U. S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL AUDIT STAFF
WASHINGTON, DC
202-205-3969
FAX 202-720-0676

NOV 20 2009

MEMORANDUM

TO: David Mergen
Agricultural Counselor
US Embassy, Buenos Aires
4300 Columbia
1425 Buenos Aires
Argentina

FROM: James Adams, DVM
Director
International Audit Staff, OIA, FSIS, USDA

SUBJECT: FSIS FINAL AUDIT REPORT FOR URUGUAY

Dear Mr. Mergen,

Please deliver the attached final audit report to Dr. Hector J. Lazaneo, Director, Ministerio de Ganaderia, Agricultura y Pesca, Dirección General de Servicios Ganaderos, Division Industria Animal. Please contact me via email at james.adams5@fsis.usda.gov, if you have any further questions.

Best regards,

James Adams, DVM

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

NOV 20 2009

Dr. Hector J. Lazaneo
Director
Ministerio de Ganaderia, Agricultura y Pesca
Dirección General de Sevios Ganaderos
Division Industria Animal
Constituyente 11476
11200 Montevideo
Uruguay

Dear Dr. Lazaneo:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Uruguay's meat inspection system July 15 through August 7, 2009. Comments from the government of Uruguay have been included as an attachment to the final report. 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) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

for Manzoor H. Chaudry

James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

cc list:

David Mergen, Agricultural Counselor, US Embassy, Buenos Aires
Francisco Pirovano, Agricultural Specialist, US Embassy, Buenos Aires
Dwight Wilder, Agricultural Attaché, US Embassy, Buenos Aires
Ricardo Romero, APHIS, US Embassy, Montevideo
Hugo Cayrus Maurin, Minister Counselor, Embassy of Uruguay
FAS/OSTA
Hugh Maginnis, Western Hemisphere Area Director, FAS
Ann Ryan, State Department
Lisa Wallenda Picard, Chief of Staff, OA
Alfred Almanza, Administrator, FSIS
Ronald K. Jones, Assistant Administrator, OIA
Philip Derfler, Assistant Administrator, OPPD, FSIS
Daniel Engeljohn, Deputy Assistant Administrator, OPPD, FSIS
James Adams, Director, IAS, OIA, FSIS
Manzoor Chaudry, Deputy Director, IAS, OIA
Rick Harries, Director, EPS, OIA
Andreas Keller, Director, IES, OIA
Jerry Elliott, Director, IID, OIA
Yolande Mitchell, IES, OIA
AJ Ogundipe, IES, OIA
Uruguay Country File

FSIS:OIA:IAS:DIRECTOR:202-205-3969:URUGUAY
FINAL AUDIT LETTER November 19, 2009

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

JULY 15 THROUGH AUGUST 7, 2009

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

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
DI.LA.VE	Division of Veterinary Laboratories
DSA	Animal Health Division
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
GOU	Government of Uruguay
Lm	*Listeria monocytogenes*
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
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standards
SRM	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures

1. Summary

1.1 Description/Eligibility

This report summarizes the results of the audit conducted in Uruguay from July 15 through August 7, 2009. This was a routine audit with a special emphasis on corrective actions taken in response to a Notice of Intent to Delist (NOID) issued during the previous audit conducted in April-May of 2008. Uruguay is eligible to export red meat and red meat products to the United States. Between January 1 and July 31, 2009, Uruguay exported 38,549,014 pounds of meat and poultry products to the United States, of which 7,635429 pounds were re-inspected at United States Ports Of Entry (POE). A total of 173,063 pounds were rejected at POE. No rejections were for food-safety concerns. The activities of the current audit appear in the table below.

The findings of the previous audit during April-May 2008 did not result in a change to the ability of any establishment in Uruguay to export meat products to the US.

1.2 Comparison of the Current Audit and the Previous Audit

		07/15-08/07, 2009	04/09-05/14, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Establishment Level	10	11
Laboratories Audited			
	Microbiology	1	1
	Residue	1	1
Establishments Audited			
	Slaughter/processing	9	10
	Processing	1	1
	ID Warehouses	0	0
Enforcement Actions Initiated			
	NOID	0	1
	Delistment	0	0
Risk Area Findings		(10 Ests. audited)	(11 Ests. audited)
	Sanitation Controls (SSOPS, SPS)	8	10
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	6	6
	Residue Controls	1	1
	Microbiology Controls	1	1
	Inspection/Enforcement Controls	9	10
	Special Emphasis (HH, O157:H7)	0	2
	Facilities for Inspection	0	0

1.3 Summary Comments for the Current Audit

Several of the establishments were chosen for audit this year because of POE violations. The investigations by the establishments and by MGAP personnel were very thorough

and reflected good knowledge of conditions, investigative methodologies, corrective actions and preventive measures. One investigation covered a POE notice that the establishment was a possible source of product adulterated with *Escherichia coli* O157:H7 that was a part of a US grinding establishment recall. Although the internal investigation did not reveal the presence of the adulterant, the follow-up testing did provide positives for the adulterant in new product. The entire equivalent process approved for Uruguay was followed with all appropriate testing and documentation. Another investigation in another establishment was done for POE violations for the moisture-protein ratio in a dried beef product. The investigation showed there was a process problem and this has been corrected resulting in no more violations for this product. One investigation was for sour product received at POE and that investigation showed no problems in the product that was returned to the establishment and this product has been approved for the domestic market.

The establishment that received a Notice of Intent to Delist (NOID), Establishment 0012, Tacuarembó, during the previous audit of 2008, had extensive remodeling and new construction. All of the previous findings had been resolved to meet regulatory requirements.

2. INTRODUCTION

The audit took place in Uruguay from July 15 through August 7, 2009.

An entrance meeting was held on July 15, 2009, 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).

3. OBJECTIVE OF THE AUDIT

This was a routine audit. 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, ten government offices at the local establishment level, one laboratory performing analytical testing on United States-destined product, six beef slaughter and deboning establishments, three beef slaughter, deboning, and further processing establishments, and one beef processing establishment.

4. 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 ten establishments: six slaughter and deboning establishments, three 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 entrance 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, SPS, 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.

5. 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.

6. SUMMARY OF PREVIOUS AUDITS

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

The following deficiencies and non-compliances were documented during the FSIS audit of Uruguay's meat inspection system in March 2007:

- In two establishments, there were SSOP implementation non-compliances documented.
- In two establishments, there were SPS implementation non-compliances documented.
- In one establishment, there was an SRM handling deficiency documented.
- In the government microbiological laboratory, there were four deficiencies documented including sample size for testing, scale calibration, the lack of a procedures manual, and incubation conditions.

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

The following deficiencies and non-compliances were reported during the FSIS audit of Uruguay's meat inspection system in April/May 2008:

- One establishment was issued a Notice of Intent to Delist (NOID).
- In two establishments, there were documented deficiencies in the assignment of competent, qualified inspectors.
- No request had been submitted to the FSIS OIA Equivalence Staff for the use of private laboratories for some of the residue analyses of official samples.
- In six establishments, there were SSOP implementation and/or recordkeeping non-compliances documented.
- In ten establishments, there were SPS non-compliances documented including building construction and maintenance, pest control, ventilation, light intensity, equipment and utensils, and sanitary operations.
- In two establishments, there were non-compliances documented in humane handling and slaughter; these noncompliances were related to the premises.
- In six establishments, there were non-compliances documented in HACCP implementation, primarily in the areas of critical limits, corrective actions and/or preventive measures, and recordkeeping.
- In three slaughter establishments, there were non-compliances documented in the generic *E. coli* programs for carcass selection or statistical process control.
- In the microbiological audit, there were two deficiencies reported, one in methods usage and one in receipt of samples.

- Overall, inspection system controls were not fully developed and implemented as in-plant inspection personnel were not fully aware of the content of the SSOP and HACCP plans of the establishments to which they were assigned.

7. MAIN FINDINGS

7.1 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.

7.1.1 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. LA. 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.

There are two circumstances in which special audit teams are assembled from CCA personnel. One is for the certification of a new establishment. The other is when there are "for cause" circumstances at an establishment, such as repeated lab failures, etc. Examples of the reports of both of these circumstances were reviewed by the auditor.

7.1.2 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 that do not require immediate action are 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. If electronic mail is not used, immediate action items can also be transmitted telephonically or by fax with follow-up of documents in the folder system.

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.

There are three slaughter establishment supervisors and a supervisor above them, two processing establishment supervisors and one cold storage supervisor attached to the MGAP headquarters in Montevideo who travel to the certified establishments for supervisory reviews. Even though the US has eliminated the monthly minimum visit requirement, Uruguay has chosen to maintain the monthly or more often as needed time frame to satisfy other trading partners' requirements. Uruguay exports to approximately 80 countries. Most of the establishments certified for the US are also certified for other countries such as Israel and the European Union. There is a check list that is filled out each time with different emphases each visit depending on what is needed at the time. At the present, *E. coli* O157:H7 is put under other, but as the program progresses and solidifies, this will become a separate part of the list. There are no other levels of command between the CCA and the official inspection teams in the establishments.

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.

7.1.3 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. 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).

There have been no significant changes in this process. Between June of 2008 and March of 2009, MGAP hired approximately 100 new individuals from outside the system. This included about 28 veterinarians, 25 advanced assistants and 40 assistants. In addition, MGAP had 27 transfers from other parts of the Ministry. These new personnel are all now working their new positions. The auditor had an opportunity to meet and observe many of these new personnel.

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

There were no deficiencies documented in the assignment of competent, qualified inspection personnel.

7.1.4 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.

7.1.5 Adequate Administrative and Technical Support

The request was submitted electronically to the FSIS International Equivalence Staff (IES) for the use of private laboratories for some of the residue analyses of official samples of product destined for US export. However, the request did not reach the Equivalence Staff. A copy of this request has been hand-carried back by the current auditor to give to the Director of the Equivalence Staff. This will be presented on

Sunday, September 13, 2009. A letter was sent from the IES in March with a number of specific questions to the Technical Staff of MGAP. The response to this information request was sent in March and included a folder detailing the contract with the Brazilian (Microbioticos in Sao Paulo) and Argentine (Xenobioticos S.R.L. in Buenos Aires) laboratories. The folder also now contains the report of the MGAP audit of the Brazilian laboratory, Microbioticos, and the corrective actions required of that laboratory. The audit for the Argentine laboratory, Xenobioticos, is scheduled for September 2009. The specific compounds for chemical residue analyses in the Microbioticos Laboratory are the Nitroimidazoles and those for Xenobioticos Laboratory are Monensin, the Carbamates, and Xylazine.

DILAVE, the government laboratory for residue and microbiological analyses, reports directly to the Director General. For the oversight of the Argentine and Brazilian laboratories the following procedures are in place. Each year the Director General sends a letter to the laboratory describing the compounds, methods, limits of detection and number of samples requested for analyses. The labs send monthly records of their Quality Assurance departments that are associated with the requested analyses. These QA records are sent to DILAVE for verification. Results of analyses are sent directly to the Meat Inspection Division, not to DILAVE.

The choice of these laboratories came as the result of an EU audit that detailed additional analyses that they required of Uruguay. They recommended these two particular labs in Brazil and Argentina as labs that they audited and knew performed the required analyses. These particular laboratories are involved in the national residue programs of their respective countries so receive audit by those countries' governments. One of the official audits was just completed and the other is scheduled for September 2009.

There are formal agreements between Uruguay and Paraguay for DILAVE to do some residue analyses for chemical compounds that the Paraguayan laboratories do not have the capability of those specific analyses. These are for official government sampling programs for the Paraguayan meat inspection agency.

MGAP has demonstrated the ability to support an audit by a third party to determine that their system approach to meat inspection and exportation of safe, wholesome and properly labeled meat products is adherent to regulatory requirements.

7.2 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.

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of ten establishments. Of these, six were slaughter and deboning establishments, three were slaughter, deboning, and further processing establishments, and one was a processing establishment. No establishments were delisted by the CCA of Uruguay. No establishments received a notice of intent to delist (NOID) from the CCA of Uruguay.

Specific non-compliances are documented in the attached individual establishment audit checklists.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to the 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:

- In the residue laboratory, there were many solvent bottles attached to different analytical instruments containing liquids but without labels identifying the contents. Without identification, the wrong solvents could be used in an analysis and the results would therefore be suspect. As this laboratory is preparing for accreditation under ISO 17025, the requirements within ISO 17025 call for labeling of all compounds used in the laboratory.
- The samples being sent to the residue laboratories in Argentina and Brazil for residue analyses are being delayed by customs at the borders so the results are not

being received in a timely manner. In a review in several establishments, many residue reports from the Argentine and Brazilian laboratories were not being received within the 30 day time frame. The Uruguayan residue program calls for the receipt of results within 30 days from the receipt of the sample at MGAP headquarters. The samples are shipped to these laboratories on the same day they are received at MGAP headquarters. Therefore, the results were not being received as was called for in the Uruguayan plan.

- In the microbiological laboratory, the forms for reporting the results of testing for *Salmonella* and *E. coli* O157:H7 do not clearly report the dates of analysis and the date of reporting the results. There is only a line or block marked "Date" and no designation to tell whether this date is a date of analysis or a date of the reporting of the results of the analysis. Therefore, it is not possible to determine if the analyses were conducted in the specified time frames from the date of sampling and the receipt of the sample in the laboratory..

10. SANITATION CONTROLS

As stated previously, 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.

10.1 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met. The SSOP in one establishment did not meet basic requirements. This establishment's SSOP did not clearly designate frequencies for monitoring of operational sanitation.

The SSOPs in the other nine establishments were found to meet the basic FSIS regulatory requirements, with the following non-compliances:

- Six of ten establishments had non-compliances in SSOP in implementation and/or recordkeeping.

- Five establishments had non-compliances in implementation of SSOPs. These included:

- One establishment had potential cross-contamination from the misplacement of the brisket saw position prior to the completion of the dehiding process.
- Two establishments had cross-contamination between carcass parts and nonfood contact surfaces during operations.
- One establishment had potential cross-contamination from a deteriorated seal in a product contact area of a mixer. This was found during pre-operational sanitation verification.
- One establishment had actual and potential head cross-contamination from SRM tonsil materials.
- One establishment had potential cross-contamination from the mishandling of a dropped handheld product contact utensil (meat hook).

Two establishments had non-compliances in SSOP recordkeeping. These included:

- Two establishments had SSOP operational sanitation monitoring records that did not consider the possible involvement of product in the documenting of corrective actions.
- In one establishment, during records review of the SSOP monitoring records for both pre-operational and operational sanitation, the descriptions of deficiencies and of corrective actions did not contain details sufficient to allow for MGAP to visualize the situation for adequate verification of establishment actions.

Specific non-compliances are documented in the attached individual establishment audit checklists.

10.2 Sanitation Performance Standards

The following non-compliances were documented:

- Eight of ten establishments audited had non-compliances in sanitation performance standards. These non-compliances included:
  - Six establishments had less than regulatory light intensity at inspection and/or re-inspection stations.
  - Two establishments had non-compliances in construction maintenance.
  - One establishment had condensate present.
  - One establishment had non-compliances with soap availability at handwash stations and blocked sinks in the boning department.
  - One establishment had a non-compliance with the potential creation of an insanitary condition by the stacking procedures in the boxed product freezer.

Specific non-compliances are reported in the attached individual establishment audit checklists.

11. 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 non-compliances or deficiencies were reported.

There had been no outbreaks of animal diseases with public health significance since the previous FSIS audit.

12. 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 of livestock, 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.

12.1 Humane Handling and Slaughter of Livestock

None of the nine slaughter establishments had non-compliances in humane handling and slaughter of livestock activities.

12.2 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 defined in 9 CFR Part 417, the HACCP Systems.

The HACCP programs were reviewed during the on-site audits of all ten establishments.

One establishment had non-compliance in basic HACCP in that the flow diagrams and hazard analyses did not include the receipt and storage of packaging materials, an integral part of the process.

Six of ten establishments had not adequately implemented the HACCP requirements. These non-compliances were primarily in the areas of verification and recordkeeping and included:

- In two establishments, the HACCP plan did not include records review and/or observation of the monitor in the verification tasks.
- In three establishments, pre-shipment review was unclear on the correlation between slaughter dates and deboning dates.
- In two establishments, verification records did not record the results of the verification tasks.

Specific non-compliances are reported in the attached individual establishment audit checklists.

12.3 Testing for Generic *Escherichia 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.

Nine of the ten establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria defined in 9 CFR 310.25.

Testing for generic *E. coli* was not properly conducted in two of the nine slaughter establishments. The non-compliances reported were in the areas of carcass selection and/or the records of sampling, analysis, and results.

- In one establishment, true randomness was not accomplished in the written program for carcass selection and the implementation of that program; one side of each carcass (either the leading side or the following side) could never be selected by using the procedure specified.
- In one establishment, the written program's procedure for analysis of the results using m/M values did not match the actual procedure in use (statistical process control). Since the establishment was using the sponging procedure rather than excision, statistical process control is the correct procedure for the analysis of results.

Specific non-compliances are reported in the attached individual establishment audit checklists.

12.4 Testing for *Listeria monocytogenes*

Two of the ten 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 non-compliances were reported.

13. 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 (DI. LA.VE) in Montevideo was audited.

The deficiencies in the residue laboratory have been previously discussed in this report.

Uruguay's National Residue Testing Plan for 2009 was being followed and was on schedule.

14. 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.*

14.1 Daily Inspection in Establishments

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

14.2 Testing for *Salmonella*

Uruguay has only partially adopted the FSIS regulatory requirements for testing for *Salmonella.* The auditor found no documentation to show that the program currently in use has been deemed equivalent by FSIS. This program includes taking two samples per week, one from a steer/heifer and one from a cow/bull, in each slaughter establishment. The FSIS program calls for one sample per day for the time period of the respective set and only sampling the predominant category from slaughter numbers. If any positive result is obtained in the Uruguayan program, that establishment then proceeds to sample according to the FSIS program with sample sets done for both steers/heifers and for cows/bulls. Since this program does not use the FSIS sampling regimen for routine sample sets, it is non-compliant. The program will be submitted to IES again for equivalency determination.

Nine of the ten establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria defined in 9 CFR Part 310.25 and the written program from the Uruguayan government.

Testing for *Salmonella* was properly conducted in all of the establishments according to the Uruguayan program, not the FSIS program; therefore, it is being reported as non-compliant.

14.3 Testing for *Escherichia coli* O157:H7

There were no non-compliances reported in the testing program for *E. coli* O157:H7.

14.4 Species Verification

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

14.5 Periodic Reviews

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

14.6 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. The HACCP verification system as written by MGAP headquarters does not differentiate between the recordkeeping component of inspection service verification and the review of records that would be done if the random choice was monitoring or verification. As this component is not explained or expanded, only records are reviewed, not other supporting documentation, the hazard analysis, the HACCP plan or other relevant documentation of the HACCP systems. The SSOP verification task does not include review of the SSOP plan, only the records produced in accordance with the plan.
- Inspection system controls at all levels were not fully developed and implemented. This was demonstrated that in eight of ten establishments audited, the inspection system personnel, including in-plant and supervisory personnel, failed to note and document SPS, SSOP, and HACCP non-compliances prior to the audit that were then found by the auditor. Part of this was due to the above deficiency of the failure to be aware of the details of SSOP and HACCP plans and partly due to the written guidelines from headquarters to inspection personnel in the field.

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.

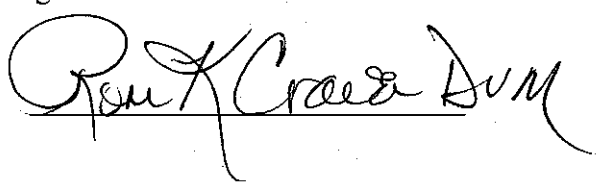
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

15. CLOSING MEETING

An exit meeting was held on August 7, 2009, 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
Senior Program Auditor



16. ATTACHMENTS

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
Establecimientos Colonia S.A. Ruta 22, Km 30 Tarariras, Colonia 70002	07/20/09	2	Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT [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.	X
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	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
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: 07/20/09 Est #: 2 (Establecimientos Colonia S.A. [S/P/CS]) (Tarariras, Uruguay)

10. During the audit of slaughter operations, it was observed that there was occasional contact (cross-contamination) between the carcass legs, the offal being removed from the carcass, and the boots of the eviscerator. The veterinary service took immediate control and the establishment employee was instructed in the proper placement of his boots to avoid cross-contamination of product. The establishment planned to add a kick plate to the front of that platform for use for the next day's production. There was no previous record from either the veterinary service or the establishment documenting this situation. The offal product observed being contaminated by the boots was condemned and the carcass legs were trimmed. [Regulatory reference(s): 9 CFR §416.13]

15/51. In a basic review of the HACCP programs present in this establishment, it was observed that the flow diagrams and hazard analyses for the various HACCP categories did not include the receipt and storage of packaging materials; these materials only appeared on the flow chart at the point in the process where they were used. The establishment does look at packaging materials under a GMP program, but this program is not referenced in the HACCP programs. Establishment reassessment of these programs had not noticed this omission nor had it been noted in the records of HACCP verifications tasks performed by the veterinary service. These omissions will be corrected immediately. [9 CFR §417.2(c), 417.8]

19/22/51. During a recordkeeping review of establishment HACCP plans, it was observed that the verification activities listed did not include review of the monitoring records. The verification area of the HACCP CCP records did not record results of the verifications conducted. This lack of recording verification results was prevalent in all CCP records reviewed by the auditor. This omission had not been documented in the review of records by the establishment or in the records of HACCP verification tasks performed by the veterinary service. The veterinary service manual of procedures for HACCP verification tasks does not include records review of verification procedures, only the observation of the three possible procedures (observation of the monitor, records review, and calibration of process-monitoring instruments). The auditor explained what was needed in the veterinary service verification tasks and there were some misunderstandings compared to what is delineated in FSIS Directive 5000.1. The veterinary service will notify their personnel in all establishments and the manual will be updated to include the correct procedures. These omissions in the establishment paperwork and practices will be corrected immediately. [9 CFR §417.5, 417.8]

40/51. There was insufficient light intensity at the veterinary head inspection station; this intensity was measured at 380 lux instead of the required 538 lux (equal to 50 foot candles). This lack had not been noted in inspection or establishment records. In fact, lighting levels had been taken by the veterinary service in February of 2008 when the new slaughter floor opened and had a reading of 1000 lux at that time. These readings had been taken when no operations were ongoing. The establishment immediately added more light for the completion of operations and installed new lighting overnight for a permanent solution. The readings taken the following day showed sufficient intensity. Pictures were provided to the auditor of the new lights and light intensity readings. [9 CFR §307.2(m)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Rori K. Craver, DVM	Rori K Craver DVM 20 July 09

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
Frigorifico Pul, Pulsa S.A. Ruta 8, Km. 389 Melo, Cerro Largo 37000	07/29/09	7	Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT [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.	
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	X
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
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: 07/29/09 Est #: 7 (Frigorifico Pul, Pulsa S.A. [S/P/CS]) (Melo, Uruguay)

10. The specified risk material (SRM) receptacle for tonsils (removed by the head inspector) was too high and in a location allowing for cross-contamination to passing heads as the inspector had to move the tonsilar materials around the head in order to dispose of them. The container was moved to a more convenient location and its height will be lowered overnight. This was noticed by the MGAP supervisor at the same time as the auditor. [Regulatory reference(s): 9 CFR §416.13]

10/51. During the audit of the slaughter floor, the auditor observed that the brisket saw was located before the hide puller. Even though most of the hide had been skinned away from the brisket area, this presented a potential of contamination from the loose ends of the hide to an opening into the carcass. For the rest of this day's slaughter, carcass hides were skinned farther down and away from the area. This area is the only part of the slaughter line not yet reconstructed. The plan is in progress and due to start shortly. In the meantime, the order of hide removal and brisket saw will be corrected by completing the hide skinning before the use of the brisket saw. Neither establishment records nor MGAP records showed that this error in the order of operations had been observed. [9 CFR §416.17, 417.8]

22/51. During recordkeeping review, it was observed that the records for pre-shipment review did not represent review of the CCPs for a specific lot. The records represented review of CCPs on the day of slaughter and/or the day of production, whatever process had occurred on that specific date. So, any particular pre-shipment review only covered whether there was slaughter and/or processing on that date, not the CCPs from the slaughter and processing of a specific lot. However, all CCPs from slaughter and processing were accounted for by using different days of pre-shipment review. Establishment reassessment had not found this non-compliance nor had the HACCP verification done by MGAP personnel. This will be corrected for future pre-shipment reviews. [9 CFR §417.5, 417.8]

39/51. During onsite review of the red offal area, it was observed that there were many small holes in the ceiling. Also, many of the tiles covering the walls were chipped or broken. Some repair had been done to these walls but did not provide the type of wall surface required by the regulations. These conditions may lead to the development of unsanitary conditions as they inhibit complete cleaning. No comments about either of these findings were found in establishment or MGAP sanitation records. [9 CFR §416.2(b)]

40/51. There was insufficient light intensity at the head inspection station. The readings were in the 200-300 lux range as opposed to the regulatory requirement of 50 foot candles equal to 538 lux. Two of the current lights present were adjusted for angle and one other will be moved overnight. This provided sufficient intensity to continue slaughter. These low readings did not appear in any establishment or veterinary records. The DIA slaughter department is creating a new national program for the verification of light intensity and documentation of the results. [9 CFR §307.2(m)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE
Rori K Craver DVM 29 July 09

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
Frigorifico Tacuarembo S.A. Rutas 5 y 26 Tacuarembo, Tacuarembo 45000	07/27-28/09	12	Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT [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.	
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.	
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	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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: 07/27-28/09 Est #: 12 (Frigorifico Tacuarembo S.A. [S/P/CS]) (Tacuarembo, Uruguay)

10. A meat hook, which is a food contact surface, was dropped on the floor during the deboning process. The operator's actions following this event were not in accordance with the company's established procedures and led to cross-contamination of the employee's hands and the meat hook. She then prepared to continue work. The auditor told the MGAP personnel and they told the establishment Quality Assurance (QA) personnel. The operator was instructed by QA to follow the correct procedures before continuing to work. The establishment's SSOPs have a section on the correct procedures to follow when equipment is dropped on the floor. The entire section will be retrained on these procedures. [Regulatory reference(s): 9 CFR §416.13]

All findings from the previous audit (2008), an NOID, have been corrected.

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K Craver DVM 28July09

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
Frigorifico Durazno Frigocerro S.A. Santa Bernadina Durazno, Durazno 97000	08/04/09	14	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Rori K. Craver, 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.	X
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.	
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.	
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	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
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: 08/04/09 Est #: 14 (Frigorifico Durazno Frigocerro S.A. [S/P/CS]) (Durazno, Uruguay)

10/51. As the hide removal process is completed, the carcasses swing and the front feet contact the opposite wall, not a food contact surface. This event causes cross-contamination of carcasses as the feet of each carcass may touch the wall. The immediate corrective action was to station an employee at the location to clean the wall after every carcass touch. Over the weekend, a cutout area will be constructed to eliminate the possibility of contact. A review of establishment and MGAP operational sanitation monitoring and verification records revealed no notations on this event. [Regulatory reference(s): 9 CFR §416.13, 416.17]

13/51. Upon a review of the SSOP records, the establishment had failed to document the possible involvement of product in the corrective actions for deficiencies found in operational sanitation. The SSOP plan and records format will be rewritten to include product evaluation and disposition as a part of corrective actions. No notations of this were found in either MGAP or establishment records verification. [9 CFR §416.16, 416.17]

40/51. The light intensity at several veterinary inspection and re-inspection stations was less than the required 538 Lux. Both the inspection personnel and the establishment had taken light intensity reading, but not documented them. However, these readings had not been taken during the real conditions of operations and not at the actual levels and angles at which work is performed. Additional lights and the change of some present lights' angles were done during production and during breaks to allow production to continue. All areas will be reevaluated and other changes made as needed. No documented readings were available. [9 CFR §416.17, 416.2(c)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Rori K. Craver, DVM	Rori K Craver-DVM 4 Aug 09

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
Establecimientos Colonia S.A. Ruta Puerto de Fray Bentos Puente Grai, San Martin, Km. 310.700 Rio Negro 65000	07/21/09	30	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Rori K. Craver, 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.	
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 07/21/09 Est #: 30 (Establecimientos Colonia S.A. [P/CS]) (Rio Negro, Uruguay)

10/51. During pre-operational sanitation verification inspection, the auditor found a seal inside of a mixing machine that was deteriorating; this was a product contact surface and a potential source of contamination of the product. The veterinary service took immediate control of the apparatus. The establishment replaced the seal, rewashed and sanitized the equipment and presented it for re-inspection. It was re-inspected and released for production. There was no documentation from either the establishment or the veterinary service showing that this seal had been noted by anyone prior to it being found by the auditor. [Regulatory reference(s): 9 CFR §416.13, 416.17]

22/51. A review of HACCP verification records showed that the establishment failed to record results for establishment verification activities; checkmarks were used to show the activities had been performed, but no results were recorded. This omission had not been found in establishment record review or in the HACCP verification tasks performed by the veterinary service. This will be corrected by the following day's production records. [9 CFR §417.5, 417.8]

39/51. The floors in the canning area contain numerous cracks and chipped tiles which could lead to the development of insanitary conditions in the area. There is evidence of some minor repair. The findings on the condition of this floor as recorded in both establishment sanitation records and veterinary service sanitation verification records delineated the need for spot repairs, but did not accurately reflect the conditions observed during the audit. The veterinary service and the establishment will discuss this situation and establish a plan with a timetable for more permanent repairs. [9 CFR §416.17, 416.2(b)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE
Rori K Craver DVM 21 July 09

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
Frigorifico Suc. Carlos Schneck S.A. Camino Colman 4598 Montevideo, Montevideo 12400	08/05/09	52	Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT [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.	
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	X
28. Sample Collection/Analysis	X
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	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
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.	

h

60. Observation of the Establishment Date: 08/05/09 Est #: 52 (Frigorifico Suc. Carlos Schneck S.A. [S/P/CS]) (Montevideo, Uruguay)

22/51. (A) During a recordkeeping review of the HACCP plan for hamburger patties, it was noted that there was no supporting documentation for the choice of the critical limit (CL) of CCP2. The CL was the ambient temperature in the freezer but no correlation had been made between the ambient temperature and product temperature.

22/51 (B) During a recordkeeping review of the HACCP plan for slaughter, it was noted that the justification for residues not being a hazard was that there is a national MGAP residue surveillance program. The fact that such a program exists does not impact the possible hazard of animals arriving at the establishment containing residues.

22/51 (C) During a recordkeeping review of the hazard analysis of the HACCP system for hamburger patties, it was noted that rework was shown as a process step on the flow diagram, but no hazard analysis of this step had been done.

None of the above three HACCP recordkeeping non-compliances had been noted in any establishment HACCP reassessment documentation or MGAP HACCP verification records. All will be investigated and appropriate documentation and justifications provided. [Regulatory reference(s): 9 CFR §417.5, 417.8]

27/28/51. The procedure and records reviewed for carcass selection for analysis for generic *Escherichia coli* called for counting back five half carcasses from the randomly chosen number. This means that it is always the same side of the carcass that is evaluated; this does not allow for true random selection. The procedures will be rewritten in a manner that the choices will involve both sides of the carcass as random selections. This had not previously been noted in evaluation of the procedures either by the establishment or by the MGAP veterinary service. [9 CFR §310.25(a)(2)(ii)]

40/51. There was insufficient light intensity at the head inspection station on the following side of the head. The leading side intensity was 760 Lux but the following side was only 450 Lux. The FSIS requirement is 50 foot-candles of light intensity at inspection and re-inspection stations; this converts to 538 Lux. The angle of one light in the area was adjusted as a temporary measure. Another light will be installed overnight. Both the establishment and MGAP had done light intensity readings but no documentation was available. These readings had not been conducted in the correct manner or during the time of operations. Two of the three lights in the veterinary necropsy area were not functioning. The MGAP IIC stated that all were working the last time he had to do a necropsy, about a week ago. The establishment will repair the lighting immediately. There are no records generated to cover this area. [9 CFR §307.2(m), 310.25(a)(2)(ii), 416.2(c)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE
Rori K Craver DVM 5 Aug 09

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
Frigorifico Las Moras (Chiadel S.A.) Camino Tomas Aldabalde LaPaz, Canelones 90100	08/03/09	104	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Rori K. Craver, 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.	X
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.	
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	X
41. Ventilation	X
42. Plumbing and Sewage	X
43. Water Supply	
44. Dressing Rooms/Lavatories	X
45. Equipment and Utensils	
46. Sanitary Operations	
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: 08/03/09 Est #: 104 (Frigorifico Las Moras (Chiadel S.A.) [S/P]) (LaPaz, Uruguay)

13/51. (A) During records review of the SSOP monitoring records for both pre-operational and operational sanitation, it was observed that the descriptions of deficiencies and of corrective actions did not contain details to allow for MGAP to understand the situation for adequate verification. The establishment will train their monitors to write more complete descriptions. There were no comments addressing this issue in either records verification by the establishment or verification by the veterinary service.

13/51 (B) The written operational sanitation plan required that product should be considered in corrective actions; however, no corrective actions as recorded in the operational sanitation records showed any evaluation of the involvement of product in any non-compliances. MGAP personnel verified that the correct actions had taken place, and that MGAP had been contacted to provide disposition of product, but these actions had not been recorded in the establishment records as it was MGAP that took the actions. Both establishment and MGAP records reviews had not noted this deficiency. Both MGAP and the establishment will record these actions in the future. [Regulatory reference(s): 9 CFR §416.16, 416.17]

22/51. (A) During recordkeeping review of the records of pre-shipment review, it was observed that these records did not record the date of slaughter so you could not tell from the record which slaughter records were reviewed in correlation with the lot of fabricated product. This will be immediately corrected. Review of these records had not noted this deficiency. Both the establishment quality control personnel and MGAP personnel assured the auditor that all CCP records were reviewed prior to shipment.

22/51 (B) During recordkeeping review of the records for verification of HACCP CCPs, it was observed that these records did not show results for verification tasks performed. Verifiers will be retrained and results blocks will be added to the records. This had not been noted previously by either MGAP personnel or the establishment in their review of records.. [9 CFR §417.5, 417.8]

40/51. During the operational review of boning room, it was observed that the light intensity on part of the re-inspection table was only 310 lux instead of the 538 lux (50 foot-candles) required by regulations. The table will be moved to a location for the day that will allow for the required intensity. Overnight more lighting will be installed. The MGAP personnel working in the area were instructed to assure that they worked in the area with sufficient light intensity. No notations were found in either MGAP or establishment records showing this lack of light intensity. [9 CFR §307.2(m)]

41. During onsite operational review of the establishment, dripping condensate was found in two areas. The first location was over the return chain in the hallway to deboning; no product is on this part of the chain. The area was wiped down. The second location was several pipes in the red offal room. The area was wiped down. No product was under the pipes, but bags for product were in the area. These bags were moved to another location and the top ones of each stack were disposed of. Condensate had been noted as a problem in the red offal area in both establishment and MGAP records in the past. [9 CFR §416.2(d)]

42. During onsite operational review of the boning area, the auditor observed that several sinks that were blocked with water backing up inside them. This blockage was caused by small pieces of meat. An immediate control action was taken by MGAP personnel. Establishment personnel in the area were instructed to use other available sinks and maintenance was called to unstop the sinks. Corrective actions were verified by MGAP before the tags were removed. Overnight, maintenance will construct a better drainage system for these sinks. No notations were found in either establishment or MGAP records for operational sanitation in this area. [9 CFR §416.2(e) and (f)]

44/51. During the onsite review of the establishment, the auditor observed that hand soap in many areas of the establishment was of the wrong viscosity to work with the dispensers provided. Either the soap could not flow through the spout, or it dripped down the sides. This could lead to inadequate personnel hygiene thereby leading to an insanitary condition. The present soap was diluted to flow easier and the establishment will obtain new soap that will work with the present dispensers or look into new dispensers. Soap problems were a recurring theme in both the establishment and MGAP SSOP records. [9 CFR §416.17, 416.2(h)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE
Rori K Craver DVM 3 Aug 09

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
Frigorifico Lorsinal S.A. Camino Melilla 10270 Montevideo, Montevideo 12500	07/27/09	224	Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT [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.	
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.	
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	
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: 07/27/09 Est #: 224 (Frigorifico Lorsinal S.A. [S/P/CS]) (Montevideo, Uruguay)

46/51. The freezer contains more pallets of frozen deboned beef than it was designed for. This has been going on for a few weeks. The excess pallets are stacked on top of each other with nothing between the feet of the upper pallet and the boxes of the lower pallet. The top boxes of the lower pallets are turned upside down so the feet of the pallet rest on the bottom of the boxes. However, as these are readied for shipping, these contaminated bottoms will be in contact with the tops of other boxes. Also, these boxes were not meant to take this kind of direct pressure from the pallet feet. Although none were visibly broken at the time of the audit, the products inside are in danger of their packaging being disrupted from the strain. No comments about this situation were found in either the veterinary service or establishment records for the conditions in this area. Corrective actions have not yet been established as they do not have another place to put these pallets. I will hear their proposal to the veterinary service in a day or two. [Regulatory reference(s): 9 CFR §416.17, 416.4(a)]

All findings from the previous audit of 2008 have been corrected.

The primary reason for the visit to this establishment in the 2009 audit was to check on a POE violation of refused entry product for sour and off condition. The establishment did a thorough investigation and found nothing in the records of the days of production that had been included in this export lot. The veterinary service also checked the product on its return to the facility and found no problems. The product has been approved by the veterinary service for sale to the domestic market.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Rori K. Craver, DVM	Rori K Craver DVM 27 Jul 09

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
Frigorifico San Jacinto (Nirea S.A.) Ruta 7, Km. 59.500 San Jacinto, Canelones 91300	July 17, 2009	344	Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT [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.	
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.	
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	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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: July 17, 2009 Est #: 344 (Frigorifico San Jacinto (Nirea S.A.) [S/P/CS]) (San Jacinto, Uruguay)

There were no significant findings to report after consideration of the nature, degree and extent of all observations. The corrective actions for the one non-compliance from the previous audit were appropriate and effective.

The primary reason for the audit of this establishment this year was it's involvement in a multiple supplier recall in the US for *E. coli* O157:H7. The auditor reviewed all of the establishment and MGAP procedures taken in the investigation. The initial investigation revealed no problems detected to lead to the conclusion that this establishment may have been responsible for the adulterant. However, in the follow-up sampling, positive findings of *E. coli* O157:H7 were found in one day in one lot from one farm. Three of five samples from that lot were positive. Animals from this farm had not been purchased by the establishment in the previous two years. There were no more positives in the additional follow-up sampling that was then generated. The investigation of this farm is continuing through MGAP Animal Health. All steps as stipulated in the equivalent national program were completed as specified.

61. NAME OF AUDITOR
Rori Craver, DVM

62. AUDITOR SIGNATURE AND DATE
Rori K Craver DVM 17 Jul 09

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
Frigorifico La Caballada (Cledinor S.A.) Tomas Berretta y Harriague Salto, Salto 50000	07/22/09	394	Uruguay
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT [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	X
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.	
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.	
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.	
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	X
28. Sample Collection/Analysis	X
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	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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.	

p

60. Observation of the Establishment Date: 07/22/09 Est #: 394 (Frigorifico La Caballada (Cledinor S.A.) [S/P/CS]) (Salto, Uruguay)

07. The written SSOP for operational sanitation is extremely unclear in the designation of frequencies for monitoring. There was an understanding between the quality control of the establishment and the veterinary service of twice per shift, but in reading the plan, that was not clearly stated. The plan will be rewritten to clearly define frequencies. This was not found as a deficiency by the veterinary service in their verification of operational sanitation. [Regulatory reference(s): 9 CFR §416.11-.12]

19. The verification procedures as delineated in the HACCP plan for CCP 2, time and temperature for maturation of beef before deboning, did not include observation of the monitor or records review. This omission was not found in the annual reassessment of HACCP or in the HACCP verification procedures as conducted and recorded by the veterinary service. This omission will be immediately corrected and new records designed to include these verification activities and results will be ready for the next days production. [9 CFR §417.2(c)(7)]

27/28. The plan for generic E. coli calls for analysis using the m/M values of 1 and 100. They are actually using statistical process control as is required for an establishment using the sponging method. The requirement for the listing of the m/M values as stated above to be put in the plan comes from direction from DILAVE, the national government laboratory. This requirement will be discussed in DILAVE. The establishment cannot remove it from their plan as it is at present required. This was not found as an error by the service as this follows current direction. [9 CFR §310.25(a)(2)(ii)]

40. There was insufficient light intensity at the veterinary head inspection station and at the veterinary viscera inspection station. These light intensities varied from 380 to 420 lux as opposed to the required 538 lux (equal to 50 foot candles). Both the establishment and the veterinary service had taken previous readings showing sufficient intensity, but these readings had not been recorded. Also, these readings had been taken at a time when operations were not ongoing. The establishment provided sufficient light to complete the days operations and will install new lighting overnight. The service will prepare a program at headquarters for all slaughter establishments delineating how and when to check for light intensity, what the required limits are, and how to document the results. [9 CFR §307.2(m)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE
Rori K Craver DVM 22 Jul 09

MINISTERIO DE GANADERÍA
AGRICULTURA Y PESCA
REPÚBLICA ORIENTAL DEL URUGUAY

DIRECCION GENERAL DE SERVICIOS GANADEROS
DIVISION INDUSTRIA ANIMAL

CONSTITUYENTE 1476
11200 MONTEVIDEO
URUGUAY

TEL: 5982 412 6346
FAX: 5982 412 6317

Montevideo, November 13th 2009

DR. JAMES ADAMS
DIRECTOR
INTERNATIONAL AUDIT STAFF
OFFICE OF INTERNATIONAL AFFAIRS
FOOD SAFETY AND INSPECTION SERVICE, USDA

Dear Dr. Adams,

I refer to your request to provide comments regarding the information in the audit report made by Dr. Aurora K. Craver, after her on-site audit of Uruguay's meat inspection system, from July 15 through August 7, 2009.

At present, we have studied it and have found no objections to Dr. Craver's information in the audit report and we have no further comments to make to the document.

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