United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

NOV 0 3 2009

Dr. Daniel Rojas Lopez
President
SENACSA
Ruta Mariscal Estigarribia Km 10 y Avda. Ciencias Veterinarias
Asunción
Paraguay

Dear Dr. Lopez:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Paraguay's meat inspection system March 31through April 8, 2009. Comments received from the government of Paraguay have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions, please contact me by telephone at 202.720.6400, by facsimile at 202.720.6050 or by electronic mail at internationalequivalence@fsis.usda.gov

Sincerely,

Andreas Keller, Director
International Equivalence Staff
Office of International Affairs

Enclosures

FINAL

FINAL REPORT OF AN ON-SITE AUDIT CARRIED OUT IN PARAGUAY COVERING PARAGUAY'S MEAT INSPECTION SYSTEM

MARCH 31 THROUGH APRIL 8, 2009

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
DIGECIPOA	General Direction of Quality and Safety of Products of Animal Origin
DIGELAB	General Direction of Laboratory
DIGHR	General Direction of Human Resources
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
Salmonella	*Salmonella* species
SENACSA	National Service of Quality and Animal Health
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
U.S.	United States

1. INTRODUCTION

Background:
In 1997, FSIS suspended Paraguay's export eligibility status because of its failure to implement PR/HACCP and SSOP requirements or equivalent measures. In 2005, Paraguay sent a letter to FSIS requesting to initiate a process of regaining its eligibility to export meat products to the United States (U.S.). FSIS held a teleconference with Paraguay's meat inspection officials and followed up with an official letter notifying Paraguay about requirements that needed to be in place and implemented before Paraguay could regain meat export eligibility to the U.S.

Paraguay responded and submitted inspection documents as requested. FSIS completed the document review and held series of teleconferences to discuss the next steps for Paraguay to regain its eligibility to export meat to the U.S. FSIS advised Paraguay that the next steps would be an on-site audit of Paraguay's meat inspection system following Paraguay's full implementation of the FSIS inspection requirements.

In December 2008, Paraguay made an official request for an on-site audit of its meat inspection system. FSIS held a teleconference meeting with Paraguay and followed up with an official letter to establish the dates for the on-site-audit and discuss the audit strategy.

On-Site Audit:
The audit took place in Paraguay from March 31 – April 8, 2009.

An opening meeting was held on March 31, 2009, in Asuncion, Paraguay with the Central Competent Authority (CCA), which is the National Service of Quality and Animal Health (SENACSA). At this meeting, the Food Safety and Inspection Service (FSIS) team leader confirmed the objective and scope of the audit, the team's itineraries, and requested additional information needed to complete the on-site audit of Paraguay's meat inspection system.

Representatives accompanied the team members during the entire audit from the SENACSA.

2. OBJECTIVE OF THE AUDIT

This on-site audit of Paraguay's meat inspection system was part of the process for Paraguay to regain eligibility to export meat to the U.S. The overall objective of this audit was to determine whether Paraguay might regain its eligibility to export meat products to the U.S.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA in Asuncion, 3 local inspection offices, 3 slaughter and processing establishments, one residue laboratory, and one microbiological laboratory.

Competent Authority Visits			Comments
Competent Authority	Central	1	SENACSA
	Establishment	3	Local Inspection Offices
Laboratories	Microbiological	1	Government laboratory
	Residue	1	Private laboratory
Slaughter and Processing Establishments		3	Beef

3. PROTOCOL

This audit was conducted in three parts. One part involved visits with CCA officials in Asuncion, Paraguay to review the government of Paraguay's (GOP) inspection and enforcement programs. The second part involved on-site visits to three slaughter and processing establishments to audit establishment operations. The third part involved on-site visits to audit laboratory operations at one government microbiology laboratory and one private residue laboratory.

The scope of the audit included government oversight, establishment operations, microbiology programs, laboratory operations, and five risk areas. The five risk areas included: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS), (2) slaughter/processing controls, including ante-mortem inspections, human slaughter of livestock, post-mortem inspections, Hazard Analysis and Critical Control Point (HACCP) system, and a testing program for generic *Escherichia coli* (*E. coli*), (3) residue control programs, (4) animal disease controls and (5) enforcement controls, including inspection coverage in establishments, inedible controls, species verifications, and periodic supervisory reviews. Program effectiveness determinations of Paraguay's inspection system focused on this scope.

During the on-site audit of headquarters, the team assessed how meat inspection services were carried out by the GOP and determined if GOP's oversight and enforcement strategies were in place and effectively communicated to the field inspection personnel for implementation to ensure that meat products were safe, unadulterated, and properly labeled.

During the on-site audit of establishment operations, the team assessed whether (1) the establishment's food safety systems (design and execution) were in place and effectively implemented to ensure food Safety and (2) verification and enforcement activities of the GOP inspectors were in place and effectively implemented to assure that establishments were complying with food safety regulations. In addition, the team evaluated the nature, extent, and degree to which findings influenced food safety and public health.

During the on-site audit of laboratory operations, the team assessed whether (1) FSIS laboratory methods or equivalent measures were in place and (2) GOP's laboratory analysts were accurately and correctly applying FSIS laboratory methods or equivalent measures to ensure the maximum opportunity for the detection and identification of pathogens and targeted residues.

At the opening meeting, the lead auditor explained that since FSIS has not made any equivalence determination for Paraguay at this time, Paraguay's meat inspection system would be solely assessed against FSIS regulatory requirements. FSIS requirements include, among other things, daily inspection in all certified establishments, periodic supervisory visits to 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, sanitation of facilities and equipment, testing of ready to eat product for *Listeria monocytogenes* and *Salmonella*, residue testing, species verification, and requirements for HACCP, SSOP, SPS, and testing for generic *Escherchia coli* (*E. coli*) and *Salmonella*.

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 regulations.

5. SUMMARY OF PREVIOUS AUDITS

In 1997, FSIS suspended Paraguay's export eligibility status because of its failure to implement PR/HACCP and SSOP requirements or equivalent measures.

6. MAIN FINDINGS

6.1 Government Oversight

Headquarter Office in Asuncion:
During the on-site audit of the headquarters, the team assessed how meat inspection services were carried out by the GOP and determined if GOP's oversight and enforcement strategies were in place and effectively communicated to the field inspection personnel for implementation to ensure that meat products are safe, unadulterated, and properly labeled.

In pursuit of the government oversight audit, the team focused on the following areas: (1) Organizational Structure and Staffing, (2) Control and Supervision, (3) Assignment of Competent, Qualified Inspectors, (4) Authority and Responsibility to Enforce U.S. Requirements, and (5) Administrative and Technical Support.

6.1.1 Title 9 CFR 327.2 Organizational Structure and Staffing

The National Service of Quality and Animal Health (SENACSA) is the CCA for enforcing the laws and regulations regarding inspection for export establishments. The SENACSA is divided into five different program areas headed by the president. The president of SENACSA is the chief veterinary officer. One of the program areas responsible for directing and managing the Paraguay's meat inspection programs is the General Direction of Quality and Safety of Products of Animal Origin (DIGECIPOA). The director general who reports to the president of SENACSA heads the DIGECIPOA. The DIGECIPOA has a procedure in place to ensure that FSIS requirements and SENACSA inspection directives are communicated to field inspection personnel via faxes, mail, and emails. Under the director general of DIGECIPOA are the technical coordinator, director of the slaughterhouses and cold storages, and head of the veterinary inspection office.

The technical coordinator is responsible to coordinate microbiology and residue testing, export certification, and Sanitary and Phytosanitary programs. The director of the slaughterhouses and cold storages is directly responsible for supervising and managing inspection oversight and enforcement activities at the field level. The head of the veterinary inspection reports to the director of the slaughterhouses and he/she conducts periodic supervisory reviews 3-4 times per year.

Because the SENACSA has no district or regional meat inspection offices, the inspection personnel at the establishments directly report to the head of the veterinary inspection at the headquarters, in Asuncion. The inspection personnel at the establishments are the official employees of the national government. The national government of Paraguay uses tax revenues to pay for inspection programs.

Area of concern:
The CCA needed to address this issue: direct payment of some overtime charges to inspection personnel by the establishments. This is an appearance of a conflict of interest.

6.1.2 Title 9 CFR 327.2 Ultimate Control and Supervision

The DIGECIPOA has direct control of inspection activities at export establishments. The director of the slaughterhouses is responsible for supervising and managing inspection oversight and enforcement activities at the field level. The head of the veterinary inspection reports to the director of the slaughterhouses and cold storages and he/she conducts periodic supervisory reviews 3-4 times per year. The periodic supervisory reviews focused on establishment compliance and job performance of inspection personnel at the establishment. The DIGECIPOA informed the audit team that apart from periodic supervisory reviews, it had an audit program in place to assess inspection activities and performance of inspection personnel every two months but the DIGECIPOA did not provide documentation to support this program. The veterinarian-in-charge is supervised by the head of the veterinary inspection. Implementation of verification procedures and enforcement activities at the export establishments is accomplished by the veterinarian-in-charge. The supervision of non-veterinary inspectors (paratechnical staffs) at the

establishment level is the responsibility of the veterinarian-in-charge assigned to the establishment. The DIGECIPOA has controls in place regarding transportation security between establishments and port facilities. The official veterinarian-in-charge is responsible for the sealing of meat trucks to maintain security and integrity of meat products during transportation between establishments and port facilities. With proper documentation, the seal can only be broken by the official veterinarian-in-charge at the point of destination or port.

No finding:
The CCA has ultimate control and supervision over the official activities of all employees or licensees of the system.

6.1.3 Title 9 CFR 327.2 Assignment of Competent, Qualified Inspectors

The DIGECIPOA is responsible for assigning qualified veterinarians and paratechnical inspectors to perform inspection oversight and enforcement activities at the export establishments. The DIGECIPOA staffs consist of 57 veterinarians, 92 paratechnical inspectors, and 18 administrative staff employees. All official veterinarians have veterinary medical degrees from an accredited university. Paratechnical inspectors assist official veterinarians in inspection duties and they have at least a Bachelor Degree in agricultural sciences from an accredited university. Because the inspection personnel turnover rate is very low and no inspection personnel have retired lately, the DIGECIPOA did not have any formal hiring procedures in place for inspection personnel.

Area of concern:
Although, the CCA showed attendance records to demonstrate that inspection personnel attended several inspection seminars, the CCA did not have formalized initial and on-going training programs that specifically focus on FSIS requirements.

6.1.4 Title 9 CFR 327.2 Authority and Responsibility to Enforce Meat Inspection Laws and Regulations

The CCA has the legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not prepared in export establishments. The veterinarian-in-charge at each establishment and designated headquarters personnel have the legal authority to suspend operations and delist certified establishments. The legal framework for Paraguay's meat inspection consists of laws, articles, decrees, and resolutions. Law number 2426/04 provides legal authority to establish the National Service of Quality and Animal Health (NSQAH), the CCA. Article 7 gives the CCA the authority to elaborate, coordinate, execute, and supervise the national policy of animal health, quality and safety of products and by products of animal origin. Resolution 47/71 gives the CCA the authority to inspect slaughterhouses and abattoirs.

In addition, the CCA has procedures in place and authority to issue directives to establish export requirements and create inspection manuals for inspection personnel. The CCA has NSQAH directives 686/06 and 1656/06 in place to establish hygienic sanitary requirements in slaughter and processing establishments and to implement compulsory HACCP in all establishments that export to the European Union. The CCA implemented NSQAH directives 801/06 and 1049/06

to establish instructions and procedures for inspection personnel on veterinary inspection methods and implementation of HACCP in establishments.

Area of concern:
Because the CCA did not have training programs for FSIS requirements in place or implemented, some of the FSIS regulatory requirements were not met.

6.1.5 Title 9 CFR 327.2 Administrative and Technical Support

Two program areas that are responsible for providing administrative and technical support are General Direction of Human Resources (DIGHR) and General Direction of Laboratory (DIGELAB). Both DIGEHR and DIGELAB report to the chief veterinary officer of SENACSA. The director general of the DIGEHR is responsible for providing adequate administrative functions to support inspection programs while the director general of the DIGELAB is responsible for providing adequate oversight of the laboratory operations that support inspection programs. The administrative staffs provide these functions: Employee salaries and benefits, budget, hiring of employees, personnel actions, training programs, maintenances of inspection facilities and vehicles, and the computer information systems that supports inspection programs. The technical staffs provide scientific and laboratory analysis to support inspection programs. The Technical Coordinator of the DIGECIPOA is responsible to coordinate implementation strategies for microbiology and residue programs with the DIGELAB and the field inspection personnel.

Area of concern:
The CCA did not have initial and on going training programs to maintain competency of the laboratory analysts.
The CCA has residue programs in place, but it did not provide adequate oversight over the third party laboratories that conduct residue analyses.

Three Local Inspection Offices:
The SENACSA has no district or regional meat inspection offices. The field inspection personnel report to DIGECIPOA at the headquarters. The purpose of on-site audit of the three local inspection offices was to verify that all the information obtained from the headquarters were effectively communicated to the field personnel for implementation. In addition, the team determined whether verification and enforcement activities of the GOP inspectors were in place and effectively implemented to ensure that establishments were complying with food safety regulations.

In all the three local inspection offices, the inspection documents were properly disseminated from the CCA to inspection personnel at the establishments. The inspection personnel implemented inspection information to carry out their daily inspection activities. The verification and enforcement activities were in place and implemented to ensure that establishments were complying with Paraguay's food safety laws and regulations, and exporting countries' food safety requirements.

Area of concern:
Because the CCA did not have training programs on FSIS requirements, the inspection personnel were unable to recognize and identify that establishments were not meeting some of the FSIS regulatory requirements.

7. AUDIT OF ESTABLISHMENT OPERATIONS

Three meat establishments that are seeking certification to export meat products to the United States were audited. During the on-site audit of establishment operations, the team assessed whether (1) the establishment's food safety systems were in place and effectively implemented to ensure food safety and (2) verification and enforcement activities of the GOP inspectors were in place and effectively implemented to assure that establishments were complying with food safety regulations.

In addition, the team evaluated the nature, extent, and degree to which findings influenced food safety and public health. Refer to the attachments in section 16 for individual foreign establishment audit checklists. The audit checklists provide detail description of establishment's food safety findings.

8. SANITATION CONTROLS

As stated earlier, the scope of the audit included five risk areas. The first of these risk areas is sanitation controls. Sanitation controls are part of the establishment's food safety systems and they include Sanitation Standard Operating Procedures and Sanitation Performance Standards.

8.1 Title 9 CFR 416.11-416.17 Sanitation Standard Operating Procedures (SSOP)

Each establishment was evaluated to determine if FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The CCA has NSQAH directives 686/06 and 1656/06 in place to establish hygienic sanitary requirements in slaughter and processing establishments and to implement compulsory HACCP in slaughterhouses.

No findings (Design of SSOP):
The establishment met FSIS requirements.

Areas of concern (Execution of SSOP)
The written sanitation procedures specified that monitoring would be conducted twice per shift, but the records indicated that the monitoring of the deboning room was conducted sporadically, once per shift, over a 60-day period.
Fat residue and pieces of meat and fat remained on the product contact surfaces of the viscera pans after the final cleaning.

8.2 Title 9 CFR 416.1-416.6 Sanitation Performance Standards (SPS)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SPS were met, according to the criteria employed in the United States' domestic inspection program. The CCA has NSQAH directives 686/06 and 1656/06 in place to establish hygienic sanitary requirements in slaughter and processing establishments and to implement compulsory HACCP in slaughterhouses.

Areas of concern:
Beading condensate from the refrigeration units was observed over several areas where exposed products were handled.
Black mechanical grease was accumulating on the head chain support rail and two pieces of fat were observed on the head drive chain located above the beef heads.
The evisceration platforms were not designed to preclude contamination of exposed products from employees' boots and the work platform.
The platform for the beef carcass eviscerator contained standing water that posed a potential for contamination of the viscera and carcass shanks.
Equipment such as knife sharpening steels, hand brushes, and para-acetic acid bottles were stored in hand wash sinks.

9. SLAUGHTER/PROCESSING CONTROLS

The second of these risk areas was Slaughter/Processing controls. Slaughter/Processing controls are part of the establishment's food safety systems and they include ante-mortem inspection requirements, humane slaughter of livestock, and post-mortem inspection requirements. The controls also include the implementation of Hazard Analysis and Critical Control Point systems in the three establishments and implementation of a testing program for generic *E. coli.*

9.1 Title 9 CFR 309 Ante-mortem inspections

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for ante-mortem inspections were met, according to the criteria employed in the United States' domestic inspection program. Article 7 of Paraguay's inspection law specifies the coordination, execution, and supervision of animal health quality and safety of products and byproducts of animal origin. Resolution MAG 47/71 of Paraguay's inspection law gives the CCA the authority to inspect meat and byproducts, construction, sanitary engineering of slaughterhouses and abattoirs.

No finding:
The CCA met FSIS regulatory requirements for ante-mortem inspections.

9.2 Title 9 CFR 313 Humane slaughter of livestock

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for humane slaughter of livestock were met, according to the criteria employed in the United States'

domestic inspection program. NSQAH 631/08 of Paraguay's inspection manual specifies procedures on animal welfare and humane slaughter.

No finding:
The CCA met FSIS regulatory requirements for humane slaughter of livestock.

9.3 Title 9 CFR 310 Post-mortem inspections

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for post-mortem inspection were met, according to the criteria employed in the United States' domestic inspection program. Article 7 of Paraguay's inspection law specifies the coordination, execution, and supervision of animal health quality and safety of products and byproducts of animal origin. Resolution MAG 47/71 of Paraguay's inspection law gives the CCA the authority to inspect meat and byproducts, construction, sanitary engineering of slaughterhouses and abattoirs.

No finding:
The CCA met FSIS regulatory requirements for post-mortem inspections.

9.4 Title 9 CFR 417 Hazard Analysis and Critical Control Point (HACCP) systems

All establishments that will be 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 in the three establishments were evaluated according to the criteria employed in the United States' domestic inspection program. The CCA has a legal authority and procedure in place to implement HACCP regulations. NSQAH 686/06 and 1656/06 give the CCA the authority to establish hygienic sanitary requirements in slaughter and processing establishments and implement compulsory HACCP in slaughterhouses. In addition, NSQAH 1049/06 of Paraguay's inspection manual specifies procedures for implementation of HACCP in slaughterhouses and abattoirs.

Areas of concern (Design of HACCP):
The establishment did not have decision-making documents to support its decision of not having a CCP for zero-tolerance for fecal material, ingesta, and milk in the offal HACCP plan.
The establishment did not have decision-making documents to support its decision of not considering *E.coli* O157:H7 as a pathogen reasonably likely to occur in the slaughter process.
In the deboning HACCP plan, return products were not identified as a processing step in the flowchart and not considered in the hazard analysis.
The establishment did not include offal products in the hazard analysis for the slaughter HACCP plan.

Areas of concerns (Execution of HACCP):
Review of 14 records for CCP 2 (temperature) indicated that the establishment did not verify record verifications and direct observations of the monitor.

The establishment's corrective actions for a deviation from the critical limit (zero tolerance) for fecal material, ingesta, and milk did not address whether (1) the process was under control, (2) preventive measures had been implemented, and (3) the verification of the effectiveness of the establishment's corrective actions.
The establishment's written instructions for the calibration of thermometers for measuring the temperature of beef carcasses (CCP 2) did not specify: (1) the calibration deviation tolerance, (2) corrective actions for calibration deviations, and (3) instructions to add or subtract the deviation.
The establishment could not calibrate or adjust thermometers with calibration deviations.
The establishment did not conduct temperature-monitoring procedures for red offal as specified in the HACCP plan.
The establishment conducted verification procedures for CCP 1for red offal, but the verification activity was not documented.
The establishment conducted verification procedures for all CCPs, but it did not clearly distinguish between direct observation of the monitor and record verification.
The establishment did not record verification results on the monitoring form.
The establishment failed to reassess the adequacy of its HACCP plan when the daily monitoring records indicated that there were 12 consecutive documented deviations from the critical limit for CCP 1, zero tolerance for fecal material, ingesta, and milk.
The establishment did not have pre-shipment review procedures in place and no pre-shipment review records had been generated.

9.5 Title 9 CFR 310 Testing program for generic *E. coli*

All establishments that slaughter livestock and intend to be certified to export meat products to the U.S. are required to implement testing programs for generic *E. coli*. The generic *E. coli* testing programs in the three establishments were evaluated according to the criteria employed in the United States' domestic inspection program. The CCA has adopted FSIS regulatory requirements for the *E. coli* testing program.

No findings:
The generic *E.coli* testing program for process control is in place and implemented in accordance with 9 CFR Part 310.

10. Title 9 CFR 309.16, 310.21, and 327.2 RESIDUE CONTROL PROGRAMS

The third of these risk areas was Residue Controls. The CCA implemented the European Commission's (EC) residue program specified in EC directive 96/23 which has been found equivalent by FSIS.

11. Title 9 CFR 310.25 and 430 MICROBIOLOGY PROGRAMS

The CCA has the following microbiology testing programs in place and implemented establishments' generic *Escherichia coli (E. coli)* testing procedure for process control and *Salmonella* in raw product for performance standard.

No finding (Generic *E. coli*)
The establishment met the requirements.

Area of concern (*Salmonella* testing in raw meat)
The CCA did not have the FSIS *Salmonella* testing program for raw meat products or an equivalent program in place (9 CFR Part 310.25).

Area of concern (Ready-to Eat meat products)
The CCA did not have *Listeria monocytogenes* and *Salmonella* testing programs in ready-to-eat (RTE) products or an equivalent program in place (9 CFR Part 430.4).

12. AUDIT OF LABORATORY OPERATIONS

Two laboratories (microbiology and residue) that will be conducting required laboratory analyses on meat product samples destined for the U.S. export were audited. During the on-site audit of laboratory operations, the team assessed whether (1) FSIS laboratory methods or equivalent measures were in place and (2) GOP's laboratory analysts were accurately and correctly applying FSIS laboratory methods or equivalent measures to ensure that the maximum opportunity for detection and identification of pathogens and targeted residues.

The DIGECIPOA is responsible for developing sampling procedures including scheduling of meat samples for field inspection personnel. Upon receiving the sampling request from the DIGECIPOA, field inspection personnel implement the sampling procedures by collecting and sending meat samples to the specified laboratory. The inspection personnel receive sample results from the laboratory via electronic format (Excel program), fax, and mail delivery. The inspection personnel manual specifies what enforcement action to be taken in response to positive results.

12.1 Audit of the residue laboratory

Residue laboratory audits focused on sample handling, sampling frequency, timely analysis and data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions. Paraguay has signed contracts with two residue laboratories in third countries (Uruguay and Brazil) and one private laboratory in Paraguay. The team audited one private laboratory in Paraguay (Diaz Gill). The Diaz Gill laboratory is an ISO 17025 accredited laboratory.

Areas of concern:
The CCA did not have a sampling handling procedure in place to ensure security and integrity of samples sent to third party laboratories.
The CCA did not maintain temperature records for equipments used to store samples and testing kits.
The CCA did not have a procedure for intra-laboratory performance check samples to validate test results and to monitor trends or biases.
The CCA did not have records to show that the internal audit was being conducted.

The CCA had corrective action procedures in place, but no corrective actions were documented.
The CCA indicated that turnaround times for testing results from the third party laboratories could be 5-8 weeks depended on when the payment was received by the laboratories.

12.2 Audit of the microbiology laboratory

Microbiology laboratory audits focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. The team audited one government laboratory in Paraguay.

Areas of concern:
The CCA did not have FSIS or equivalent analytical testing method in place for detecting *Listeria monocytogenes* and *Salmonella* in RTE meat products.
The CCA did not have proficiency testing in place for either *Salmonella* or *Listeria monocytogenes.*
The CCA did not maintain positive and negative controls in a consistent manner for *Salmonella* and *Listeria monocytogenes* testing.
There were several critical instruments in use for media preparation and analysis where verification, calibration and/or maintenance records were either not maintained or not consistent with the U.S. guidelines.
Examples include: thermometers were not being calibrated, no records for sterilizing media, no testing for conductivity/resistivity or total plate count for water used for preparing culture media, and no maintenance records for instruments such as autoclaves, micro liter pipettes, analytical and other balances.

13. Title 9 CFR 94.1 ANIMAL DISEASE CONTROLS

The fourth of these risk areas was Animal Disease Controls. Animal and Plant Health Inspection Service (APHIS) disease status restrictions are in place for Foot and Mouth Disease (FMD). As a result, Paraguay is not eligible to export raw meat products to the United States.

No finding:
The CCA met the requirements for animal disease control.

14. ENFORCEMENT CONTROLS

The fifth of these risk areas was Enforcement Controls. These controls include the daily inspection coverage, continuous inspection coverage in slaughter operations, inedible controls, species verification, and periodic supervisory reviews.

14.1 Title 9 CFR 327 Inspection coverage in establishments

The establishment was evaluated to determine if the FSIS requirements for daily inspection coverage were met according to the criteria employed in the United Sates' domestic inspection program.

No finding:
The CCA had daily inspection coverage for all export establishments and continuous inspection coverage for slaughter operations in accordance with 9 CFR Part 327.

14.2 Title 9 CFR 327 Inedible controls

The establishment was evaluated to determine if the FSIS requirements for inedible controls were met according to the criteria employed in the United Sates' domestic inspection program.

No finding:
The inedible control program was in place and implemented in accordance with 9 CFR Part 327.

14.3 Title 9 CFR 327 Species Verification

The establishment was evaluated to determine if species verification procedures were in place and implemented.

No finding:
The species verification control program was in place and implemented in accordance with 9 CFR Part 327.

14.4 Title 9 CFR 327 Periodic Supervisory Reviews

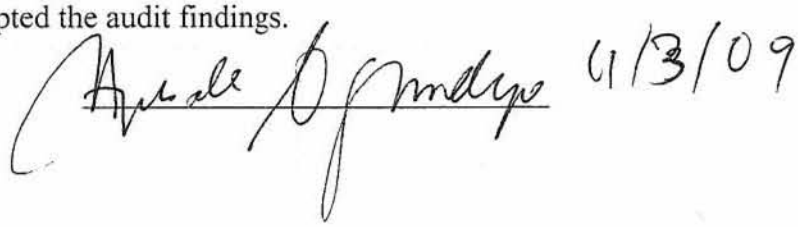
The establishment was evaluated to determine if the FSIS requirements for periodic supervisory reviews were met according to the criteria employed in the United Sates' domestic inspection program.

No finding:
The periodic supervisory review was in place and implemented in accordance with 9 CFR Part 327.

15. CLOSING MEETING
A closing meeting was held on April 8, 2009, in Asuncion, Paraguay with the CCA. At this meeting, the preliminary findings from the audit were presented by the team leader.

The CCA understood and accepted the audit findings.

AJ Ogundipe
Team Leader



16. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Checklists
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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
FrigoMeric Lombardo and Calle Corta Asuncion, Central	04/06/09	2	Paraguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) *Ongoing Requirements*	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 04/06/09 Est #: 2 (FrigoMeric [S/P/CS]) (Asuncion, Paraguay)

14/22/51. The establishment did not consider offal products in the slaughter hazard analysis and were not included in the process flow chart. The establishment did not have decision-making documents to support this decision. [Regulatory reference(s): 9 CFR §417.2(a)-(b), 417.5, 417.8]

15/22/51. E. coli O157:H7 was not considered as a pathogen reasonably likely to occur in the slaughter process. SENACSA stated that E. coli O157:H7 had not been identified in Paraguay and therefore the establishment did not identify this pathogen in their hazard analysis. The establishment did not have decision-making document to support this decision. [9 CFR §417.2(c), 417.5, 417.8]

22/51. The establishment conducted verification activities for all CCPs, but there was no way to differentiate between direct observation of the monitoring activities and records verification. The results of the verification were not documented. [9 CFR §417.5, 417.8]

22/51. Corrective actions for a deviation from the critical limit for zero tolerence for fecal material, ingesta, and milk did not address wither the process was under control, that preventive measures had been implemented, and the verification of the effectiveness of the establishment's corrective actions. [9 CFR §417.5, 417.8]

41/51. Beaded condensate was observed under the drip pan located under a refrigeration unit in the beef quarter area and under some refrigeration units in the beef carcass cooler. No product was affected. [9 CFR §416.2(d)]

46/51. The work platform, at the red offal evisceration stand, was not designed to prevent viscera-to-viscera contamination. The guard located on the front of the evisceration stand allowed each set of viscera to contact or potentially contact the underside of this guard. [9 CFR §416.4(a)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 04/06/2009

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigochorti Aldeq Neudorf Loma Plata, Occidental 9370	04/01 & 02/09	9	Paraguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	X
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 04/01 & 02/09 Est #: 9 (Frigochorti [S/P/CS]) (Loma Plata, Paraguay)

15/51. A CCP for zero tolerance for fecal material, ingesta, and milk was not included in the hazard analysis of the offal HACCP plan. [Regulatory reference(s): 9 CFR §417.2(c), 417.8]

15/51. In the deboning HACCP plan, return products were not considered in the hazard analysis and was not identified as a process in the flow chart. [9 CFR §417.2(c), 417.8]

15/51. E. coli 0157:H7 was not considered as a pathogen reasonably likely to occur. Since E. coli 0157:H7 had not been identified in Paraguay, therefore it was not identified as a pathogen in their hazard analysis. [9 CFR §417.2(c), 417.8]

19/51. Fourteen consecutive days of records for CCP 2, temperature of beef carcass exiting the maturation coolers, were reviewed for FSIS verification requirements. One of 14 monitoring records was not verified for ongoing records verification and two of 14 monitoring records were not verified for ongoing direct observation verification of the monitor or monitoring records verification. [9 CFR §417.4(a)(2), 417.5, 417.8]

20/22/51. Corrective actions for a deviation from the critical limit for fecal material, ingesta, and milk did not address whether the process was brought back under control or the verification of the effectiveness of the establishment's corrective actions. [9 CFR §417.3(a)(b)(c), 417.5, 417.8]

21/51. Eight of 12 consecutive daily monitoring records documented deviations from the critical limit for CCP 1, zero tolerance for milk, ingesta, and feces. The establishment had not reassessed their slaughter HACCP plan. [9 CFR §417.4(a)(3), 417.8]

22/51. E. coli O157:H7 was not considered as a pathogen reasonably likely to occur in the slaughter hazard analysis. SENACSA stated that E. coli O157:H7 had not been identified in Paraguay and therefore the establishment did not identify this pathogen in their hazard analysis. The establishment did not have decision-making documents to support their decision. [9 CFR §417.5, 417.8]

22/51. Preshipment review procedures and records had not been generated. The establishment was aware of FSIS requirements, but since Paraguay is not currently eligible to export to the United States, the establishment was not compliant. [9 CFR §417.5, 417.8]

22/51. The establishment failed to provide sufficient documentation to support that a CCP for zero tolerance for fecal material, ingesta, and milk was not included in the offal HACCP plan. [9 CFR §417.5, 417.8]

22/51. The establishment had written calibration instructions for thermometers used for the measurement of the critical limit for CCP 2, carcass temperature. The instructions did not state a deviation tolerance. The thermometers could not be adjusted and therefore establishment employees were given verbal instructions to add or sub tract the deviation when measuring critical limits for temperature. [9 CFR §417.5, 417.8]

41/51. During pre-operational sanitation verification, beading condensate was observed on refrigeration piping under a refrigeration unit in the beef quarter area and on the ceiling of a hallway between the beef carcass coolers. [9 CFR §416.2(d)]

46/51. Equipment such as knife-sharpening steels, hand wash brushes and Para-Acetic Acid bottles were stored in hand-wash sinks. [9 CFR §416.4(a)]

46/51. The beef carcass evisceration platform was not designed to preclude the possibility of the viscera contacting the evisceration work platform. There was a two inch gap between the work platform and the toe guard allowing viscera to almost come into contact with the eviscerator's boots and the work platform. [9 CFR §416.4(a)]

46/51. During Pre-operational sanitation verification black mechanical grease was accumulating on the head chain support rail and two pieces of fat were observed on the head drive chain located above the beef heads. [9 CFR §416.4(a)]

46/51. The work platform for the beef carcass eviscerator contained standing water which posed a potential for contamination of the carcass viscera and the carcass shanks. [9 CFR §416.4(a)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 04/02/2009

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Figochaco Espana 2112 Asuncion c.d.c. 541	04/03/09	10	Paraguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	X
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 04/03/09 Est #: 10 (Figochaco [S/P]) (Asuncion, Paraguay)

10. The viscera pans located on the moving viscera conveyor containing viscera presented for inspection by SENACSA inspectors were not cleaned properly. Fat particles, meat particles, and fat residue remained on the product contact surfaces of the viscera pans after the final cleaning. The SENACSA veterinarian stopped production until the establishment implemented corrective actions. All products were identified as inedible until the corrective actions were in place and were determined to be effective. [Regulatory reference(s): 9 CFR §416.13]

10/51. The establishment's Sanitation Standard Operating Procedures stated that monitoring of operational sanitation would be conduct two times per shift, but the monitoring records reviewed for a 60 day period for the deboning room documented that some days, monitoring was conducted only one time per shift. [9 CFR §416.13, 416.17]

15/22/51. The establishment did not have a CCP for zero-tolerance for fecal material, ingesta, and milk in the offal HACCP plan. The establishment did not have decision-making documents to support their decision. [9 CFR §417.2(c), 417.5, 417.8]

22/51. Corrective actions records for a deviation from the critical limit for zero-tolerance for fecal material, ingesta, and milk, did not address whether the process was brought back under control, that preventive measures had been implemented, or the verification of the effectiveness of the establishment's corrective actions. [9 CFR §417.5, 417.8]

22/51. Verification activities were conducted for all CCPs, but there was no differentiation between direct observation of the monitor and records verification. The results of the verification was not documented. [9 CFR §417.5, 417.8]

22/51. Ongoing verification activities were conducted for CCP 1, red offals, but the verification activities were not documented. [9 CFR §417.5, 417.8]

22/51. E. coli O157:H7 was not considered as a pathogen reasonably likely to occur in the slaughter process. SENACSA stated that E. coli O157:H7 had not been identified in Paraguay and therefore the establishment did not identify this pathogen in their hazard analysis. The establishment did not have decision-making document to support this decision. [9 CFR §417.2(c), 417.5, 417.8]

22/51. The monitoring of the temperatures of red offals was not conducted as described the offal HACCP plan. [9 CFR §417.5, 417.8]

22/51. Preshipment review procedures or records had not been generated. The establishment was aware of the FSIS requirements, but since they were not currently certified to export to the United States, they did not comply with the requirement. [9 CFR §417.5, 417.8]

46/51. The employee work platforms were not designed to preclude the possibility of the worker's boots contacting the dehided portions of the beef carcasses. The toe guards had a two inch gap between the work platform and the bottom of the toe guard [9 CFR §416.4(a)]

51/52. The establishment did not have the required equipment to measure the voltage of the electric cattle prod. The electric prod was used to assist in the movement of live cattle into the knocking box. No inhumane handling practices were observed. [9 CFR §313]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 04/03/2009

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL

SENACSA

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San Lorenzo, August 19th 2009.-

N.P. Nº 1191.-

Mister
ANDREAS KELLER
Director
International Equivalence Staff
International Affairs Office
FSIS-USDA, United States of America
internationalequivalence@fsis.aphis.gov

I am please to write to you, regarding the letter of date June 12th 2009, by which it is requested remission of comments on the Draft Final Report of the audit carried out in Paraguay from March 31st to April 8th

On this issue, comments and their document supports are attached to this letter.

Without any other subject, I take this opportunity to grate you with the highest considerations.

DR. HUGO A. CORRALES IRRAZABAL
President

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL

SENACSA

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San Lorenzo, 19 de agosto del 2009.-

N.P. Nº 1191.-

Señor
ANDREAS KELLER
Director
Personal de Equivalencia Internacional
Oficina de Asuntos Internacionales
FSIS-USDA de los Estados Unidos de Norteamérica
internationalequivalence@fsis.aphis.gov
Presente

Tengo el agrado de dirigirme a usted, con relación a la nota de fecha 12 de junio de 2009, a través de la cual solicita la remisión de comentarios sobre el borrador del Informe Final del la Auditoria llevada a cabo en Paraguay desde el 31 de marzo al 8 de Abril de 2009.

Sobre el particular, remito adjunto para conocimiento y fines pertinentes, los comentarios con sus respectivos soportes documentales.

Sin otro motivo, hago propicia la ocasión para saludarlo con las expresiones de mi consideración más distinguida.

DR. HUGO A. CORRALES IRRAZÁBAL
Presidente

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL
S E N A C S A
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Disclaimer Report on FSIS draft final audit report to the Paraguayan Meat Inspection System - March 31st to April 8th 2009

CFR CHAPTER	FSIS Observations	Corrective actions	Estimated date for finishing
6.1.1 Title 9 CFR 327.2 Organizational structure and Personnel	Direct payment for extra hours charge to some inspection staff by the establishment. Apparently this is a conflict of interests	SENACSA has issued Resolution 99 of June 15th 2009, by which it is forbidden payment for extra hours to IVOs by the establishment. Also, an administrative procedure that allows SENACSA to have a mechanism for charging carried out services is under evaluation, so those founds can be distributed among inspection personnel according to their extra working hours.	Implemented October 2009
6.1.3 Title 9 CFR 327.2 Assigning Competent and Qualified Inspectors	The CCA did not have formal, initial or continuous training programs, focused specifically on FSIS requirements	Until now, four SENACSA personnel have participated in courses on Meat and Poultry Inspection, carried out by FSIS in Puerto Rico and USA. A Training Program focused on FSIS Requirements is under development.	Implemented October 2009
6.1.4 Title 9 CFR 327.2 Authority and Responsibility for enforcing Meat Inspection Laws and Regulations	Because the CCA had not established training programs on FSIS requirements, some regulation requirements were not	A Training Program focused on FSIS Requirements is under development	October 2009

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	accomplished		
6.1.5 Title 9 CFR 327.2 Technical and Administrative Support	CCA had not initial and continuous training programs on FSIS requirements to maintain competence of laboratory analysts Because the CCA had not training programs on FSIS requirements, inspection personnel was not able to recognize or identify properly that establishments were not accomplishing some of the FSIS regulatory requirements	Once elaborated the training program and identified experts on FSIS regulations, training courses will be carried out, and their duration will be related to proposals and/or suggestions by the experts.	December 2009
8.1 Title 9 CFR 416.11 Standard Operation Procedures for Livestock Humane Sanitation	CCA (inspection personnel) needed to document these findings and verify that establishments have implemented effective corrective actions	Verification of SSOP and implemented corrective actions carried out 3 times per week by the IVO.	Implemented

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8.2 Title 9 CFR 416.1 – 416.6 Sanitation Performance Standards	CCA (inspection personnel) needed to document these findings and verify that establishments have implemented effective corrective actions	Daily verification of SSOP and implemented corrective actions carried out by the IVO.	Implemented
9.4 Title 9 CFR 417 HACCP Systems	CCA (inspection personnel) needed to document these findings and verify that establishments have implemented effective corrective actions CCA need to implement effective training programs on HACCP for inspection personnel	It is obligatory for all establishments that export to USA to have a HACCP Plan for viscera, approved by SENACSA Verification of HACCP and implemented corrective actions carried out 3 times per week by the IVO. Once elaborated the training program and identified experts on FSIS regulations, training courses will be carried out, and their duration will be related to proposals and/or suggestions by the experts.	Implemented implemented December 2009
11 Title 9 CFR 310.25 and 340 Microbiology Program	CCA has not Performance Analysis Program for Salmonella Standards or any other implemented equivalent program (9 CFR Part 310.25)	Performance analysis for Salmonella is considered in the review of resolution 698/06, ANNEX 2: "Microbiological	December 2009

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	CCA has not an analysis program for Listeria monocytogenes for ready-to-eat products (9 CFR Part 430.4) CCA has not equivalent analytic method for detection of Listeria monocytogenes and Salmonella in ready-to-eat food. The CCA needs to submit equivalence application for Salmonella standard testing program and develop and implements analysis program for ready-to-eat for Listeria monocytogenes and Salmonella.	Control at Slaughtering or Processing animal origin products elaboration for human consumption". This review will include Salmonella and Listeria monocytogenes programs for ready-to-eat products There are essays for Salmonella spp determination and identification ISO 6579 for sponging and BAM for products and by-products of animal original. For Listeria monocytogenes the used test is FDA BAM. At the moment, there is not program for detection and identification of above mentioned pathogens. These essays are performed by owner's request.	
12. Audit of Laboratory operations and activities	ACC does not apply laboratory methods or measures equivalent to FSIS to ensure maximum opportunity to achieve detection and identification of specific pathogen agents	The method used for Salmonella spp determination and identification is ISO 6579 by sponging and BAM for products and by-products of animal origin. For Listeria monocytogenes the	

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	ACC need to make an application for equivalence. Refer to sections 12.1 and 12.2 of specific findings	used test is FDA BAM.	
12.1 Audit of Residue Laboratory	1. The CCA has residue programs in place but it did nor provide adequate oversight over the third party laboratories that conduct residue laboratories 2. The CCA did not have sampling handling procedure in place to ensure security and integrity of samples sent to third party laboratories 3. temperature for equipment storing samples and testing kits were not documented	See annex 12.1.1 See annex 12.1.2 It is understood that point refers to DIAZ GILL Laboratory, the ACC is planning follow audits to verify relevant documents regarding this point	

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	4. No intra laboratory check samples were conducted	It is understood that point refers to DIAZ GILL Laboratory, the ACC is planning follow audits to verify relevant documents regarding this point
	5. No internal audit was conducted by the laboratory	It is understood that point refers to DIAZ GILL Laboratory, the ACC is planning follow audits to verify relevant documents regarding this point
	6. The laboratory had corrective action procedures in place but no corrective actions were documented	It is understood that point refers to DIAZ GILL Laboratory, the ACC is planning follow audits to verify relevant documents regarding this point
	7. The CCA indicated that turnaround times for results depended on when payment was received by the laboratories. This could be up to 5-8 weeks	Yes, but this situation is not the will of the CCA Laboratory. When DILAVE or MICROBIOTICOS Laboratories detect some positive the report immediately by e-mail or phone call, so actions can take place and corrective actions can be performed. Regarding presence of positives of DIAZ GILL Laboratories, DIGECIPOA is only and exclusive responsible direction in charge of sampling

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		management and everything regarding livestock establishments.	
12.2 Audit of Microbiology Laboratory	1. There was no proficiency testing for either Salmonella or Listeria Monocytogenes	Yes, there is not proficiency testing for Salmonella and Listeria Monocytogenes.	
	2. Positive and negative controls were not used in a consistent number for Samonella and Listeria Monocytogenes testing	Regular recurrence of positive and negative controls for Salmonella and Listeria Monocytogenes essays is carried out according to the frequency of samples received at the Laboratory for analysis. For samples arriving once a month, one control is performed as minimum. Salmonella Control essays are bigger because there is bigger requested amount of samples for this analysis.	
	3. There were several critical instruments in use for media preparation and analysis where verification, calibration and/or maintenance records were either not maintained or not consistent with the U.S. guidelines	There is records for critical instruments as thermometers: Two mercury thermometers were calibrated by the Technology Standard and Metrology National Institute INTN, being calibration certificates are: DM-DME – LTE N° 0329	

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		(measure range -10 °C to 110°C) date: July 8th 2009 DM-DME – LTE N° 0328 (measure range -20 °C to 110°C) date: July 9th 2009	
	4. Examples include: thermometers were not being calibrated, no records for sterilizing media, no testing for conductivity/resistively or total plate count for water used for preparing culture media and maintenance record for instruments such as autoclaves, micro litter pipettes and analytical and other balances	See annex 12.3.4	

DIGELAB annex 12.1.1

12.1.1 Technicians of the residue control laboratory from the General Direction of Laboratories of SENACSA perform evaluation audits of technical competence to sub-contracted laboratories: Diaz Gill of Paraguay, DILAVE of Uruguay and MICROBIOTICOS of Brazil respectively.

In Laboratory DIAZ GILL were evaluated used methodologies (standards, reagents, kits, etc.), equipments (Elisa reader, washer, pipettes, and their calibration), training of essays involved staff (personal data), their training program, the implemented quality system because this laboratory is accredited with ISO 17025. Regarding samples management, issued results reports and their scientific analytic evaluation is performed by

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DIGECIPOA, which is the direction in charge of sampling management and everything regarding to livestock establishments. DIAZ GILL laboratory provides services to SENACSA in the Anabolic Control. The audit report is available at the Residues Control Department. (See annex Diaz Gill audit report).

In DILAVE laboratory, were also evaluated used methodologies (standards, reagents, etc.), equipments (HPLC liquid chromatographers, GC gas chromatographers, AA Atomic Absorption chromatographers, calibrations, their verification, etc.), and training of essays involved staff (personal data), their training program, the implemented quality system because this laboratory is accredited with ISO 17025. Regarding samples management, issued results reports and their scientific analytic evaluation is performed at the CCA Laboratory. DILAVE laboratory provides services to SENACSA in the Veterinary Drugs Control Area and Environmental Contaminants. The audit report is available at the Residues Control Department. (See annex DILAVE audit report).

In MICROBIOTICOS laboratory, were also evaluated used methodologies (standards, reagents, etc.), equipments (HPLC liquid chromatographers, HPLC –MS-MS liquid mass chromatographers , GC gas chromatographers, GC-MS gas mass chromatographers, calibrations, their verification, etc.), and training of essays involved staff (personal data), their training program, the implemented quality system because this laboratory is accredited with ISO 17025. Regarding samples management, issued results reports and their scientific analytic evaluation is performed at the CCA Laboratory. MICROBIOTICOS laboratory provides services to SENACSA in the Veterinary Drugs Control. The audit report is available at the Residues Control Department. (See annex MICROBIOTICOS audit report).

The Residue Control Laboratory of DIGELAB is at the moment in upgrading and equipment acquisition process, therefore no inter-laboratorial essay control was performed among these laboratories.

DIGELAB annex 12.1.2

The residue control laboratory from the General Direction of Laboratories of SENACSA has a procedure called "Handling of samples for foreign countries", PE-CR-18 that is exclusively applied to remission of samples for residues analysis to DILAVE Laboratory from Uruguay as well as

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MICROBIOTICOS of Brazil. The CCA is in process of implementation a control system to verify that samples arrive to destination keeping the cold chain.

DIGELAB annex 12.3.4

Equipment as: analytic and semi-analytic scales, autoclaves, micro-pipettes are waiting for calibration and maintenance in September 2009 because it depends on the 2009 public tender.

The media preparation form and other reagents, with code RE/CA-16, are used for preparation of culture media submitted to boiling or autoclave. Copy of the form is attached.

Water conductivity determination for culture media preparation will be performed with BOECO conductivity measurer model CT-470. the mentioned equipment is waiting to be placed by the providing company. Microbiological control of water used for culture media preparation is being performed with monthly frequency. Control includes aerobic mesophils and E. Coli determination.

1. Audit Objective

To evaluate technical competence of sub-contracted Diaz Gill Laboratory, EcoNatura Division (Laboratory of Food and Environment Control) specifically about methodologies used to perform essays on anabolics, sub-contracted by SENACSA.

2. Audit Scope

To verify technical competence on analytic methodology used for anabolics essay, specifically stilbenes (DES,DIE, HEX), steroids (19-NT, 17□- TBOH), zeranol, y □-Agonists (salbutamol, clembuterol, brombuterol).

2. Details of the audit plan

The audit was carried out according to the following plan:

Opening meeting: February 10th, 2009

Document review of Technical Requirements for stilbene essays (DES, DIE, HEX), steroids (19-NT, 17□- TBOH), zeranol, y □-Agonists (salbutamol, clembuterol, brombuterol)

Closing meeting: February 10th, 2009

The following people attended the opening meeting:

Dr. Laura Mújica: EcoNatura Quality Manager

Dr. Arlene Schuller: Person in charge of EcoNatura

Chem. Mirtha Carrillo de Vera: Head of Anabolics Division, SENACSA

Bach. Edith Magdalena Gayoso: Anabolics Analist, SENACSA

4. Identification of the Auditor/ auditing team

Bach. Edith Magdalena Gayoso: Anabolics Analyst, SENACSA
Chem. Mirtha Carrillo de Vera: Head of Anabolics Division, SENACSA

5. Identification of auditee representatives

Dr. Laura Mújica: EcoNatura Quality Manager
Dr . Arlene Schuller: Person in charge of EcoNatura

6. Audit Dates

Dates: February 10th, 2009

7. Identification of the organization and audited area

Anabolics Department from the "EcoNatura" Division, Diaz Gill Laboratory.

8. Reference Documents:

Check List according to ISO/IEC 17025/2005. RG- 08 Check List

9. List of interviewed people:

Dr. Laura MUjica: EcoNatura Quality Manager
Dr . Arlene Schuller: Person in charge of EcoNatura

10. Findings description:

Documentation, provided by EconNatura, related to technical proficiency is attached.

11. Judgment of the auditor on the accomplishment extension of the auditee in relation to the corresponding regulation and documentation.

Requested documents where verified, according to RG-08 Check List

12. System capability to achieve proposed quality objectives:

There is a good predisposition of EcoNatura representatives, to achieve and keep proposed objectives in order to accomplish what is stipulated in the Contract signed by
SENACSA and Diaz Gill Laboratory.

13. Report distribution: This report is delivered to the Quality Management Department for distribution to involved areas

14. Report date: February 12th, 2009

15. Opening of non-conformity

Do not apply

16. Corrective Actions

Do not apply

17. Assignation

Do not apply

18. Responsible:

Do not apply

19. Follow-up:

Do not apply

20. Closing:

Do not apply

21. Cause Investigation:

Do not apply

22. Signature of Auditors:

Chem. Mirtha Carrillo de Vera
Auditor

Bach. Edith Magdalena Gayoso
Auditor

1. Audit Objective

To evaluate efficiency and compliance of the Quality System that was implanted, according to the requirements of ISO/ IEC 17025 "General Requirements for competence of Essay and Calibration Laboratories".

Review of activities under accreditation

Review of technical requirements

2. Audit scope

Apply this procedure to the Department of Quality Management and Department of Human Food Residues Control of DILAVE Laboratory.

3. Details of the audit plan

The audit was carried out according to the following plan:

Opening meeting December 1st, 2008: 8:30 a.m.

Review of Quality Management System documents [These are in stage of implementation for ISO 17025]

Closing meeting December 1st, 2008: 1:30 p.m.

Opening meeting December 2nd, 2008: 8:30 a.m.

Review of documents related to technical requirements for Veterinary Drugs essays as Sulphonamides, Avermectins, Benzimidazoles, Thyreostatic and Antibiotics.

Reunión de cierre 02 de diciembre de 2008, 15:30 hs.

Closing meeting December 1st, 2008: 3:30 p.m.

Opening meeting December 3rd, 2008: 8:30 a.m.

Review of documents related to technical requirements for essays on Environmental Contaminants as Organic Chlorides and PBC, Phosphorated, Piretroids and Heavy Metals.

Closing meeting December 3rd, 2008: 3:30 p.m.:

3. The following people attended the opening meeting:

Eng. Renata Antonaz: Laboratory Head

Phar. Chem. Nancy Machado: In charge of Veterinary Medicines

Phar. Chem. Osvaldo Rampoldi: In charge of Environment Contaminants

Phar. Chem. Adriana Rainuzzo: In charge of Anabolic Substances

4. Identification of the Auditor/ auditing team

Chem. Oscar Iglesias

5. Identification of auditee representatives
Eng. Renata Antonaz: Laboratory Head
Phar. Chem. Nancy Machado: In charge of Veterinary Medicines
Phar. Chem. Osvaldo Rampoldi: In charge of Environment Contaminants
Phar. Chem. Adriana Rainuzzo: In charge of Anabolizant Substances

6. Audit Dates

Dates: December 01, 02 and 03, 2008

7. Identification of the organization and audited area

Ministry of Livestock, Agriculture and Fishery – general Direction of Livestock Services – Division of Veterinary Laboratory "MIGUEL C. RUBINO" – Montevideo- Uruguay.

8. Reference Documents:

ISO/ IEC 17025 "General Requirements for competence of Essay and Calibration Laboratories"
Auto evaluation questionnaire on Accomplishment of ISO/ IEC 17025: 2005 for Laboratories

9. List of interviewed people:

Phar. Chem. Nancy Machado: In charge of Veterinary Medicines
Phar. Chem. Osvaldo Rampoldi: In charge of Environment Contaminants
Phar. Chem. Adriana Rainuzzo: In charge of Anabolizant Substances

10. Findings description:
Documents provided by Microbioticos are attached

Those deviations that have been corrected within the audit are not pointed in the audit findings table

11. Judgment of the auditor on the accomplishment extension of the auditee in relation to the corresponding regulation and documentation.

Requested documents have been verified, according to Check List

12. System capability to achieve proposed quality objectives:

There is total predisposition of the DILAVE's High Level Direction to achieve and keep proposed objectives in order to accomplish what is stipulated in the contract signed by both parties, and therefore to accomplish ISO / IEC 17025: 2005

13. **Report distribution:** This report is delivered to the Quality Management Department for distribution to involved areas

14. Report date: December 12th, 2008

15. Opening of non-conformity
Do not apply

16. Corrective Actions
Do not apply

17. Assignation
Do not apply

18. Responsible: Quality Management Department, Residues Control Department

19. Follow-up: Quality Management Department, Residues Control Department

20. Closing: According to follow-up evaluation.

21. Cause Investigation: Do not apply

22. Signature of the Auditor:

Chem. Oscar Iglesias
Auditor

Audit Objective

To evaluate efficiency and compliance of the Quality System that was implanted, according to the requirements of ISO/ IEC 17025 "General Requirements for Competence of Essay and Calibration Laboratories".

Review of activities under accreditation
Review of technical requirements

1. Audit scope

To apply this procedure to the Quality Management Department and the Department of Human Food Residues Control of Microbioticos Laboratory Ltd.

2. Details of the audit plan

The audit was carried out according to the following plan:

Opening meeting: March 17th, 2009

Opening meeting and review of Management System documents: March 17th, 2009.

Document review of Technical Requirements of the Residues Control Department: March 18, 19 and 20, 2009

Closing meeting: March 20th, 2009

The following people attended the opening meeting:

Dr. Rodrigo Granja: Executive Director

Dr. Roberto Zucchetti: Technical Director

Dr. Norberto Aichino: General Manager

Chem. Ivanessa Oliveira Magallanes: Responsible for the Quality Management System

Chem. Tech. Luana Araujo Naves: Assistant of the Quality Management System

4. Identification of the Auditor/ auditing team

Chem. Oscar Iglesias

5. Identification of audited representatives

Dr. Roberto Alcantara Martins Zucchetti: Technical Director

Chem. Ivanessa Oliveira Magallanes: Responsible for the Quality Management System

Chem. Tech. Luana Araujo Naves: Assistant of the Quality Management System

Comp. Tech. Fabiano Rony de Almeida: Responsible for the Computer System

Biologist Fernanda Rabone: Adjunct Technical Director

Sabrina Keity Siquiera de Freitas: Results Reports

Robson Anacleto Cirqueira: Responsible for Reception of Samples

6. Audit Dates

Dates: March 17, 18, 19 and 20, 2009

7. Identification of the organization and audited area

Department of Quality Management System, the area "Control of Veterinary Medicine Residues" and area of "Anabolic Substances" of Macrobioticos Laboratory Ltd.

8. Reference Documents:

ISO/ IEC 17025 "General Requirements for competence of Essay and Calibration Laboratories"
Auto evaluation questionnaire on Accomplishment of ISO/ IEC 17025: 2005 for Laboratories

9. List of interviewed people:

Dr. Roberto Alcantara Martins Zucchetti
Chem. Ivanessa Oliveira Magalhaes
Chem Tech. Luana Araujo Naves
Comp. Tech. Fabiano Rony de Almeida
Biologist Fernanda Rabone
Sabrina Keity Siquiera de Freitas
Robson Anacleto Cirqueira

10. Findings description:

Documents provided by Macrobioticos are attached.
Those deviations corrected within the audit are not pointed in the audit findings table

11. Auditor judgment of the auditee accomplishment extension in relation to the corresponding regulation and documentation:

The accomplishment of the regulation in the audited areas is implemented.

12. System capability to achieve proposed quality objectives:

There is total predisposition of the Microbioticos' High Level Direction to achieve and keep proposed objectives in order to accomplish what is stipulated in the contract signed by both parties, and therefore to accomplish ISO / IEC 17025: 2005 .

13. **Report distribution:** This report is delivered to the Quality Management Department for distribution to involved areas.

14. Report date: March 27th, 2009

15. Opening of non-conformity

Do not apply

16. Corrective Actions
Do not apply

17. Assignation
Do not apply

18. Responsible: Quality Management Department

19.Follow-up: Quality Management Department

20. Closing: According to follow-up evaluation.

21. Cause Investigation:
Do not apply

22. Signature of the Auditor:

Chem. Oscar Iglesias
Auditor

INDEX

Elaborated by: Residues Laboratory Technician. Signature: Date:	Reviewed by: Head Department of Residues Control Chem. Oscar Iglesias Signature: Date:	Approved by: Head Department of Residues Control Chem. Oscar Iglesias Signature: Date:

1.0 OBJECTIVE

The objective of this procedure is to describe the process and handling of samples since leaving the laboratory.

2.0 SCOPE

This procedure is applied to samples remission for Residues analysis to DILAVE Laboratory, dependent of the General Direction of Livestock Services of the Ministry of Livestock, Agriculture and Fisheries (DGSG) of Uruguay, as well as to MICROBIOTICOS Laboratory of Brazil.

3.0 REFERENCES

Paraguayan regulation NP-ISO/IEC 17025

4.0 RESPONSIBILITIES

Reception of samples and later remission could be performed by laboratory technical personnel. The Head of the laboratory is responsible for application of this procedure.

5.0 PERFORMING STAGES

Samples Refrigeration

Received samples from corresponding Slaughterhouses (refrigerated), transported by Veterinary Inspectors, are stored in double polyethylene bag, appropriately labeled in way they will not have contact with the substrate to test.

Wrapped samples are frozen at (-20℃) and later on, loaded to a thermal box (Styrofoam coolers) with a thickness of 5cm, set up with dry ice, proper lid and sealed with strapping tape to ensure cold chain.

Samples Sending

Coolers are labeled on the sides, indicating the transported material and, storage condition and handling.

Samples must attach a "Samples Remission Record to Brazil (RE/CR-03)" and "Samples Remission Record to Uruguay (RE/CR-04)", stating identification, substrate and compound to be analyzed.

This is transported to the airport by an official responsible for the L.C.R, with corresponding export authorization by the Department of External Surveillance (INTERNATIONAL VETERINARY CERTIFICATE)

Samples Entrance

When samples arrive to destination, they are presented to competent authorities for entrance to the country and later on, transferred to the authorized Laboratory.

6.0 RECORDS

RE/CR-03 Record of Samples Remission to Brazil
RE/CR-04 Record of Samples Remission to Uruguay

7.0 DISTRIBUTION

Head of Dpt. Control of Residuals, Original
Head of Dpt. Administration of Quality, Nº Copies 1
DIGECIPOA, Nº Copies 2

DIGELAB SENACSA	CULTURE MEDIA AND REAGENTS PREPARATION FORM	RE/CA -16 Version: 1.0 Date: 13/04/09 Page: 1 of 1

Media Opening	Date	Requested Media	Weigth Time:	Amount Weigthed	Final Volume	pH	Boiling		Autoclaving		Final pH	Plate Quantity	Tube Quantity	Media Lot
							Initiation	Ending	Initiation	Ending				

Notes/ Observations: _____