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

JUN 0 3 2011

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

Dear Dr. Lazaneo,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Uruguay's meat inspection system February 3 to March 11, 2010. Enclosed is a copy of the final audit report. Comments received from the government of Uruguay are included as an attachment to the finaol 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 andreas.keller@fsis.usda.gov.

Sincerely,

for Mangsoo H. Choudry

Andreas Keller, PhD
Acting Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

URUGUAY

FEBRUARY 17 THROUGH MARCH 3, 2010

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING THE PRODUCTION OF MEAT PRODUCTS INTENDED FOR EXPORT TO THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site audit of Uruguay's meat inspection system conducted by the Food Safety and Inspection Service (FSIS) from February 17 through March 3, 2010.

This was a routine ongoing equivalence verification audit. The audit objective was to ensure that Uruguay continues to maintain a food safety system for meat that is equivalent to that of the United States, with the resultant capacity to produce products that are safe, unadulterated, and properly labeled. Between January 1 and December 31, 2009, Uruguay exported 55,399,643 pounds of raw and processed beef products to the United States.

The central competent authority (CCA) maintains the legal authority and the responsibility to enforce all applicable laws and regulations governing Uruguay and third- country requirements. The auditor found that these requirements were consistently applied throughout the system, as no enforcement actions were initiated by the CCA in the three establishments audited.

The CCA demonstrated systemic control and their ability to provide sufficient oversight within their system. The audit revealed improvement in all areas of Uruguay's meat inspection system, and there were no non-compliances reported at the establishment level.

However, the audit revealed two specific non-compliances, which were previously reported during the July-August 2009, Audit concerning the CCA's ability to provide an equivalence determination by FSIS in the following areas:

- Uruguay continued to use private laboratories in Argentina and Brazil for certain residue analyses without an equivalence determination by FSIS; this was repetitive and had been first reported in the 2008 FSIS Uruguay audit report.

  On March 19, 2010, FSIS received a letter from Uruguay, which stated that all laboratory residue analyses on product eligible for export to the U.S. would be performed at the Uruguayan Official Laboratory only.

- An alternative sampling protocol for carcass testing for *Salmonella* species had been in place since 1999. The CCA stated that they had received verbal assurance from FSIS of its equivalence. On May 27, 2010, Uruguay formally submitted a request for the equivalence determination of an alternative sampling program for *Salmonella* species in beef through official channels. This equivalence document submitted is currently under review by FSIS.

An additional minor area of concern related to documentation review by DILAVE was immediately corrected. Uruguay assured that routine evaluation of the report forms would include verification checks to ensure that the methods indicated are current and accurate.

The overall audit process revealed that the CCA demonstrated adequate verification in the following areas: sanitation, humane handling and slaughter, Hazard Analysis Critical Control Points (HACCP) Systems, microbial and residue control, testing for generic *E. coli*, testing for *Listeria monocytogenes* and *Salmonella* in ready-to-eat products, and species verification.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (MGAP—see below)
CCP	Critical Control Point
DGSG	*Dirección General de Servicios Ganaderos* (General Directorate of Livestock Services)
DIA	*División Industria Animal,* Animal Industry Division
DICOSE	*Division de Controlar de Semovientes,* Livestock Control Division
DILAVE	*Division de Laboratorios Veterinarios,* Division of Veterinary Laboratories
DSA	*Division de Salud Animal,* Animal Health Division
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
IVO	*Inspector Veterinario Oficial,* IVO (Veterinarian-In-Charge)
Lm	*Listeria monocytogenes*
MGAP	*Ministerio de Ganaderia, Agricultura y Pesca,* Ministry of Livestock, Agriculture and Fisheries
MLG	Microbiology Laboratory Guidebook
POE	Port-of-Entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SAFSR	Statutory Authority and Food Safety Regulations
Salmonella	*Salmonella* species
SSOPs	Sanitation Standard Operating Procedures

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an audit of Uruguay's meat food safety system from February 17 through March 3, 2010.

The audit began with an entrance meeting held on March 17, 2010, in Montevideo with the participation of representatives from the Central Competent Authority (CCA) – the Ministry of Livestock, Agriculture and Fisheries [*Ministerio de Ganadería, Agricultura, y Pesca* (MGAP)] and one auditor from the FSIS.

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure that Uruguay's food safety system governing meat maintains equivalence to that of the United States, with the outcome to produce products, which are safe, unadulterated, and properly labeled.

In pursuit of this objective, FSIS applied a risk-based procedure to determine the audit scope which involved an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, port-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included data collected by FSIS over a three-year timeframe.

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government oversight, (2) Statutory authority and food safety regulations, (3) Sanitation, (4) HACCP, (5) Chemical residues, and (6) Microbiological testing programs.

Administrative functions were reviewed at CCA headquarters and three local inspection offices, during which the auditor verified the implementation of those management control systems in place, which ensure the national system of inspection, verification, and enforcement was implemented as intended.

A sample of three establishments was selected from a total of 30 establishments certified to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

Additionally, no residue or microbiology laboratory was included in the scope of this audit. The concerns that involved the chemical and microbiological testing programs will be discussed in Sections 9 and 10 of this report.

Table 1: Audit Scope Summary

Competent Authority Visits			Locations
Competent Authority	Central Authority	1	Montevideo
	Local Offices	3	Melo, Tacuarembo, Tarariras
Bovine Slaughter/Processing Establishments		3	Melo, Tacuarembo, Tarariras

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- The 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/Hazard Analysis and Critical Control Point (PR/HACCP) regulations.

The audit standards applied during the review of Uruguay's meat inspection system included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Uruguay has equivalence determinations in place for the following:

- An alternative (Brilliant Green) agar may be used in the analysis of samples for *Salmonella* species.
- Uruguay's testing and enforcement programs for *E. coli* O157:H7 are equivalent.
- Uruguay's generic *E. coli* program for sheep and goats is equivalent.

4. BACKGROUND

Uruguay is eligible to export raw and processed red meat products to the United States. Between January 1 and December 31, 2009, Uruguay exported 55,399,643 pounds of raw and processed beef products to the United States, of which 11,938,459 pounds were re-inspected at U.S. Ports of Entry (POE). A total of 187 pounds were rejected at POE, of which none involved food-safety concerns.

The Uruguay Food Safety System was last audited by FSIS in July/August of 2009. The findings of that audit resulted in no restrictions of any establishments certified as eligible to export meat products to the United States. This routine audit identified deficiencies in the following risk areas:

- *Government Oversight*:
    - An alternative sampling protocol for carcass testing for *Salmonella* species had been in place since 1999, and MGAP stated that they had received only verbal assurance from FSIS of its equivalence. On May 27, 2010, Uruguay formally submitted a request for the equivalence determination of their alternative

sampling program for *Salmonella* species in beef through official channels. This equivalence request is currently under review by FSIS
    - Some samples for residue analysis were being sent to laboratories in Argentina and Brazil. This will be discussed further in Section 9 of this report.
    - Non-compliance with testing requirements for generic *E. coli* was reported in two of the nine slaughter establishments audited.
    - Non-compliance regarding enforcement of some aspects of FSIS regulatory requirements were reported in eight of the ten establishments audited indicating a lack of inspection system control.
- *Sanitation Controls*: inconsistent implementation and verification of sanitation programs within the system, including deficiencies in performing pre-operational and operational sanitation procedures, and verification of recordkeeping requirements.
- *Slaughter/Processing Controls*: inconsistent implementation and verification core HACCP regulatory requirements, including those for reassessment, recordkeeping, and scientific support of critical control points (CCPs).
- *Residue and Microbiology Laboratory Audits*:
    - In the residue laboratory, many solvent bottles containing liquids were not labeled.
    - In the microbiology laboratory, the forms reporting the results of microbiological testing (*Salmonella* species and *E. coli* O157:H7) did not contain clear indication of the dates of analysis or the dates of reporting of the results.

The deficiencies were addressed and/or verified by the MGAP.

The FSIS final audit reports for Uruguay's Food Safety System are available on the FSIS website at:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

5. GOVERNMENT OVERSIGHT

The first of the six equivalence components that the auditor reviewed was Government Oversight.

FSIS import eligibility requirements require that the foreign inspection system be organized and administered by the national government of the foreign country and must provide standards equivalent to those of the Federal system of meat and poultry inspection in the United States.

The CCA maintains the legal authority and the responsibility to enforce all applicable laws and regulations governing Uruguay requirements, it was observed that these requirements were consistently applied throughout the system.

For Uruguay, the authority to enforce MGAP inspection laws is granted in the Law on Animal Health Police No. 3606 of April 13, 1910 - Veterinary Inspection Official Rules of Origin of Goods Animal: meat, byproducts, derivatives and Meat Products, Order 369/983 of 10.07.1983. It is exercised through the MGAP Procedures Manual Oversight Functions (Department of the Slaughter – Department Industrializers Establishments).

The auditor conducted a review of inspection system documents at the headquarters office and in the inspection offices in the three establishments audited. These document reviews focused primarily on food safety hazards. Two concerns resulted from the review of these documents:

- Some residue analyses were being sent to private laboratories in Argentina and Brazil, although no equivalence determination had been made by FSIS for this. More details are provided in Section 9 of this report.
- A stamp affixed by the microbiology laboratory to the hard copy of the analysis report to note the method used for testing for *Listeria monocytogenes* did not reflect the current method being used, indicating a lack of review and verification of documentation during the laboratory audits conducted by DILAVE.

All regulatory microbiological samples and approximately 95% of the residue samples are analyzed in the official, government-owned and -operated Division of Veterinary Laboratory (DILAVE); the other approximately 5% is sent to private laboratories in Argentina and Brazil. This is discussed further in Section 9 of this report.

The General Directorate of Livestock Services (DGSG) has oversight of the DILAVE laboratory. There are two levels of DGSG control. The General Committee of Biological Residues performs one once per year and compares the number of samples analyzed with the number indicated in the national residue-testing plan. The second is performed once per month by a DGSG committee coordinator, who reviews the number and types of samples submitted by each slaughter establishment. If a sample is not submitted according to the schedule, the veterinarian in-charge (IVO) is instructed to explain the reason.

There is an official audit team in the DILAVE laboratory that performs monthly internal audits according to the written Quality Assurance program; in general, various areas are audited during different months; all areas are covered at least once over the course of a year. Every hard-copy analysis report produced by DILAVE and provided to MGAP includes a notation (either pre-printed on the form or stamped with ink) of the methodology employed. The most recent results were requested; MGAP presented the following:

- *E. coli* O157:H7, analyzed 2/5/10, using Microbiology Laboratory Guidebook (MLG) 5.04 (1/28/08),
- *Salmonella,* analyzed 2/5/10, using MLG 4.04, (2/4/08), and
- *Salmonella/Listeria monocytogenes* on RTE samples of cooked, frozen beef, analyzed 10/25/10, using MLG 4.04 (2/4/08) for *Salmonella* and (according to provided documentation) MLG 8.06 (2/19/08) for *Listeria monocytogenes*.

The auditor noted that although all methods being used were FSIS-approved, the one that was indicated (by ink stamp) as having been used for *Listeria monocytogenes* was not currently listed on the Microbiology Laboratory Guidebook: The 8.06 method (2/19/08) had been superseded by two improved methods (8A.04 and 8.07), both dated 8/13/09.

The laboratory had incorporated the new 8A.04 procedure promptly in August 2009, but had not updated the stamp to reflect the new method. Uruguay immediately corrected this deficiency. It

was noted that neither the DGSG nor the IVOs in the establishments of origin had noticed that the stamp did not reflect that the method being used was consistent with FSIS requirements. Additionally, there was no indication that this aspect of documentation is reviewed during the laboratory audits conducted by DILAVE.

Oversight of the private laboratories in Argentina and Brazil that are employed to analyze US-eligible residue samples is carried out by a DILAVE team dedicated to external audits; the team is called *Unidad de Habilitación de Laboratorios* (UHL) (Laboratory Approval Unit). This unit also audits the domestic in-plant microbiology laboratories. The UHL conducted an audit of the Argentina laboratory during September 2009; however, the results were not available to FSIS at the time of the audit.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations (SAFSR).

The inspection system must be organized and administered by the national government of the foreign country. The system must provide for humane handling and slaughter of livestock; ante-mortem inspection of animals or birds; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection and periodic supervisory visits to official establishments.

The review of manuals and procedures at MGAP's administrative offices indicated that the CCA continues to maintain equivalent legislative controls for SAFSR.

The establishment visits by the auditor indicated that both in-plant inspection personnel and individuals conducting supervisory reviews were routinely carrying out the procedures as described in MGAP's Procedures Manual Oversight Functions (Department of the Slaughter Department Industrializers Establishments). There were no non-compliances to report for this equivalence component.

7. SANITATION

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

The review of manuals and procedures at MGAP's administrative offices indicated that the CCA continues to maintain equivalent legislative controls for sanitation. The actual conditions of the establishment visits were consistent with the corresponding documentation.

The establishment visits by the auditor indicated that both in-plant inspection personnel and individuals conducting supervisory reviews were routinely carrying out the procedures as described in the MGAP's Procedures Manual Oversight Functions. There were no non-compliances to report for this equivalence component.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

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

The review of applicable legislation and procedures indicated that the MGAP continues to maintain sufficient written controls with respect to this equivalence component regarding implementation and verification of HACCP systems within the MGAP.

The auditor's observance of the establishments HACCP system resulted in no non-compliances to report for this equivalence component for MGAP, indicating process control by the CCA.

9. CHEMICAL RESIDUE CONTROL PROGRAMS

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

As part of the verification methodology, the auditor's preparatory review of POE findings before going to Uruguay did not identify areas of concern within this risk area. An on-site audit of the residue laboratory was not included in the scope of this audit; however, the auditor reviewed sampling protocols and testing results at the headquarters and establishment levels. Two concerns resulted from these reviews:

- Uruguay was continuing to send some samples to private laboratories in Brazil and Argentina for residue analyses, although no equivalence determination had been made by FSIS for this alternative practice. As stated earlier, all regulatory microbiological samples and approximately 95% of the residue samples are analyzed in the official, government-owned and -operated DILAVE laboratory; the other approximately 5% are sent to a private laboratory in Argentina (for carbamates, coccidiostats, and sedatives) and to a private laboratory in Brazil (for nitroimidazoles).

  It was noted during the FSIS audit of 2008 that Uruguay had not submitted a request to FSIS for an equivalence determination for the use of private laboratories. Consequently, a letter was sent to Uruguay on March 5, 2009, requesting more information. The majority of the requested information was provided to FSIS in August 2009. Uruguay's report of the audit conducted of the laboratory in Argentina in September 2009 had not been provided to FSIS.

  At the time of this audit, the Uruguayan officials stated that they were preparing another submission of all the materials requested by FSIS in a March 5, 2009, letter formally requesting an equivalence determination through official channels.

Since Uruguay was still using private laboratories without this alternative measure having been determined to be equivalent, FSIS advised Uruguay on March 18, 2010, of its intent to suspend the eligibility of all meat products from Uruguay, unless Uruguay either; (1) reverts to the residue laboratory program that was initially determined by FSIS to be equivalent, or (2) receives an equivalence determination from FSIS in response to a formal request by Uruguay, accompanied by all of the supporting documentation outlined in the letter of March 5, 2009.

On March 19, 2010, Uruguay informed FSIS that they would revert to the residue laboratory program initially determined equivalent by FSIS. Therefore, all laboratory residue analysis on product eligible for export to the U.S. will be performed at the official Uruguay laboratory.

10. CCA MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs used by the CCA. The system must implement certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

Uruguay does not maintain national microbiological databases *per se*; however, national zero-tolerance policies are enforced for *E. coli* O157:H7, *Listeria* and *Salmonella* in RTE product, and *Salmonella* on fresh meat. No positive *Salmonella* results have been reported in any beef samples for the past 6 years. In the event of a positive *Salmonella* result, the sample is not routinely analyzed to determine the serotype.

The sampling strategy for Uruguay's regulatory testing program for *Salmonella* species in beef has differed from that employed by FSIS since 1999. In brief, following negative results from a probationary period of testing conducted in all US-eligible slaughter establishments in 1999, MGAP officials take four samples each per month from the two categories (steers/heifers and cows/bulls) until sample sets of 58 and 82, respectively, are completed. In the event of a positive sample, the FSIS sampling strategy (daily sampling of the predominant category for a full sample set) will be immediately implemented.

According to the CCA officials, Uruguay's alternative program was recognized at that time as equivalent by FSIS - Office of International Affairs, Director of the International Equivalence Staff; however, as of the date of this audit, no documentation of that determination is available.

On May 27, 2010, Uruguay formally submitted a request for the equivalence determination of their alternative sampling program for *Salmonella* species in beef through official channels. This equivalence request is currently under review by FSIS.

There have been no positive results for *Salmonella* sampling of beef carcasses in Uruguay for the past six years. Two of the three establishments audited were producing ready-to-eat products that were required to meet the basic FSIS regulatory requirements for testing for *Listeria monocytogenes* and were evaluated according to the applicable regulations.

Testing for *Listeria monocytogenes* was conducted in accordance with their written procedures in both establishments in which it was required. In one establishment, no positive results had ever been reported. In the other establishment, a positive result for *Listeria monocytogenes* was detected in both regulatory and establishment samples from cooked, frozen cheek meat on September 9, 2009.

In response to the positive results, in-plant inspection personnel issued a Non-Compliance Report. The establishment took corrective actions and preventive measures and conducted subsequent testing (all results since the incident have been negative). All inspection and establishment reports were well documented including the verification of the establishment's corrective actions by in-plant inspection personnel.

In addition, in one establishment, a sample taken from a drain in the plate-freezer area was reported as positive in January 2009. Full disinfection was conducted immediately and follow-up sampling was conducted daily for 10 days. All results were negative and the normal sampling plan was resumed.

The stamp affixed to the hard-copy form by the DILAVE used to report the results of testing ready-to-eat products for *Listeria monocytogenes* had not been updated to reflect the current analytical method. This issue was discussed in more detail in Section 5.

There were no non-compliances identified concerning MGAP's verification testing programs for the relevant pathogens, in addition to no non-compliances associated with the enforcement of sanitation and HACCP requirements by the MGAP.

11. EXIT MEETING

An exit conference was held in Montevideo on March 3, 2010, with the MGAP. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The audit revealed improvement in all areas of Uruguay's meat inspection system, with two exceptions:

First, Uruguay continued to use private laboratories in Argentina and Brazil for certain residue analyses without an equivalence determination by FSIS; this had been first reported in the 2008 FSIS Uruguay audit report.

On March 19, 2010, FSIS received a letter from Uruguay that stated they have decided to revert to the residue laboratory program that was initially determined equivalent by FSIS. Therefore, all laboratory residue analysis on product eligible for export to the U.S. will be performed at the official Uruguay laboratory.

Second, an alternative sampling protocol for carcass testing for *Salmonella* species had been in place since 1999 and MGAP had received only verbal assurance of its equivalence. As of the

time of this audit, Uruguay was preparing formal submissions of documentation to request an equivalence determination through official channels, which was submitted on May 27, 2010. This equivalence request is currently under review by FSIS.

An additional minor area of concern was identified related to the review of documentation by DILAVE for the accurate reflection of the current analytical method used on the laboratory hard-copy analysis report. During the exit meeting, MGAP officials gave assurances that routine evaluation of the report forms will now include verification checks to ensure that the methods indicated are current and accurate.

Additionally, the audit revealed that there were no non-compliances reported at the establishment level.

Gary Bolstad, DVM
Senior Program Auditor

f/ Manzoor H. Chaudry

13. ATTACHMENTS

Foreign Country Response to the Draft Final Audit Report

BICENTENARIO URUGUAY 1811 - 2011

MINISTERIO DE GANADERÍA AGRICULTURA Y PESCA
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Montevideo, May 31st 2011

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. Gary Bolstad, after his on-site audit of Uruguay's meat inspection system, from February 17 through March 3, 2010.

At present, we have studied it and have found no objections to Dr. Bolstad'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