



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

APR 28 2004

U.S.
5/19/04

Dra. Mercedes Erazo
Chief of the Official Inspection Service of Products of Animal Origin (SIOPOA)
Servicio Nacional de Sanidad Agropecuaria (SENASA)
Secretaria de Agricultura y Ganaderia (SAG)
Boulevard Miraflores, Avenue La FAO
Cotiguo a INJUPEM
3er Edificio, 3er Nivel
Tegucigalpa, Honduras, C.A.

Dear Dra. Erazo:

The Food Safety and Inspection Service completed an on-site audit of Honduras' meat inspection system. The audit was conducted from December 2 through 12, 2003. Comments from Honduras are included in the final report, a copy of which is enclosed.

As a result of this audit, FSIS recognizes the progress Honduras has made to address the issues that arose in the previous FSIS audit of April - May 2003. However, the December 2003, audit findings indicate that Honduras needs to continue to make progress to ensure that certified establishments maintain compliance with U.S. import requirements. Accordingly, FSIS is continuing the suspension of Honduras' authority to certify additional establishments to export meat to the United States until further notice.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by facsimile at 202-690-4040, or by email at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Steven Heute, Agriculture Counselor, US Embassy, Guatemala City

Maria Bennaton, Minister, Embassy of Honduras

Jeanne Bailey, FAS Area Officer

Amy Winton, State Department

Linda Swacina, Deputy Administrator, FSIS

Karen Stuck, Assistant Administrator, Office of International Affairs, FSIS

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FINAL

MAR 30 2004

FINAL REPORT OF AN AUDIT CARRIED OUT IN HONDURAS
COVERING HONDURAS' MEAT INSPECTION SYSTEM

DECEMBER 2 THROUGH DECEMBER 12, 2003

Office of International Affairs
Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

APHIS	Animal and Plant Health Inspection Service
CCA	Central Competent Authority
CCP	Critical control point
DAC	Corrective Action Demands
CVO	Chief Veterinary Officer
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
LANAR	Laboratorio Nacional de Análisis de Residuos y Microbiología
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
<i>Salmonella</i>	<i>Salmonella</i> species
SAG	Secretaria de Agricultura y Ganaderia (Department of Agriculture and Livestock)
SENASA	Servicio Nacional de Sanidad Agropecuaria (National Plant and Animal Health Service)
SIOPOA	Servicio de Inspección Oficial de Productos de Origen Animal (CCA for Honduras)
SSOP	Sanitation Standard Operating Procedure(s)
VIC	Veterinarian-in-Charge

1. INTRODUCTION

The audit took place in Honduras from December 2 to December 12, 2003.

An opening meeting was held on December 2, 2003 in Tegucigalpa with the Central Competent Authority (CCA), which for this audit is the Servicio de Inspección Oficial de Productos de Origen Animal (SIOPOA). At this meeting, the audit team confirmed the objective and scope of the audit, the audit itinerary, and requested additional information needed to complete the audit of Honduras' meat inspection system.

The audit team was accompanied during the entire audit by a representative from the SIOPOA and, when appropriate, representatives from the regional and local inspection (establishment) offices.

2. OBJECTIVE OF THE AUDIT

This audit was an enforcement audit with a special focus on government oversight and enforcement. The objective of the audit was to evaluate the performance of the CCA with respect to controls over meat producing and storage establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, the government laboratory performing analytical testing on U.S. destined product, and two slaughter establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	SIOPOA in Tegucigalpa
	Area Supervisor	0	Not Available Due to Hospitalization
	Local	2	Establishment Level
Laboratories		1	Tegucigalpa
Meat Slaughter Establishments		2	San Pedro Sula and Catacamus

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with SIOPOA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters. The third part involved on-site visits to two establishments. The fourth part involved visits to one government laboratory. The Laboratorio Nacional de Análisis de Residuos y Microbiología (LANAR) was conducting analyses of field samples for the presence of *Salmonella* and generic *Escherichia coli* (*E. coli*), as well as field samples for Honduras' national residue control program.

Program effectiveness determinations of Honduras' inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) programs and testing programs for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Honduras' meat inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the audit team evaluated the nature, extent and degree to which findings impacted on food safety and public health. The audit team also assessed how meat inspection services are carried out by the government of Honduras and determined if establishment and inspection system controls were in place to ensure that the meat products that Honduras exports to the United States are safe, unadulterated and properly labeled.

At the opening meeting, the audit team explained to the SENASA officials that the Honduran inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Honduras. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, species verification testing, requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*, and government oversight/enforcement.

Under provisions of the World Trade Organization (WTO) Sanitary and Phytosanitary Agreement, Honduras can submit alternate sanitary measures to FSIS for an equivalence determination. Currently, there are no equivalence determinations for Honduras. Honduras informed FSIS that they have adopted the FSIS regulatory requirements for HACCP and SSOP programs, as well as *Salmonella* and generic *E. coli* laboratory testing.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the U.S. import requirements listed in 9 CFR 327 and the Pathogen Reduction/HACCP and SSOP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofotsc.

The following deficiencies were identified during the FSIS audit of Honduras' meat inspection system conducted in June 2001:

- In one establishment, boxed product destined for export to the U.S. was not marked as such and was not separated from local product.
- Maintenance issues included broken floors, damaged freezer doors and rust on rails in carcass coolers.

- Beef tails in one establishment were contaminated with feces and hair.
- In one establishment, an esophagus, ready for export, was not spilt open and cleaned.
- In one establishment, the SSOP program was not signed by an establishment official and dated.
- No corrective actions were taken by establishment or government officials when pieces of plastic were found in product on several consecutive days.
- The HACCP plans in both establishments did not specify critical limits and monitoring procedures for each CCP in both establishments.

The following deficiencies were identified during the FSIS audit of Honduras' inspection system conducted in June 2002:

- Inspection controls were ineffective.
- One establishment had not signed and dated the SSOP plan and did not address the hazards and corrective actions in each of the steps in the hazard analysis.
- The required HACCP programs were found to be deficient.
- One establishment had deeply scored cutting boards with product residues and had broken plastic product containers.
- The SSOP were found not to meet the basic FSIS regulatory requirements.
- There were deficiencies in employee hygienic practices.
- One establishment did not have its SSOP plan signed and dated.
- One establishment did not address the re-conditioning of meat contaminated during processing procedures.
- Neither establishment had conducted annual re-assessments of their HACCP plan.

The following deficiencies were identified during the March 2003, audit conducted by FSIS of Honduras' meat inspection:

- Implementation of HACCP and SSOP requirements was inadequate.
- In one establishment, the written SSOP did not specify the responsible person for sanitation activities, but listed the responsible department.
- Preventive measures were not specified in the daily observation records.
- In both establishments, the verification procedure was incomplete.
- In one establishment, no sampling frequency was specified for monitoring of the critical control point (CCP) for zero visible contamination with feces of ingesta.
- In one establishment, validation not included in the HACCP plan.
- In one establishment, validation activities were incorrectly described as verification.
- In one establishment, improper sampling sites were used for testing for generic *E. coli*, the location in the cooler where the samples were taken was not designated in the written program, and the sampling techniques were not aseptic.

6. MAIN FINDINGS

6.1. Legislation

The government of Honduras has incorporated the FSIS regulations into its legislation as Decree Nos. 078-00 and 157-94.

6.2. Government Oversight

The meat inspection of the Republic of Honduras is administered by the Official Inspection Service of Animal Origin Products (SIOPOA), an agency within the National Service of Plant and Animal Health (SENASA), Agriculture and Livestock Secretariat (SAG). SIOPOA has direct authority over all meat establishments, including those certified to export meat to the United States. SIOPOA also has direct authority over Honduras' National Laboratory of Residue Analysis (LANAR). This government laboratory performs both chemical and microbiological analytical testing of meat products.

SIOPOA employs approximately 21 veterinarians and 31 auxiliary inspectors to carry out its domestic and export meat inspection programs and related enforcement activities. All inspection personnel assigned to establishments certified to export meat to the United States are full-time government employees receiving no remuneration from either industry or establishment personnel. Inspection personnel can hold outside employment provided it does not cause a conflict of interest with their official inspection duties.

Meat export certificates are controlled by the Chief Veterinary Officer (CVO) and are signed and distributed on an as-needed basis to the official inspection personnel stationed in the certified establishments. The CVO also maintains documented control of all official government seals and stamps. The Veterinarian-in-Charge (VIC) maintains physical control of all assigned government seals and stamps.

6.2.1 CCA Control Systems

SIOPOA is headed by a CVO and three Area Supervisors. One Area Supervisor has the responsibility for Honduras' meat and poultry establishments. During this audit, the audit team was unable to meet with the Area Supervisor for meat and poultry due to his illness.

SENASA has eight regional offices that provide only administrative functions relative to the meat establishments certified to export meat to the United States. SIOPOA also has authority over live animal matters in Honduras relative to livestock and poultry movement controls and diseases.

6.2.2 Ultimate Control And Supervision

At each certified meat establishment, the Veterinarian-In-Charge (VIC) has the authority to cease the establishment's production operations any time the wholesomeness and safety of the product is jeopardized. The VIC reports directly to the area supervisor for meat and poultry and the CVO regarding enforcement activities. The VIC uses Corrective Action Demands (DAC) as the official government documentation for citing the establishment for non-compliance activities. The decision to suspend the operations of an establishment or delist an establishment from exporting to the United States is a combined effort of the VIC, the area supervisor, and the CVO. The CVO will make the ultimate decision consulting with her immediate supervisors.

The VIC has direct supervision over all other inspection personnel assigned to certified establishments, including supervision over the auxiliary inspectors. For the two establishments certified to export meat to the United States, SIOPOA has a sufficient number of inspection personnel to adequately carry out the U.S. import requirements.

The government of Honduras has the organizational structure and adequate staffing to ensure uniform implementation of U.S. import requirements. The CVO satisfactorily demonstrated immediate corrective actions regarding official inspection activities and establishment activities relative to meeting U.S. import requirements. However, the government of Honduras could improve its control and supervision over official activities to ensure compliance with U.S. import requirements.

6.2.3 Assignment of Competent, Qualified Inspectors

All inspection personnel assigned to certified establishments undergo induction training, as well as participate in on-the-job practical training under the combined supervision of the CVO, VIC and Area Supervisor. Further training is provided for all inspection personnel as needed. SIOPOA recently used the services of the Canadian Food Inspection Agency to train Honduran inspection personnel in the principles of HACCP. This training was provided through the Central American Freed Trade Agreement. SIOPOA maintains individual training records of inspection personnel.

The official veterinarians in both U.S.-certified establishments are qualified and earned their degrees in veterinary medicine from accredited colleges in Brazil or Mexico (there is no accredited veterinary college in Honduras). The auxiliary meat inspectors received their academic training in animal/farm science from Honduras' vocational school.

The government of Honduras has competent inspection personnel in certified establishments, but additional training would improve their knowledge and understanding of the U.S. import requirements.

6.2.4 Authority and Responsibility to Enforce the Laws

The official inspection personnel are authorized to enforce the government of Honduras' meat inspection legislation and U.S. import requirements, including animal health and welfare, control of animal disease, veterinary medicines, and the production of safe foods of animal origin. SIOPOA, with the assistance of the regulatory enforcement group of SENASA, has the legal authority to suspend and delist certified establishments to prevent the export of unsafe meat to the United States.

6.2.5 Adequate Administrative and Technical Support

During this audit, the FSIS audit team determined that the CCA has the administrative and technical support to operate Honduras' meat inspection system and has the capability to support a third-party audit. However, additional resources would improve the ability of the government of Honduras to maintain an equivalent meat inspection system. In addition, the government of Honduras recently applied to FSIS for approval to export poultry products to the United States, which may enhance the need for additional resources.

6.3 Headquarters Audit

The audit team met with the CVO and other government officials at SENASA/SIOPOA headquarters to obtain a better understanding of the oversight and enforcement responsibilities of the government of Honduras. No concerns resulted from this meeting.

6.3.1 Audit of Regional and Local Inspection Sites

As previously mentioned, the area supervisor for meat and poultry was not available during this audit due to serious illness. Thus, the FSIS audit team was not able to obtain information regarding adequate oversight and enforcement by the area supervisor.

The audit team reviewed meat inspection records at the two certified establishments and in the government laboratory (LANAR). The records review focused primarily on food safety controls relative to meat exports to the United States. This included the following:

- Internal audit reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for laboratory personnel.
- Applicable laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory testing methods for microbiology and residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Export product inspection and control including export certificates.
- Enforcement records including examples of DACs, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents:

- Laboratory records of meat samples collected at the two certified establishments for generic *E. coli* and *Salmonella* testing did not show receipt of samples from cattle slaughtered the previous week at the two establishments. The CVO took immediate action to determine the whereabouts of the samples. For one establishment, documentation indicated that the samples were picked up by a courier service. For the other establishment, there was a misunderstanding of the FSIS requirement of a minimum of one sample per week. This establishment normally slaughtered less than 300 cattle during a week.
- The laboratory was using the “Simplate” method instead of the Petrifilm method for generic *E. coli* analysis. The government of Honduras had previously advised FSIS that it was following the FSIS procedure of using the Petrifilm method. The laboratory immediately reverted to the Petrifilm method. FSIS advised the government of Honduras that it can send a description of the Simplate method to FSIS for an equivalence judgment.

The audit team concluded that:

- All relevant regulations, notices, and other inspection documents and records were disseminated from headquarters to the two local inspection sites (certified establishments). This was accomplished by both hard copy and faxes.
- Inspection personnel demonstrated adequate knowledge of inspection requirements relative to the export and distribution of meat to the United States. However, additional training would be beneficial to further enhance knowledge and understanding of U.S. import requirements by inspection personnel.

7. ESTABLISHMENT AUDITS

The FSIS audit team visited two establishments that were certified to export meat to the United States. These two establishments conducted both slaughtering and processing. No establishments were delisted by SIOPOA, although one establishment received a notice of intent to delist (NOID) from SIOPOA.

Specific deficiencies are noted on the attached Foreign Establishment Audit Checklists (FSIS Form-5000-6).

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDIT

During the laboratory audit, emphasis was placed on the application of procedures and standards that are equivalent to U.S. requirements.

The residue laboratory audit focused on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

The microbiology laboratory audit focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test samples eligible for export to the United States, the auditor evaluated compliance with the criteria established for the use of private laboratories under the Pathogen Reduction (PR)/HACCP requirements. In Honduras, no private laboratories are used to test U.S.-eligible products.

The following laboratory was reviewed:

- The National Laboratory of Residues and Microbiology (LANAR) located in Tegucigalpa, which conducts analyses of meat samples for Honduras' national residue program, as well as analyses of meat samples for the presence of *Salmonella* and *E. coli*.

The findings in the residue section of the LANAR laboratory will be discussed in Section 12 (Residue Controls) and the findings in the microbiology section will be discussed in Sections 11.3 and 13.2.

9. SANITATION CONTROLS

As previously stated, FSIS focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the audit team reviewed was Sanitation Controls.

Except as noted below, Honduras' meat inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices.

In addition, Honduras' inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in the both establishments were found to meet the basic FSIS regulatory requirements. The following deficiency was identified:

- In one establishment, condensation had formed on ceilings, rails, and cooling units in the carcass cooler and was dripping on exposed carcasses.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS audit team reviewed was Animal Disease. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The audit team determined that the inspection system of Honduras had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit. The Animal and Plant Health Inspection Service (APHIS) continues to have import restrictions on pork products due to the presence in Honduras of Hog Cholera (Classical Swine Fever). Honduras is eligible to export cooked pork products to the United States provided they meet the APHIS and FSIS requirements.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS audit team reviewed was Slaughter/ Processing Controls. These include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

All establishments certified to export meat products to the United States, with the exception of facilities dedicated to cold storage, are required to have adequately developed and implemented HACCP programs. The HACCP programs were evaluated according to the criteria employed in the U.S. domestic inspection program.

During this audit, both establishments were required to meet the HACCP requirements. Honduras had adequately implemented the HACCP requirements.

11.3 Testing for Generic *E. coli*

Honduras has adopted the FSIS regulatory requirements for testing generic *E. coli*.

Both establishments were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the U.S. domestic inspection program.

FSIS concluded that testing for generic *E. coli* was properly conducted in both the establishments with the following exceptions:

- In one establishment, the location in the establishment where sampling for generic *E. coli* is conducted was not described in the establishment's sampling program. The SIOPOA official ordered immediate correction of this deficiency to meet U.S. requirements.
- Neither establishment had developed a statistical process control procedure to analyze the results of the testing program for generic *E. coli*. The method intended for excision sampling was being used. It was noted that the upper limit employed (100 cfu/cm²) was recommended to both establishments in Honduras that were certified for U.S. export by the government-owned and -operated microbiology laboratory where the samples are analyzed. The U.S. requirement had been misunderstood and SIOPOA officials gave assurances that they would amend the appropriate regulation accordingly via a ministerial agreement and that an appropriate statistical process control procedure will be developed promptly.
- The official government laboratory was using the "Simplate" method, which is similar to the Petrifilm method for analyzing meat samples for the presence of generic *E. coli*. Honduras had informed FSIS that the FSIS method (Petrifilm) was being used and had requested an equivalence determination for the "Simplate" method. The audit team advised the Honduran officials to submit the details of the new method to FSIS if this is the method they prefer to use. In the meantime, use of the "Petrifilm" method was immediately implemented for U.S.-eligible product.

11.4 Testing for *Listeria monocytogenes*

Neither of the establishments was producing ready-to-eat meat products for export to the United States. As a result, the FSIS requirements for *Listeria monocytogenes* testing did not apply.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS audit team reviewed was Residue Controls. These include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

No deficiencies were noted regarding residue controls.

Honduras' National Residue Control Program for 2003 was being followed as scheduled.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in both certified establishments.

13.2 Testing for *Salmonella*

Honduras has adopted the FSIS regulatory requirements for testing for *Salmonella* species.

Both establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* species testing and were evaluated according to the criteria employed in the U.S. domestic inspection program.

Testing for *Salmonella* species was properly conducted in both establishments.

13.3 Species Verification

Species verification was being conducted in both establishments as required.

13.4 Monthly Reviews

In both establishments, monthly supervisory reviews were being performed and documented as required.

13.5 Inspection System Controls

Except as noted below, the CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of

dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market. One deficiency was identified:

- In one establishment, post-mortem inspection of beef forequarters was being conducted after the final carcass wash. The SIOPOA official implemented a requirement for inspection officials to conduct full carcass post-mortem inspection prior to the carcass wash.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on December 12, 2003 in Tegucigalpa with the CCA. At this meeting, the primary findings from the audit were presented by the audit team.

The CCA understood and accepted the findings.

FSIS Audit Team

Mr. Steven McDermott
Lead Auditor
FSIS, Office of International Affairs

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

15. ATTACHMENTS TO THE AUDIT REPORT

Foreign Laboratory Audit Form
Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report

Att. A-1

Dec 8, 2003

Laboratorio Nacional de Analisis de Residuos /
 SENASA

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 SIOPOA

CITY & COUNTRY
 Tegucigalpa, Honduras

ADDRESS OF LABORATORY
 Apt. 3416

NAME OF REVIEWER
 Gary D. Bolstadk, DVM

NAME OF FOREIGN OFFICIAL
 Dra. Mercedes Erazo, Chief of the Dept., SIOPOA

Residue Code/Name			chc	abc	cap	tet	op	te	des	sul	ivm	bmz	Ec	Sal	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A	A	C	A
	Timely Analyses	03		A	A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O	O	O
	Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A	A	
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A	LC	LC	C	A	
	Correct Tissue(s)	08		A	A	kid	A	A	A	A	A	kid	liv	A	A
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	O	A	O	A	A	A	O	A	A	O	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	4ppb	.01pp	O	O	
	Recovery Frequency	12		A	A	A	A	A	A	A	A	A	A	A	A
	Percent Recovery	13		A	A	A	A	A	A	A	A	80-95	77-95	O	O
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A	A	A
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A	A	A	A	A
	Corrective Actions	16		C	C	C	C	C	C	C	C	C	C	C	C
	International Check Samples	17		O	O	O	O	O	O	O	O	O	O	O	A
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O	O	O	O	O	
OTHER REVIEW	Documentation	19	EVAL. CODE	C	C	C	C	C	C	C	C	C	C	C	
		20													

SIGNATURE OF REVIEWER

G.D. Bolstadk

DATE

December 8, 2003

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE Dec 8, 2003	NAME OF FOREIGN LABORATORY Laboratorio Nacional de Analisis de Residuos / SENASA	<i>A-2</i>
FOREIGN GOV'T AGENCY SIOPOA		CITY & COUNTRY Tegucigalpa, Honduras	ADDRESS OF LABORATORY Apt. 3416	
NAME OF REVIEWER Gary D. Bolstadk, DVM		NAME OF FOREIGN OFFICIAL Dra. Mercedes Erazo, Chief of the Dept., SIOPOA		

RESIDUE	ITEM NO.	COMMENTS
		Abbreviations: CHC = chlorinated hydrocarbons, ABC = antibiotics, CAP = chloramphenicol, TET = tetracyclines, DES = diethylstilbestrol, SUL = sulfonamides, IVM = ivermectin, BMZ = benzamidazoles, Ec = generic <i>E. coli</i> , Sal = <i>Salmonella</i> species
<i>E. coli</i>	02	The sampling requirement for generic <i>E. coli</i> had been misunderstood. The two establishments were submitting samples at the required frequency of one per 300 beef carcasses, but not a minimum of one per week when a total of 300 carcasses was not achieved during one week's time. This was corrected immediately.
<i>E. coli</i>	07	The laboratory uses the Simplate method, a procedure similar to Petrifilm. Honduras had informed FSIS that the FSIS method was being used; Honduras has not informed FSIS that an alternate method is being used. The laboratory director issued instructions to resume use of the Petrifilm method immediately, and gave assurances that the use of this method would be in place by the next working day.
All	16	Corrective actions to be taken in the event of problems with methodologies, materials, or analyst performance were not described in the written quality control program, although corrective actions were well documented for such occurrences. The laboratory director gave assurances that he would correct this immediately.
All	19	Several illegible corrections had been made in recent months in the sample receipt logs and in the log books for the documentation of analytical results. The laboratory director ordered that, starting immediately, all entries in all official documents must remain legible.

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Empacadora C & D Catacamas, Honduras	2. AUDIT DATE Dec.3-4,2003	3. ESTABLISHMENT NO. 4	4. NAME OF COUNTRY Honduras
	5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		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	O
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.		X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light	X
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	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils	
18. Monitoring of HACCP plan.			46. Sanitary Operations	X
19. Verification and validation of HACCP plan.			47. Employee Hygiene	
20. Corrective action written in HACCP plan.			48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing	
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage	
23. Labeling - Product Standards			51. Enforcement	X
24. Labeling - Net Weights			52. Humane Handling	
25. General Labeling			53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection	X
27. Written Procedures			Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		X	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

B-16

Empacadora C & D, Est. 4; Catacamas, Honduras; December 3-4, 2003.

13/46/51 Condensation had formed on ceilings, rails, and cooling units in the carcass cooler, and was dripping onto exposed carcasses. Effective corrective actions were implemented prior to the end of the audit. Condensation problems had been identified several months ago by the same SIOPOA official during an internal supervisory review, and she gave assurances that some improvement in prevention had been noted between then and the time of this audit. Establishment documentation of corrective actions when condensation problems occur during operations was not adequate; the SIOPOA officials ordered documentation of this problem by the establishment to begin immediately and gave assurances that the in-plant inspection staff would also increase their surveillance of this problem area.

28/51 The establishment had not developed a statistical process control procedure to analyze the results of the testing program for generic *E. coli*; the method intended for excision sampling was being used. It was noted that the upper limit employed (100 cfu/cm^2) is required according to the Honduran meat inspection legislation: the U.S. requirement had been misunderstood. The SIOPOA officials gave assurances that they would ensure that the regulation would be amended accordingly via a ministerial agreement and that a statistical process control procedure is developed promptly. It was noted that, over the course of the past year no results had exceeded the upper limit.

40/51 FSIS requires a minimum of 50 foot-candles (fc) of shadow-free light at inspection surfaces. The FSIS auditor measured light levels of 40 fc in the viscera trays and 30 fc at the level of abdominal cavities. The SIOPOA officials ordered prompt installation of new light sources to meet the requirement.

46 Both sanitizers in one small boning room were below the 180° F (82° C) requirement: one was measured at 150 and the other at 130. The SIOPOA official stopped the operations in the room immediately until the problem could be corrected.

51/55 Post-mortem inspection of beef forequarters was being conducted *after* the carcass wash. The SIOPOA officials gave assurances that they would conduct the full carcass final inspection prior to the carcass wash.

Following a discussion of the observations, the SIOPOA official who was the leader of the audit issued a Notice of Intent to Delist to the establishment management: the establishment will be delisted if the above deficiencies are not corrected within 30 days of this audit.

NOTE: All deficiencies identified during the previous FSIS audit On March 27, 2003, had been adequately addressed and corrected.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

GDB December 3-4, 2003

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Empacadora Continental San Pedro Sula, Honduras	2. AUDIT DATE Dec 5, 2003	3. ESTABLISHMENT NO. 12	4. NAME OF COUNTRY Honduras
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		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
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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	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	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

B-26

Empacadora Continental, Est. 12; San Pedro Sula, Honduras; December 5, 2003.

28/51 The establishment had not developed a statistical process control procedure to analyze the results of the testing program for generic *E. coli*; the method intended for excision sampling was being used. It was noted that the upper limit employed (100 cfu/cm² was recommended to both establishments in Honduras that were certified for U.S. export by the government-owned and -operated microbiology laboratory where the samples are analyzed. The SIOPOA officials gave assurances that they would ensure that a statistical process control procedure is developed promptly. It was noted that, over the course of the past year no results had exceeded the upper limit.

NOTE: All deficiencies identified during the previous FSIS audit On March 27, 2003, had been adequately addressed and corrected.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

J. D. Bolstad December 5, 2003

[SEAL]

SECRETARY OF AGRICULTURE AND LIVESTOCK

DGSA Note No. 085-2004

Tegucigalpa, M.D.C. February 27, 2004

Ms. Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs

Dear Ms. Stratmoen:

First of all I would like to convey my sincerest greetings and wish you all the best as you carry out your important duties.

We are pleased to send you the observations from the draft Inspection document resulting from the FSIS inspection in our country December 2-12 of 2003. We are also including observations regarding the note that you sent us attached to said report.

With nothing further for the moment, we remain,

Yours sincerely,

Dr. Mercedes Erazo
[SIGNATURE]

Dr. Lazaro Reyes
[SIGNATURE]

[SEAL]

Head of SIOPOA

Director General of SENASA

Cc: Dr. Nidia Garcia/Assistant Technician Director for Animal Health

Ms. Ana Gomez/ Agriculture attaché, U.S. Embassy in Honduras

Ms. Maria Bennaton/Honduran Embassy in Washington

[SEAL]

SECRETARY OF AGRICULTURE AND LIVESTOCK

REPORT IN RESPONSE TO THE DRAFT
REPORT REGARDING THE AUDIT OF THE
MEAT INSPECTION SYSTEM

Regarding those items still pending for the facility to which the NOID was applied, the corrections implemented were documented in the memorandum of December 22, 2003 Note No. 558-2003. Said facility has been complying with the FSIS' requested measures, such as:

1. Control of condensation in the diffusers, rails, and roof of the meat 'chiller' area was corrected before the inspection was completed.
2. Logs and condensation control procedures for the chillers are maintained in accordance with the HACCP of the facility.
3. There is a procedure with data starting April 4 2003 for analysis of generic E.Coli in the facility through statistical methods.
4. Sufficient lighting was installed in the entrails, front quarter, and head inspection areas. Said lighting may not fall below 550 units lux.
5. Controls are maintained on the sterilizers, which should function with the proper temperatures.
6. There is a permanent inspector for the front quarters before they are sent to the final cleaning. This inspector was hired starting December 12, 2003.

In addition, the report indicates several situations that the Inspection service had indicated needed compliance. These have now been corrected:

1. The pre-operational activities between facility personnel and SIOPOA are carried out separately, and SIOPOA maintains a record

[SEAL]
SECRETARY OF AGRICULTURE AND LIVESTOCK

of all findings after the procedures are carried out at the plant (see attached form).

2. Currently, the facilities read the E. Coli results based on their own statistical control procedures that have been designed for each plant. A Ministerial Accord, No. 101-04, was issued on February 10 2004 was issued in this regard. (See attached copy of the Accord as well as the results for two plants.)

We should clarify that the Inspection service and the SENASA authorities had not been informed of this requirement in previous audits. It was never mentioned.

3. In terms of the use of the SIMPLATE method for diagnosing generic E. Coli, we remind you that we asked the FSIS on December 22 in Note No. 570-2003 for its approval of both methods (SIMPLATE and PETRIFILM). We have still not received a response. But before the inspection visit was finalized, the facilities and the official laboratory modified the diagnostic method to PETRIFILM. This method shall be maintained until we receive an affirmative response from the FSIS regarding the use of the other method. (See attached copy of the note from the laboratory where the method was immediately changed).

The report recognized that all the problems encountered during the previous visit in March/April 2003 had been corrected, including recurring problems in the HACCP and SSOP.

Therefore, we request that the suspension be lifted so that the Honduran authorities maybe certify additional facilities for the export of meat products to the United States.