



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

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Dr. Hector J. Lazaneo
Director
Ministerio de Ganaderia, Agricultura y Pesca
Dirección General de Servicios Ganaderos
Division Industria Animal
Constituyente 1476
11200 Montevideo
Uruguay

Dear Dr. Lazaneo:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Uruguay's meat inspection system April 9 through May 14, 2008. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 690-5646, by facsimile at (202) 720-0676, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

cc:

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Uruguay Country File

FSIS:OIA:IAS:DSMART:202-690-5646:Uruguay FINAL Audit Report /Letter 110308

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

APRIL 9 THROUGH MAY 14, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority [Ministerio de Ganaderia, Agricultura y Pesca]
CCP	Critical Control Point
DGSG	General Direction of Livestock Series
DIA	Meat Inspection Division
DICOSE	Division for the Control of Livestock
D.I.L.A.VE	Division of Veterinary Laboratories
DSA	Animal Health Division
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
GOU	Government of Uruguay
<i>Im</i>	<i>Listeria monocytogenes</i>
MGAP	Ministerio de Ganaderia, Agricultura y Pesca
MLG	Microbiology Laboratory Guide
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SRM	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures

1. INTRODUCTION

The audit took place in Uruguay from April 9 through May 14, 2008.

An opening meeting was held on April 9, 2008, in Montevideo with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Uruguay's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Ministerio de Ganaderia Agricultura y Pesca (MGAP).

2. OBJECTIVE OF THE AUDIT

This was a routine audit with special emphases on humane handling and slaughter and on the control of and testing programs for *Escherichia coli* O157:H7 (*E. coli* O157:H7). The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing 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, eleven government offices at the local establishment level, one laboratory performing analytical testing on United States-destined product, eight bovine slaughter and deboning establishments, two bovine slaughter, deboning, and further processing establishments, and one bovine processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Local	11	Establishment level
Laboratory		1	
Meat Slaughter and Deboning Establishments		8	
Meat Slaughter, Deboning, and Further Processing Establishments		2	
Meat Processing Establishment		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA 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 eleven establishments: eight slaughter and deboning establishments, two slaughter, deboning, and further processing

establishments, and one processing establishment. The fourth part involved visits to two divisions of one government laboratory. The Division Laboratorios Veterinarios (DI. LA.VE) Microbiology Division was conducting analyses of field samples for the presence of *Escherichia coli* O157:H7 (*E. coli* O157:H7), *Listeria monocytogenes* (*Lm*), species verification, and *Salmonella*. In the same laboratory, the Chemistry Division was conducting analyses of field samples for Uruguay's national residue control program.

Program effectiveness determinations of Uruguay's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs, humane handling and slaughter programs, and testing programs for generic *E. coli* and *Lm*, (4) residue controls, and (5) enforcement controls, including testing programs for *Salmonella* and *E. coli* O157:H7. Uruguay's inspection system was assessed by evaluating these five risk areas.

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

At the opening meeting, the auditor explained that Uruguay's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Uruguay. FSIS requirements include, among other things, daily inspection in all certified establishments, periodic reviews of 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, residue testing, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli*, *Lm*, *Salmonella*, and *E. coli* O157:H7.

Equivalence determinations are those that have been made by FSIS for Uruguay under provisions of the Sanitary/Phytosanitary Agreement.

Currently, there are three equivalence determinations requested by Uruguay.

- a.) FSIS has determined that Uruguay's use of an alternative agar, Brilliant Green Agar, in *Salmonella* sample analysis is equivalent.
- b.) Uruguay's generic *E. coli* testing program for sheep and goats is equivalent.
- c.) Uruguay's testing and enforcement programs for *E. coli* O157:H7 are equivalent.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States 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 Pathogen Reduction/HACCP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&Policies/ForeignAuditReports/index.asp

The following deficiencies were reported during the FSIS audit of Uruguay's meat inspection system in November/December 2005:

- SPS implementation deficiencies were reported in four of the thirteen establishments audited.
- HACCP implementation deficiencies were reported in two establishments.
- A deficiency was reported in the government microbiological laboratory for the use of a wooden work surface for the analysis of microbiological samples.
- Minor housekeeping deficiencies were reported in the government residue laboratory.

During the audit of March 2007, it was observed that all of the above specific deficiencies had been corrected.

The following deficiencies were reported during the FSIS audit of Uruguay's meat inspection system in March 2007:

- SSOP implementation deficiencies were reported in two of the eight establishments audited.
- SPS implementation deficiencies were reported in two establishments.
- An SRM handling deficiency was reported in one establishment.
- Four deficiencies including sample size for testing, scale calibration, the lack of a procedures manual, and incubation conditions, were reported in the government microbiological laboratory.

During the current audit of April/May 2008, it was observed that all of the above specific deficiencies had been corrected.

6. MAIN FINDINGS

6.1 Government Oversight

Uruguay's meat inspection system is directed from the central headquarters in Montevideo. Located in the Meat Inspection Division (DIA) Office, are the DIA Director and Deputy, the Heads of Departments, Area Supervisors, and administrative personnel.

6.1.1 CCA Control Systems

Uruguay's Central Competent Authority (CCA) is the Ministry of Livestock, Agriculture and Fisheries (MGAP). Uruguay's meat inspection system is directed from the central headquarters in Montevideo. There are no local, district, or regional levels. This is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced.

The structure of the DIA is organized under the general direction of Livestock Services, together with the Animal Health Division (DSA), the Division of Veterinary Laboratories (DI. I.A. VE), and the Division for the Control of Livestock (DICOSE). The General Director of Livestock Services reports directly to the Minister of MGAP.

Under DIA, there are five departments. These are the Technical Department, the Slaughter Establishments Department, the Processing Establishments Department, the International Trade Department, and the Grading Department. Each department has official staff in the certified establishments who are in charge of direct control of the activities. All field personnel are supervised directly from the DIA office in Montevideo.

6.1.2 Ultimate Control and Supervision

When any establishment initially wishes to be certified by DIA as eligible to export to the United States, they must first approach DIA for instructions on how to achieve compliance with the requirements. There is a resolution issued by DIA specifying the procedure to approve establishments for export to "high requirements markets" such as the United States, Canada, China, the European Union, and Israel. The procedure involves the creation of a special team of higher-level personnel from the different departments who are responsible for assessing the establishment's capability for achieving compliance. This team conducts an in-depth on-site audit of all aspects of the facilities, operations, and controls and then submits a report to the Director of DIA. The report is reviewed by the Director, and if the establishment is determined to be in compliance with the respective requirements, the establishment is granted certification for eligibility for access to the requested market. If this market is the United States, FSIS is notified of the new certification.

Inspection documents are normally distributed to field personnel via a "folder system." This system was developed to ensure that the information effectively reaches its destination and all records are properly maintained. Each establishment has a special private folder kept at the headquarters office in Montevideo. Documents are put into each folder, such as the national residue sampling plan, any upcoming microbiological sampling, any resolutions or instruction, and similar documents. Each week, personnel from the establishments pick up the contents from the folder and sign a form indicating that they have received the information. Electronic mail is being implemented to augment this system, especially in the area of positive and/or violative sampling results and resolutions/instructions that require immediate implementation. A request has been submitted to acquire additional electronic equipment for better communications to and from the field.

Periodic reviews of each certified establishment were being performed at least monthly and these reports covered U.S. regulatory requirements in detail. One copy of these reports is kept at headquarters and one in the government office of each establishment.

The FSIS auditor verified that the most recent reports from each establishment audited included a review of the SSOP, SPS, and PR/HACCP systems as well as Bovine Spongiform Encephalopathy/Specified Risk Materials (BSE/SRM) controls, and the new *E. coli* O157:H7 testing program and results.

Government employees cannot perform any activities for which they would receive compensation from the establishment. Government veterinarians can work in a private practice as long as they have no work with animals eligible to enter the slaughter facilities. Veterinarians can also engage in teaching activities at a school or university level. Private practitioners or establishment employees cannot be hired as part-time government employees. All salaries of meat inspection personnel are paid by the national government, including a special compensation built into the salary schedule for "full-time availability."

Establishments choose the laboratories and pay for any sampling programs (such as water potability) that are performed by the official veterinarians that are not a required part of the FSIS requirements for sampling. The establishment also purchases the official service equipment such as brands, seals, certificates, sampling equipment and shipping cases. However, once purchased, these items are shipped directly from the manufacturers to the official veterinary personnel in the establishments. These manufacturers are approved by MGAP.

6.1.3 Assignment of Competent, Qualified Inspectors

Full-time, permanent MGAP veterinarians must have a University degree in Veterinary Science or Veterinary Medicine to be considered qualified to apply for the inspection service. Assistant inspectors must be advanced students of Veterinary Medicine with third year curricula courses completed or Agricultural Technicians (Polytechnic School diploma) since December 1997. There were two training courses in 2004 given by the U.S. HACCP Consulting Group for all veterinarians working in meat inspection and meat industry officials. Additionally, DIA veterinarians have received training in ISO standards 9000, 10013, 10011 and 17025. They have also received training in advanced HACCP and auditor HACCP training from the International HACCP Alliance, European Regulations, and certification of product training from the Uruguay Institute of Standards (UNIT).

The following trainings were given in 2007:

- Humane Handling and Slaughter
- Documentation for the Management System
- Congress for Meat and Food
- ISO 22000
- Animal Industry Helper Training (1-4)
- Trichina in Meat

All veterinarians and assistant inspectors employed by MGAP are full-time employees.

The following deficiencies were reported for inspection personnel:

- In one establishment, kidneys were not being inspected.
- In one establishment, tails were presented in a bag and therefore could not be adequately inspected.
- In one establishment, the inspection personnel were unaware of the requirements for corrective actions.
- In one establishment, corrective action verification was done as a random choice.
- In one establishment, only one of the three scheduled *E. coli* O157:H7 samples was collected and submitted for analysis.

6.1.4 Authority and Responsibility to Enforce the Laws

MGAP has the authority and responsibility to enforce the applicable laws relevant to establishments certified to export. MGAP has the authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not have adequate and/or effective controls in place to prevent, detect, and eliminate product contamination/adulteration. The Area Supervisors are in charge of verifying and evaluating the implementation of the official guidelines, resolutions, and instructions.

6.1.5 Adequate Administrative and Technical Support

No request has been submitted to the FSIS International Equivalence Staff for the use of private laboratories for some of the residue analyses of official samples.

MGAP has the ability to support a third party audit.

6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of the inspection service. The records review focused primarily on food safety hazards and included the following:

- Periodic reviews in establishments that were certified to export to the United States
- Training records for inspection and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives, resolutions, and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter, and processing inspection procedures and standards.
- Export product inspection and control including export certificates.

No concerns arose as a result of the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of eleven establishments. Of these, eight were slaughter and deboning establishments, two were slaughter, deboning, and further processing establishments, and one was a processing establishment. No establishments were delisted by Uruguay. One establishment received a notice of intent to delist (NOID) from Uruguay. This NOID was given for deficiencies in SSOP, SPS, and HACCP.

This establishment may retain certification for export to the United States provided that they all deficiencies noted during the audit are corrected within 30 days of the date the establishment was reviewed.

Specific deficiencies are noted in the attached individual establishment review forms.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States' requirements.

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

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. No private laboratories are used to test official microbiology samples of products intended for export to the United States.

The following laboratory was audited:

The government Division Laboratorios Veterinarios (DI. LA.VE) in Montevideo was audited on two separate occasions, once for the Microbiology Division and once for the Chemistry Division.

The following deficiencies were reported:

- No request has been submitted to the FSIS International Equivalence Staff for the use of private laboratories for some of the residue analyses of official samples.
- MLG 5A.01 and 5.04 are not being followed as written as the five 65-gram samples are being combined into one sample in the Microbiology Division.
- Temperatures of incoming samples are not routinely taken or recorded in the Microbiology Division.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused on five areas of risk to assess Uruguay's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Uruguay's 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 practices, and good product handling and storage practices.

In addition, and except as noted below, Uruguay's 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 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOP in all eleven establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- Six of eleven establishments had deficiencies in SSOP, primarily in implementation and recordkeeping.
- Three establishments had deficiencies in product contamination and cross-contamination. These included:
 - Cross-contamination in the skinning process between the hide and the weasand, the skinned head, and the adjacent heads. Then there was contact between the contaminated weasand and the other products in the evisceration pan.
 - Contact between concrete walls and carcass legs in the cooler.
 - Condensate dripping on to heads at the inspection station.
 - Diced product falling from a conveyor belt on to open bags of product awaiting dicing.

Six establishments had deficiencies in SSOP recordkeeping. These included:

- Corrective actions and/or preventive measures in records did not contain sufficient detail to allow for verification of the actions.
- The descriptions of the non-compliances did not adequately describe the situations.
- Corrective actions did not identify whether or not product may have been involved and the subsequent disposition of such product.

Specific deficiencies are noted in the attached individual establishment review forms.

9.2 Sanitation Performance Standards

The following deficiencies were noted.

- Ten of eleven establishments audited had deficiencies in building construction and maintenance, pest control, ventilation, light intensity, equipment and utensils, and/or sanitary operations. These deficiencies included:
 - Floors and/or walls not made of impervious materials and/or not properly maintained. One moveable wall had small gaps to the outside that were not sealed.
 - Condensate, both liquid and frozen, present in varying areas of the establishments.
 - Drip pans not present under some pipes that had condensate on them.
 - A deteriorating bolt assembly in the bottom of a mixer and a product belt with damaged product contact areas.
 - Unsmooth welds which could lead to the formation of biofilms present in a number of areas in several establishments.
 - A bag of inedible product coming into contact with edible product and product contact areas as it moved along a bone conveyor belt.

Specific deficiencies are noted in the attached individual establishment review forms.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Uruguay's inspection system 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.

11. SLAUGHTER/PROCESSING CONTROLS

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

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

11.1 Humane Handling and Slaughter

Two of ten establishments had deficiencies in humane handling and slaughter. The following deficiencies were reported:

- Floor surfaces in the pens were not constructed in a manner to prevent slips and falls.

- Reflective surfaces on the ramp or in the knocking boxes that caused cattle to hesitate in their movement in these areas.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. These programs were evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of all eleven establishments. Six of eleven establishments had not adequately implemented the HACCP requirements. These deficiencies were primarily in the areas of critical limits, corrective actions and/or preventive measures, and recordkeeping and included:

- Critical limits selected did not match the hazards identified. The measurements taken for the critical limit did not match the specified critical limit.
- Corrective actions and/or preventive measures in records did not contain sufficient detail to allow for verification of the actions.
- Documentation for the choices of critical limits did not support the choices.
- Missing entries in the *E. coli* O157:H7 records had not been noticed by either establishment verification review or by MGAP personnel.
- Pre-shipment review forms did not contain the signature of the verifier.

11.3 Testing for Generic *E. coli*

Uruguay has adopted the FSIS regulatory requirements for generic *E. coli* testing of cattle. Uruguay has an equivalent program for generic *E. coli* testing in sheep and goats.

Ten of the eleven establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was not properly conducted in three of the ten slaughter establishments. The deficiencies reported were in the areas of carcass selection and/or statistical process control programs.

Specific deficiencies are noted in the attached individual establishment review forms.

11.4 Testing for *Listeria monocytogenes*

Three of the eleven establishments audited were producing ready-to-eat products for export to the United States. In accordance with United States requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

No deficiencies were reported.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls 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.

The Chemistry Division of the government Division Laboratorios Veterinarios (DL L.A.VE) in Montevideo was audited.

The equivalence deficiency for the use of private laboratories is discussed above.

Uruguay's National Residue Testing Plan for 2008 was being followed and was on schedule.

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*.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

13.2 Testing for *Salmonella*

Uruguay has only partially adopted the FSIS regulatory requirements for testing for *Salmonella*. The program currently in use has not been deemed equivalent by FSIS. This program includes taking two samples per week, one from a steer and one from a cow, in each slaughter establishment. If any positive result is obtained, that establishment then proceeds to sample according to the FSIS program with sample sets done for both steers and for cows.

Ten of the eleven establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for *Salmonella* was properly conducted in all of the establishments according to the Uruguayan program, not the FSIS program.

13.3 Testing for *Escherichia coli* O157:H7

The following deficiency was reported:

- In one establishment, only one of the three scheduled *E. coli* O157:H7 samples was collected and submitted for analysis.

13.4 Species Verification

Species verification was being conducted in those establishments in which it was required.

13.5 Periodic Reviews

During this audit it was found that, in all establishments visited, periodic reviews of certified establishments were being performed and documented as required.

13.6 Inspection System Controls

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.

The following deficiencies were reported:

- In-plant inspection personnel were not fully aware of the SSOP and HACCP plans of the establishments.
- Inspection system controls at all levels were not fully developed and implemented.
- In one establishment, kidneys were not being inspected.
- In one establishment, tails were presented in a bag and therefore could not be adequately inspected.
- In one establishment, the inspection personnel were unaware of the requirements for corrective actions.
- In one establishment, corrective action verification was done as a random choice.

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 May 14, 2008, in Montevideo with the CCA. At this meeting, the primary findings from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Rori K. Craver, DVM
International Audit Staff Officer



15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION Frigorifico Matadero Carrasco S.A. Camino Carrasco No. 5 Canelones 0	2 AUDIT DATE April 21, 2008	3 ESTABLISHMENT NO. 3	4 NAME OF COUNTRY Uruguay
	5 NAME OF AUDITOR(S) Rori K. Craver, DVM		6 TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7 Written SSOP		33 Scheduled Sample	
8 Records documenting implementation.		34 Species Testing	
9 Signed and dated SSOP, by on-site or overall authority.		35 Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10 Implementation of SSOP's, including monitoring of implementation		36 Export	
11 Maintenance and evaluation of the effectiveness of SSOP's		37 Import	
12 Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38 Establishment Grounds and Pest Control	
13 Daily records document item 10, 11 and 12 above	X	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	X	49 Government Staffing	
Part C - Economic / Wholesomeness		50 Daily Inspection Coverage	
23 Labeling - Product Standards		51 Enforcement	X
24 Labeling - Net Weights		52 Humane Handling	
25 General Labeling		53 Animal Identification	
26 Fin Prod Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54 Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55 Post Mortem Inspection	
27 Written Procedures		Part G - Other Regulatory Oversight Requirements	
28 Sample Collection/Analysis		56 European Community Directives	()
29 Records		57 Monthly Review	
Salmonella Performance Standards - Basic Requirements		58	
30 Corrective Actions		59	
31 Reassessment			
32 Written Assurance			

60. Observation of the Establishment

Date: April 21, 2008 Est # 3 (Frigorifico Matadero Carrasco S.A. [S/P]) (Canelones, Uruguay)

13/51. Corrective actions and preventive measures in SSOP records did not contain sufficient detail to allow for verification of the actions. [Regulatory references: 9 CFR § 416.16, 416.17]

22/51. The form for pre-shipment review contained the initials of the verifier, not a signature. [9 CFR § 417.5(c), 417.8]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE
 4/21/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Canelones S.A. Pando sin y Miguel Ameglio Canelones	2. AUDIT DATE Apr 23/24, 08	3. ESTABLISHMENT NO. 0008	4. NAME OF COUNTRY Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above	X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions		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	X
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	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	()
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60 Observation of the Establishment

Date: April 23, 2008 Est #: 8 (Frigorifico Canelones S.A. [S/P]) (Canelones, Uruguay)

10/51. The overhead conveyor in the diced frozen meat area did not have a collection tray underneath and the product was falling onto the table where the new bags were being opened prior to the dicer. [Regulatory references: 9 CFR § 416.13, 416.17]

13/51. Preventive measures in SSOP records did not contain sufficient detail to allow for verification of the actions. [9 CFR § 416.16, 416.17]

22/51. There were two blank spaces in the testing results records for *Escherichia coli* O157:H7, one had only four of five samples recorded and the other had no results recorded for a sample. These records are reviewed by both the establishment quality control personnel and the veterinary service before a provisional export certificate can be issued. [9 CFR § 417.5, 417.8]

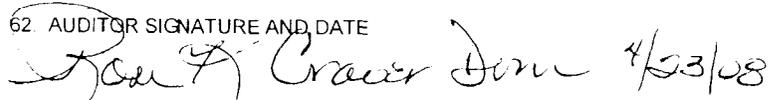
39/51. Broken tiles and deteriorating concrete and mortar were observed on the walls and floors of the can-filling area of canned products. [9 CFR § 416.2]

45. The white boards used in the frozen diced meat area had rough edges, creating the possibility of product contamination with pieces of the board. [9 CFR § 416.3(a)]

61 NAME OF AUDITOR

Rori K. Craver, DVM

62 AUDITOR SIGNATURE AND DATE

Handwritten signature of Rori K. Craver and date 4/23/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Tacuarembo S.A. Rutas 5 y 26 Tacuarembo 0	2. AUDIT DATE May 6-7, 2008	3. ESTABLISHMENT NO 12	4. NAME OF COUNTRY Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
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	X
18. Monitoring of HACCP plan	X	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	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod Standards/Boneless (Defects/AQL/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		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Notice of Intent to Delist (NOID)	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60 Observation of the Establishment

Date: May 6-7, 2008 Est #. 12 (Frigorifico Tacuarembó S.A. [S/P]) (Tacuarembó, Uruguay)

10/51. The initial activities of forequarters and head skinning involved several actions that caused direct product contamination. These included the rodding of the weasand, during which the operator contacted the hide and then reached into the carcass; freeing the weasand, allowing it to swing and contact the hide of the unskinned neck; allowing the contaminated weasand to contact other offal on the evisceration table; and skinning of the heads so that the hide flaps contacted the already skinned portion of multiple carcasses on the slaughter line. [Regulatory references: 9 CFR § 416.13, 416.17]

10/51 The positioning of the carcasses within the cooler led to contact between a low poured concrete wall and the end of the legs of the forequarters of the carcass. [9 CFR § 416.13, 416.17, 416.2(b)(2)]

13/51. In the SSOP records, the descriptions of the non-compliances do not adequately identify the problems found. In the SSOP records, the corrective actions do not identify whether product may have been involved. The preventive measures do not have adequate detail to allow for verification. These problems were present in both establishment SSOP records and official service SSOP verification records. [9 CFR § 416.16, 416.17]

18/22/51. The critical limits selected do not always match the hazard identified. The measurements taken for the critical limits do not always match the identified critical limit. These include the CCPs for metal detection and sodium nitrate. [9 CFR § 417.2, 417.5, 417.8]

39/51 The floors in the carcass coolers and adjoining hallways had multiple areas with broken and disintegrating surfaces. The floor in the deboning area had several missing and broken tiles. The new floors in the hamburger area had pockets in the grout. Some of these areas had been previously addressed but corrective actions had not been completed. [9 CFR § 416.2(b)]

39/40. The stainless steel band around the top of the wall in the hamburger raw product storage area was not sealed to the wall and there was condensate falling from this band in several areas around the room. In the same cooler, the drip pan did not extend under the pipes of the cooling equipment. These pipes had frozen condensate on them. No product was in the area at the time of the audit. [9 CFR § 416.2(b), 416.2(d)]

40/51. The freezer doors in several areas of the establishment had excessive frost and ice build-up around the edges. [9CFR § 416.2(d)]

45. (A) The bolt assembly in the bottom of the mixer in the hamburger area was not stainless steel like the rest of the mixer and the surface was deteriorating. Because of its location, the auditor could not determine if this deterioration was rust.

(B) The plastic supports under the metal mesh belt leading from the Formax machine in the hamburger area had several broken areas that would be in direct contact with product.

(C) In the hamburger area, there were several rough welds on product contact surfaces such as the dump table and the sides of the belt for transfer of patties, which could lead to the formation of biofilms. [9CFR § 416.3]

51. (A) When the official veterinary service made choices for verification activities of HACCP, they included corrective actions as a random choice rather than a mandatory verification when deviations from critical limits occurred. When reviewing corrective actions in official records, one official service official was unaware of the requirements of corrective actions as stated in 9 CFR 416.

(B) Official sampling for *Escherichia coli* O157:H7 only collected one sample in the month of March instead of the three samples that were scheduled to be collected.

55/51. The positions of the high rail and low rail for veterinary carcass inspection did not allow for the inspection of the kidneys. [9 CFR § 310.1(a)]

58. After consideration of the above findings, the MGAP official veterinary service officials issued a Notice of Intent to Delist (NOID).

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver DVM 5/7/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorífico Casa Blanca S.A. Localidad Casa Blanca Pausandu	2. AUDIT DATE April 30, 2008	3. ESTABLISHMENT NO. 58	4. NAME OF COUNTRY Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

	Audit Results		Audit Results
Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Part D - Continued Economic Sampling	
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	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above	X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions		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	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	X
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	()
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: April 30, 2008 Est #: 58 (Frigorífico Casa Blanca S.A. [S/P]) (Pausandu, Uruguay)

10:51. There was beaded and dripping condensate on the rail over the veterinary head inspection area. The line was stopped, inspection of the heads on the line was completed and then those heads were condemned. The rail was wiped and production continued. [Regulatory references: 9 CFR § 416.13]

13:51. Corrective actions and preventive measures in the SSOP records did not contain sufficient detail to allow for verification of the actions. [9 CFR § 416.16, 416.17]

22:51. The documentation for the choice of 48 hours in the CCP for the chilling of carcasses did not support the choice. [9 CFR § 417.5(a)(2), 417.8]

39:51. The metal wrapping on the insulation around pipes in the carton freezer had holes in it. In the same freezer, a piece of jacket was observed hanging over one of the pipes. The jacket was removed and the boxes in the area of the exposed insulation were moved. [9 CFR § 416.2]

52:51. (A) The floors of several livestock pens and the area at the bottom of the unloading ramp were not constructed in a manner that provided good footing for livestock. The veterinary service personnel promised to address the issue. [9 CFR § 313.1(b)]

(B) There were some surfaces in the knocking box which reflected light and resulted in hesitation by the cattle approaching the box. [9 CFR § 313.2(a)]

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Handwritten signature of Rori K. Craver, DVM, dated 4/30/08.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION Frigorifico Sarubbi (Sirsil S.A.) Coronel Raiz 2764 Montevideo	2 AUDIT DATE April 16, 2008	3 ESTABLISHMENT NO. 85	4 NAME OF COUNTRY Uruguay
	5 NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7 Written SSOP		33. Scheduled Sample	
8 Records documenting implementation.		34. Species Testing	
9 Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10 Implementation of SSOP's, including monitoring of implementation.		36 Export	
11 Maintenance and evaluation of the effectiveness of SSOP's.		37 Import	
12 Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration		38 Establishment Grounds and Pest Control	X
13 Daily records document item 10, 11 and 12 above.		39 Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40 Light	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	X
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.	X	49 Government Staffing	
Part C - Economic / Wholesomeness		50 Daily Inspection Coverage	
23 Labeling - Product Standards		51. Enforcement	X
24 Labeling - Net Weights		52 Humane Handling	
25 General Labeling		53 Animal Identification	
26 Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27 Written Procedures		Part G - Other Regulatory Oversight Requirements	
28 Sample Collection/Analysis		56. European Community Directives	()
29 Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30 Corrective Actions		59.	
31 Reassessment			
32 Written Assurance			

60. Observation of the Establishment

Date April 16, 2008 Est #: 85 (Frigorifico Sarubbi (Sirsil S.A.) [S/P] (Montevideo, Uruguay)

22/51. The documentation for the choice of 6°C in the CCP for the chilling of carcasses did not support the choice. The form for pre-shipment review contained the initials of the verifier, not a signature. [Regulatory references: 9 CFR § 417.5(a)(1), 417.5(c), 417.8]

38. Dead flies were found in several different areas during pre-operational sanitation verification. The flies were disposed of and the areas re-cleaned and sanitized before operations were allowed to begin. [9 CFR § 416.2(a)]

40/51. There was insufficient light intensity in the veterinary service head inspection area. [9 CFR § 416.2(e)]

45/51. The bagging stands used in the deboning area had a number of unsmooth welds, creating for the potential for biofilm formation. [9 CFR § 416.3(a)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver DVM 4/16/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Erel S.A. Ruta 9, Km. 148 Maldonado	2. AUDIT DATE April 28, 2008	3. ESTABLISHMENT NO. 135	4. NAME OF COUNTRY Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	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	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	()
27. Written Procedures	()	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	()	56. European Community Directives	()
29. Records	()	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	()	59.	
31. Reassessment	()		
32. Written Assurance	()		

13/51. Corrective actions in SSOP records do not include the appropriate disposition of product that may have been affected by the non-conformance. [Regulatory references: 9 CFR § 416.16, 416.17]

46. The system used transfer of pieces of marinated jerky from the large container to the small one for spreading on the screens allowed multiple opportunities for cross-contamination. [9 CFR § 416.4(d)]

61. NAME OF AUDITOR
Ron K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

 4/28/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Solis (Ersinal S.A) Ruta 8, km 87,500 Lavalleja	2. AUDIT DATE May 02, 2008	3. ESTABLISHMENT NO. 150	4. NAME OF COUNTRY Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
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	
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	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	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			

13/22/51. Preventive measures recorded in all records observed did not contain sufficient detail to allow for verification. [Regulatory references: 9 CFR § 416.16, 416.17, 417.5, 417.8]

28/51. Quality control personnel did not understand the meaning of the "last thirteen samples" in the analysis of the results of generic *Escherichia coli* testing. Because of this, statistical process control was not being used correctly. [9 CFR § 310.25]

39/51. (A) The metal wrapping on the insulation pipes over the belt preceding the drying tunnel in the vacuum packaging area had holes in it allowing for exposed insulation.

(B) The box coolers and freezers had damaged areas around the doors and gaps in the seals allowing for ice and water build-up inside and outside of the coolers. [9 CFR § 416.2]

40. Several areas in the offal room had beaded and dripping condensate, but none was observed dripping on product at the time of the audit. Product and equipment were moved away from possible contamination and the areas were cleaned before production was resumed. [9 CFR § 416.2(d)]

55/51 Tails were removed early in the skinning process and attached to the carcass enclosed in a plastic bag, therefore not allowing for adequate inspection by veterinary personnel. The line was stopped and the tails were attached by ropes for proper inspection. Tails from earlier in the production shift were re-inspected and designated for local markets only. [9 CFR § 310.1(a)]

61 NAME OF AUDITOR
Rori K. Craver, DVM

62 AUDITOR SIGNATURE AND DATE

Rori K. Craver DVM 5/2/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Lorsinal S.A Camino Melilla 10270 Montevideo	2. AUDIT DATE April 17, 2008	3. ESTABLISHMENT NO. 224	4. NAME OF COUNTRY Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	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	
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		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			

39.51. (A.) The rails in the cooler designated for the day's slaughter had a beaded oil coating them. The beaded oil was removed before carcasses were allowed into this cooler. [Regulatory references: 9 CFR § 416.2(b)]

(B.) A moveable wall in the slaughter area had not been sealed in a manner that prevented direct opening to the exterior of the establishment. [9 CFR § 416.2(b)(3)]

40.51. There was insufficient light intensity in the veterinary service post-mortem inspection areas. This deficiency was immediately corrected. [9 CFR § 416.2(c)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver DVM 4/17/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorífico San Jacinto (Nirea S.A.) Ruta 7, Km. 59 500 Canelones 0	2. AUDIT DATE April 18, 2008	3. ESTABLISHMENT NO. 344	4. NAME OF COUNTRY Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		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		56. European Community Directives	()
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: April 18, 2008 Est #: 344 (Frigorifico San Jacinto (Nirea S.A.) [S/P] (Canelones, Uruguay)

39 51. The white supports to the rails in one of the coolers had an unidentified black substance on them. These supports are directly over carcasses. This cooler contained no carcasses at the time of the audit. The establishment scheduled corrective actions prior to the use of this cooler. [Regulatory references: 9 CFR § 416.2(b)]

61. NAME OF AUDITOR

Ron K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Ron K Craver DVM 4/18/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION: Frigorifico Las Piedras S.A.
Ruta 36, Km. 26 100
Canelones ()

2. AUDIT DATE: April 22, 2008

3. ESTABLISHMENT NO.: 379

4. NAME OF COUNTRY: Uruguay

5. NAME OF AUDITOR(S): Rori K Craver

6. TYPE OF AUDIT: 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)	Audit Results	Part D - Continued Economic Sampling	Audit Results
Basic Requirements			
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	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	
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	()
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

Date: April 22, 2008 Est #: 379 (Frigorifico Las Piedras S.A. [S/P]) (Canelones, Uruguay)

28/51. Statistical process control was not being used for the analysis of the results of generic *Escherichia coli* samples.
[Regulatory references: 9 CFR § 310.25]

40/51. There was insufficient light intensity in the veterinary service head inspection area. [9 CFR § 416.2(c)]

61. NAME OF AUDITOR

Rori K. Craver

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver Don 4/22/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Matadera Pando (Ontilcor S.A.) Ruta 75, km 34 Pando, Canelones 91000	2. AUDIT DATE April 15, 2008	3. ESTABLISHMENT NO. 439	4. NAME OF COUNTRY Uruguay	5. NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT
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Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan		41. Ventilation	X
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	X
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	X	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

27/51. The written program for the selection of carcasses for sampling for generic *Escherichia coli* only chose samples within the entire number slaughtered rather than within each 300 animals slaughtered. [9 CFR § 310.25]

41/51. The primary boxed product freezer had an excessive build-up of ice and frozen condensation on the ceiling and the racks. Product pallets were covered to protect the boxes. Pallets were pushed up against the wall preventing air circulation and not allowing inspection of the area. [9 CFR § 416.2(d)]

46. A bag of inedible product was put on the bone conveyor belt in a manner that resulted in it contacting product awaiting fabrication and other product contact surfaces. The line was stopped and the area cleaned and sanitized before production continued. [9 CFR § 416.4(d)]

52. Cattle moving up the ramp into the knocking box were hesitating as they reached the end of the ramp. The exact cause of the hesitation could not be identified at the time. [9 CFR § 313.2(a)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

 Rori K. Craver DVM 4/15/08



DIRECCION GENERAL DE SERVICIOS GANADEROS
DIVISION INDUSTRIA ANIMAL

CONSTITUYENTE 1476
11200 MONTEVIDEO
URUGUAY

TEL: 5982 412 6346
FAX: 5982 412 6317

Montevideo, October 17th 2008

**MR. DONALD SMART
DIRECTOR
INTERNATIONAL AUDIT STAFF
OFFICE OF INTERNATIONAL AFFAIRS
FOOD SAFETY AND INSPECTION SERVICE, USDA**

Dear Mr. Smart,

I refer to your request to submit comments in response to the information in the audit report made by Dr. Aurora K. Craver, after her on-site audit of Uruguay's meat inspection system, from April 9 through May 14, 2008.

At present, we have studied it and have found no objections to Dr. Craver's observations and we have no further comments to make to her report.

Looking forward to hearing from you, I remain yours most faithfully,

**DR. HECTOR J. LAZANEO
DIRECTOR**

cc/ Dr. Francisco Muzio, DGSG, MGAP
Embassy of Uruguay, Washington, DC
US Embassy, Buenos Aires, Argentina
US Embassy, Montevideo, Uruguay