical residue related port-of-entry (POE) violations from January 1, 2000 through the time of the planning of the audit. There were no violations for chemical residues found in this database for this time period.

A document review was conducted of Honduras' chemical residue program for poultry in 2007, and there were no differences identified between Honduras' program and the program used by FSIS at that time. Honduras has maintained an equivalent program for detecting chemical residues in meat, and the most recent audit of their meat inspection system, conducted from March 2 through 23, 2010, included the chemical residue aspect of Honduras' inspection system. There were no specific areas of concern identified during this audit.

Based on the factors described above, FSIS concluded that Honduras' poultry inspection system meets the requirements for this component.

10. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditors reviewed was the Microbiological Testing Programs used by the CCA. The system must implement

sampling and testing programs to ensure that poultry and poultry products produced for export to the United States are safe, wholesome and unadulterated.

The CCA headquarters in Tegucigalpa and one local inspection office were audited to determine if Honduras has the regulatory authority to maintain and enforce adequate government oversight for the implementation of the CCA's microbiological program. The auditors interviewed the CCA and reviewed relevant laboratory records including analyst qualifications, sampling protocols, testing methods, test reporting procedures, enforcement strategies and communication tools. This review concluded that the CCA's microbiological program was properly designed.

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

The CCA conducts verification activities monitoring the establishment's generic *Escherichia coli* (*E. coli*) requirements for poultry products. The CCA has implemented generic *E. coli* requirements in accordance with FSIS regulations. The auditors concluded that the CCA's testing program is the same as that implemented by FSIS.

One government microbiology laboratory was audited to determine if Honduras has regulatory authority to maintain and enforce adequate government oversight for the implementation of the CCA's microbiological testing program. This record review and interview of the laboratory personnel resulted in the identification of two non-compliances for the Microbiological Testing Program component.

- Some of the laboratory sample tracking records were signed and initialed by a supervisor indicating supervisory review before the sample analysis process had concluded.
- 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 on incubators. The CCA notified the auditors that the proper corrective action was taken and not recorded. The auditors were not able to verify this claim based on document review.

The more substantive of the laboratory findings involved the supervisor signing off on the sample tracking records prior to completion of the analysis. This finding shows that the CCA did not have proper enforcement or implementation of their oversight of the laboratory quality systems.

While all of the findings specific to this component are of significance to the audit they do not warrant failure of the overall requirements for this component. However, the finding regarding the supervisor signing off on the sample tracking records prior to completion of the analysis does further support FSIS' concern regarding the Honduran CCA's lack of government oversight and enforcement.

HONDURAS' PROPOSED CORRECTIVE ACTIONS

In response to the FSIS' finding of sample tracking records being signed off on before their completion, LANAR has implemented a Quality Management System (QMS) to more efficiently regulate the activities of the lab. The QMS establishes a verifiable sequence that guarantees that the analytical results are reported accurately. LANAR has also identified that supervisory activities over the monitoring records must be performed on a weekly basis. Prior to the audit, these activities were performed on a semi-monthly basis.

The LANAR laboratory only considers temperature violations, as such, when samples are inside the incubators. LANAR's corrective actions for this finding are to identify if there are samples inside the incubators when performing temperature monitoring activities in their daily records. SENASA is verifying this during their annual audits of LANAR to ensure that the results are being recorded accurately.

After analysis of the CCA's corrective actions, FSIS has concluded that Honduras' poultry inspection system meets the requirements for this component.

11. EXIT MEETING

An exit meeting was held on June 15, 2009 in Tegucigalpa with representatives of SENASA. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors.

The CCA understood and accepted the findings.

12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The auditors confirmed that all prior audit findings were appropriately addressed. Furthermore, the auditors concluded that the CCA was able to meet the FSIS requirements for all of the equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point System, (5) Chemical Residues Programs and (6) Microbiological Testing Programs.

However, the current audit resulted in the identification of the following findings which are of concern:

- The CCA failed to provide adequate oversight and control over the establishment's sanitation practices.
- The CCA failed to provide adequate oversight and verification of the LANAR laboratory's record keeping procedures.

FSIS ANALYSIS OF HONDURAS' PROPOSED CORRECTIVE ACTIONS

The Honduran CCA has submitted a comprehensive corrective action plan that addresses the specific audit findings outlined in the report for each equivalence component. FSIS has evaluated the proffered corrective actions and decided that they sufficiently address the findings identified. FSIS recommends moving forward with the rulemaking process for system equivalence.

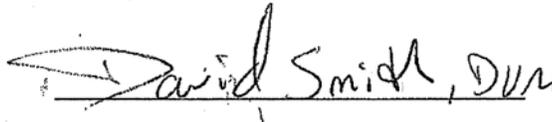
SENASA has informed FSIS that they are aware of the new performance standards for *Salmonella* and *Campylobacter* in raw poultry. The CCA is currently in the process of reviewing the National Regulation for Poultry Slaughter Agreement No. 552-05. SENASA will be evaluating how to include the performance standards for *Salmonella* and *Campylobacter* into this regulation.

LANAR is in the process of implementing the AOAC BAX® System Real-Time PCR Assay for *Campylobacter*. A verification set will be scheduled for testing *Campylobacter* in poultry carcass rinses at Establishment A-5.

SENASA has reviewed information for species verification, and will be implementing the AOAC approved ELISA-TEK® Raw Meat Species Kit.

Because SENASA is still in the implementing phase of these activities it is recommended that these issues be verified during the next audit of Honduras' poultry inspection system. Otherwise, the corrective actions provided by the CCA are satisfactory.

David Smith, DVM
Senior Equivalence Staff Officer



Nader Memarian, DVM
Senior Program Auditor



13. ATTACHMENTS TO THE AUDIT REPORT

Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Avicola del Norte, S.A. (NORAVES) Carretera Panamericana, CA-5, Soso, Santa Cruz de Yojoa, Cortes, Km 189	2. AUDIT DATE June 11, 2009	3. ESTABLISHMENT NO. A-5	4. NAME OF COUNTRY Honduras
	5. NAME OF AUDITOR(S) Dr. Nader Memarian		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	X
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	X
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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
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.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park 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	O
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

Avicola del Norte, S.A. (NORAVES), Poultry S/P, June 11, 2009

- 15/22/51A) Verification records did not document the type of the verification procedures and the results of the verification. [9CFR 417.5(a)(3) and 9CFR 417.8]
 - B) Frequency of verification procedures was not followed as written in the establishment HACCP plan. [9CFR 417.2(c)7, 417.4, and 417.8]
 - C) Monitoring records did not include the initials of the responsible establishment employee(s) making the entries. [9CFR part 417.5(b) and 417.8]

- 39/51 Maintenance of the over head structures above poultry chilling tank had been neglected with several holes in ceiling in evidence. [9CFR 416.4 and 416.17]

- 43/51 The establishment uses three private wells for its water supply. The potability of the water supply has been tested once a year by the establishment instead of semi-annually as required by FSIS. [9CFR 416.2(g)]

- 45 Rough, interrupted, and uneven welds were observed on the food contact surfaces of several stainless steel tables and containers which may prevent the adequate removal of product residue and could become a source of product contamination. [9CFR 416.3(a)]

- 46/47 A production line employee did not remove or change his working clothing before or after going to a restroom. [9CFR 416.5(b)]

61. NAME OF AUDITOR Dr. Nader Memarian	62. AUDITOR SIGNATURE AND DATE
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CCA-SENASA comments to the USDA-FSIS findings during the 2009 onsite audit to the poultry slaughter inspection system:

Following up the onsite audit to determine the equivalence of Honduras' poultry slaughter inspection system, CCA-SENASA is providing comments on the draft final audit report as well as the actions implemented by the establishment and the verification activities performed by SENASA's Official Inspection System.

Although FSIS provided the draft final audit report on January 13, 2012 the establishment and SENASA performed follow-up activities during 2009 over the deficiencies reported by FSIS during the onsite audit visit and the preliminary information provided by FSIS during exit meeting with CCA-SENASA.

Specific corrective actions were implemented by CCA-SENASA, LANAR and the establishment for each deficiency reported by FSIS and verification activities were performed by the Official Inspection Program as follows:

FSIS Finding:

SANITATION

A review of the establishment's production practices indicated that the production line employees work clothing routinely came into contact with product and food contact surfaces. During the course of the audit of the establishment, one of the production line employees was observed entering a restroom facility without removing or changing his work apron before or after going to the restroom. As described in *Guidelines for Procedures for the Inspection of Meat Products*, (DIA-GIPA-05) the official veterinary inspector, or the inspection assistants, have authority to request the change of clothing whenever it seems necessary to prevent the creation of an insanitary condition. This production-line employee was not instructed to change his work clothing before returning to the production line either by inspection personnel or the establishment management.

CCA-SENASA Comment

The employee involved in this situation was wearing a specific uniform (blue overall) which is assigned to the personnel from the loading area and cold storage rooms where product is packed and ready for distribution.

Corrective actions of the establishment

The establishment implemented specific corrective actions in order to guarantee that employees from all areas of the plant are aware and implement the procedures defined by the establishment regarding the clothing requirements to avoid the creation of an unsanitary condition as follows:

1. On June 28, 2009 the establishment performed specific training for personnel. The training involved the procedures for the correct use of uniforms inside and outside the plant in order to avoid cross contamination; (the procedures are consistent with the establishment's prerequisite program PHP-A5-03-11, which requires personnel from cold storage and loading area to remove their uniforms and store them in their lockers when exiting their working areas). *See attachment # 1*

2. The establishment assigned a specific employee to control the entrance and exit of personnel from the plant area to make sure that the GMPs are fulfilled accordingly (this includes the verification of personnel removing their uniform when entering the restroom facilities). The monitoring activities area being recorded in the form FCC BPMs A5-01-07. *See attachment # 1*

OVI Verification activities

The OVI performed verification activities on the corrective actions implemented by the establishment and has recorded these activities in the CIS-01 form. Furthermore, OVI has performed continuous verification activities over establishment personnel habits and their clothing in order to make sure that proper measures are taken to avoid cross contamination or the creation of an unsanitary condition. These verification activities are recorded on the CIS-01 form (Section B: Good Manufacture Practices #1: Verification of training, hygiene and personnel habits). *See attachment # 1*

OVS Verification activities

During the periodic supervisory visits, the Official Veterinary Supervisor (OVS) has performed verification activities on the controls that have been implemented by the establishment to guarantee compliance on GMPs. The supervisory activities have been recorded on the DIA-HA-05-08 form (Section IV Good Manufacture Practices #25: "the establishment has control over transmittable diseases, hygiene, health, cleanliness, established habits and training of personnel"). *See attachment # 1*

FSIS Finding:

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 the poultry products or by-products must be equipped with potable cold and/or hot water. Article 68 of DIA-GIPA-05 states 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 has been tested once a year by the establishment. This finding is a concern because the CCA was not enforcing the Honduran legislation and FSIS regulations.

Corrective actions of the establishment

1. The establishment performed a 2010-2012 schedule program for submitting water samples for chemical analysis on a semi-annual basis. This schedule is reviewed by the OVI to verify that the sampling was scheduled and executed. *See attachment # 2*
2. Based on the schedule, the establishment collected water samples on a semi-annual basis and submitted them to LANAR for analysis. The first sample for 2012 has also been sent for analysis. No deficiencies on chemical analysis for water have been reported for 2010-2012. *See attachment # 2*

CCA-SENASA Verification Activities

During the 2010 and 2011 supervisory visits, OVS verified that the establishment has semi-annual results for certifying the potability of the water supply and recorded this activity on the AV-01-06 form. *See attachment # 2*

FSIS Finding:

There were several holes, approximately one inch in diameter, in the ceiling above the poultry chilling tank. In DIA-GIPA-05 Part II Construction, Article 60, Number 23 it is mandated that the ceilings, false 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, fireproof and easy to clean material.

Corrective Actions implemented by the Establishment

1. On June 19, 2009 the establishment programmed the repair for the ceilings above the poultry chilling tank. *See attachment # 3*
2. Repair of the ceiling was completed by June 27, 2009. *See attachment # 3*
3. Establishment has performed microbiological evaluation of the surfaces of the ceilings above the poultry chilling tank, no deficiencies regarding the cleanliness of the surfaces have been reported. *See attachment # 3*

Verification Activities

Official Veterinary Inspector (OVI) has performed monthly verification on the overall conditions of the establishment regarding SPS requirements and has recorded the findings on the CIS-01 form Section A: SSOPs, SPS #4 Evaluation of internal structures (walls, doors, floors, ceilings and others). OVI reported non-compliances regarding SPS requirements to the establishments through Demand of Corrective Actions (DACs). *See attachment # 3*

CCA-SENASA Corrective Actions:

To guarantee that official controls are properly enforced throughout the poultry slaughter Official Inspection Program, CCA-SENASA has scheduled a semi-annual training for the Official Inspectors assigned to the poultry establishments regarding regulatory requirements, official inspection procedures accordingly with the *Guidelines for Procedures for the Inspection of Meat Products*, (DIA-GIPA-05). The specific training for 2012 has been scheduled for May 2-4 and September 5-7, 2012. *See attachment # 5*

FSIS Finding

HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

1. Verification records did not document the type of the verification procedures and the results of the verification.
2. Monitoring records did not include the initials of responsible establishment employee(s) making the entries.
3. Frequency of verification procedures was not followed as written in the establishment HACCP plan.

Corrective Actions Establishment

1. On June 17, 2009 the establishment performed a reassessment of the HACCP Plan, which included the modification of the records used by the establishment to document the verification activities of the CCPs (i.e. direct observation, review of records, and calibration of process-monitoring instruments). *See attachment # 4*
2. This reassessment also included the review and modification of the monitoring records; these records now include the initials of responsible establishment employee(s) making the entries. *See attachment # 4*
The establishment performed a specific training to the HACCP personnel regarding the changes performed on the monitoring records of the HACCP plan. *See attachment # 4*
3. The Quality Management of the establishment sent a notification to the Quality Supervisor requesting to review the compliance on the frequency of verification procedures as written in the establishment HACCP plan during the monthly internal audits. *See attachment # 4*

CCA-SENASA Corrective Actions:

To guarantee that official controls are properly enforced throughout the poultry slaughter Official Inspection Program, CCA-SENASA has scheduled a semi-annual training for the Official Inspectors assigned to the poultry establishments regarding regulatory requirements, official inspection procedures accordingly with the *Guidelines for Procedures for the Inspection of Meat Products*, (DIA-GIPA-05). The specific training for 2012 has been scheduled for May 2-4 and September 5-7, 2012. *See attachment # 5*

MICROBIOLOGICAL TESTING PROGRAMS

FSIS finding:

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

CCA-SENASA Comment

During the 2009 FSIS on-site audit visit, LANAR was on the process for the accreditation of ISO/IEC 17025 for *Salmonella spp.* in meat products; the accreditation was achieved on February 23, 2010. *See attachment # 6*

Within this process, LANAR implemented a Quality Management System (QMS) to organize, control, standardize and regulate the activities of the laboratory in order to have a verifiable sequence that guarantees the quality of the results that are being reported.

LANAR's Quality Manual has a specific procedure (P-GC-05) for corrective and preventive actions which describes the process that must be followed whenever a non-compliance is reported in the monitoring records; this procedure requires to perform an analysis of the possible causes that could have led to the non-compliance, perform corrective actions and preventive measures to address the non-compliance as well as the verification procedures that must be performed regarding the corrective actions implemented. *See attachment # 7*

Corrective actions implemented by LANAR

In order to address the deficiency reported by FSIS during the on-site audit visit, LANAR performed the established procedure for non-compliances and determined to define that the supervision activities over the monitoring records must be performed on a weekly basis. Prior to the 2009 audit visit, the supervision activities were being performed on a semi-monthly or monthly basis. *See attachment # 8*

FSIS finding:

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 on incubators. The CCA notified the auditors that the proper corrective action was taken and not recorded. The auditors were not able to verify this claim based on document review.

CCA-SENASA Comment

There may a misinterpretation because CCA SENASA couldn't at the time report that corrective actions had not been registered; during the exit meeting with CCA-SENASA on June 15, 2009, FSIS auditors reported that "the temperature monitoring logs showed deviations on several occasions and that there were no records tracking the location of the sample at the time of the temperature deviation".

According to LANAR's procedures, deviations from the set temperature are only considered as such, when samples are inside the incubators. When laboratory personnel identify a deviation, LANAR must follow the procedure established for follow-up of non-compliances.

Corrective actions implemented by LANAR

In order to address the deficiency reported by FSIS during the on-site audit visit, LANAR performed the established procedure for non-compliances and determined to identify if samples are inside the incubators when performing temperature monitoring activities in the daily records for monitoring temperature. *See attachment # 9*

CCA-SENASA Verification Activities

On February 15, 2010 and March 23, 2011 CCA-SENASA performed the annual audits to LANAR in order guarantee that the laboratory is following appropriate procedures to ensure the results that are being reported. LANAR followed the established procedures for non-compliances detected by CCA-SENASA; the documented activities were presented to CCA-SENASA for evaluation. *See attachment # 10*

FSIS draft final audit report:

Since the time of this audit, FSIS has developed new performance standards for *Salmonella* and *Campylobacter* in raw poultry.

CCA-SENASA is currently in the process of reviewing the National Regulation for Poultry Slaughter Agreement No. 552-05 and will evaluate the new standards for *Salmonella* and *Campylobacter* in raw poultry to be included in the Regulation.

LANAR is already in the process of implementing the AOAC BAX[®] System Real-Time PCR Assay for *Campylobacter*.

A verification set for 2012 for testing *Campylobacter* in poultry carcass rinse will be programmed to be performed at Establishment A-5. *See attachment # 11*

FSIS draft final audit report:

Honduras will need to resolve their outstanding issue regarding the procedure they will choose to adopt for species verification.

CCA-SENASA has reviewed the information regarding species verification and will be performing species testing for poultry using the AOAC approved ELISA-Tek[®] Raw Meat Species Kit. *See attachment # 12*

